Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century

DETAILS

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A New Regulatory Framework for the 21st Century

Committee on Federal Research Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century

Committee on Science, Technology, and Law

Board on Higher Education and Workforce

Policy and Global Affairs

The National Academies of
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Preface

The United States maintains a research enterprise that is world renowned for its productivity, innovation, and dynamism. Forged during World War II, a collaboration between the federal government as funder and academic research institutions as hubs of discovery and invention created an enduring partnership. Trust and respectful gratitude bound the parties together in generating new discoveries and educating and training new scientists.

That partnership exists to this day, though recent decades have witnessed stress on the bond between the government and academic research institutions. The institutions, their faculties, and their staffs are now committing unprecedented time and resources to meeting a flow of new regulations and process requirements generated by the federal funding agencies. Though well-intended and undoubtedly appropriate, federal oversight and its accompanying burdens raise significant questions about whether the nation is optimizing its investment in our extraordinary research enterprise. This is the time to address and fully restore the foundation of our research enterprise partnership.

At the request of the United States Congress, the National Academies of Sciences, Engineering, and Medicine convened a Committee on Federal Research Regulations and Reporting Requirements and tasked the committee with creating A New Framework for the 21st Century. Committee members included university officers and administrators, prior government personnel, investigators, clinicians, ethicists, and public policy experts. The committee reviewed and analyzed previous reports and studies and heard presentations from representatives of federal research funding agencies, from university personnel whose institutions are the beneficiaries and stewards of that funding, and from organizations that work in this field. Having appreciated and considered the views we heard, the committee prepared this report of our findings and recommendations for rebuilding the nation's research enterprise partnership.

Unlike most National Academies' reports, this report has two parts. This is a consequence of a congressional request, made shortly after the committee had begun its work, that the committee issue an expedited report. In response, the committee in September 2015 issued *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1*. That report focused on those regulatory issues identified as of most pressing concern to the research community and upon which Congress might take immediate action. It forms the first part of this volume. Part 1 was issued with the

understanding that other significant issues would be addressed in a second report. Part 2 of this volume represents the completion of this process.

In Part 1, the committee addresses regulations along the continuum of research from proposal preparation and the conduct of research through to the final accounting of research funds and achievements. We offer concrete recommendations for Congress, federal agencies, inspectors general, and universities. The committee also articulates a new regulatory framework that includes the establishment of a Research Policy Board and the creation of a new position in the White House Office of Science and Technology Policy—Associate Director, Academic Research Enterprise. Further, the committee offers a set of operational principles to undergird the new regulatory framework.

The overarching message of Part 1 is that the continuing expansion of federal regulations and requirements is diminishing the effectiveness of the U.S. research enterprise and lowering the return on the federal investment in basic and applied research by diverting investigators' time and institutional resources away from research and toward administrative and compliance matters. A new framework, the committee argues, is needed to ensure that regulatory requirements are justified, proportional to the problems being addressed, and harmonized across funding agencies so as to create a more effective and efficient partnership between funding agencies and research institutions.

In Part 2, the committee discusses the impact of federal regulations on university technology transfer, human subjects research, select agent research, and access to and use of technology (export controls). The committee believes that a consideration of regulations governing human subjects research is critically important. As Part 1 of the committee's report was going to press, the Department of Health and Human Services issued a Notice of Proposed Rulemaking (NPRM) that seeks to revise the Common Rule governing human subjects research. The committee made initial comments on human subjects research regulations in Part 1, but it postponed additional analysis and recommendations so as to be able to incorporate a consideration of and response to the expected NPRM. It provides this analysis and additional recommendations in Part 2, Chapter 9.

In Part 2, the committee also illustrates how the new regulatory framework articulated in Part 1 might be operationalized in the future. Appendix B contains the committee's recommendations from both parts of its report.

> ***Having benefited from the opportunity to brief numerous groups on Part 1 of our report, the committee has become even more convinced that the nation is far from optimizing its investment in academic research. We continue to believe that the only clear path to strengthening the U.S. research enterprise and preparing it for continued leadership in the 21st century is through the creation of a Research Policy Board as an analytical, anticipatory, and coordinating forum on research regulatory policy. We continue to believe further that the health of the academic research enterprise requires creation of a permanent position within the White***

House Office of Science Technology Policy established for the primary purpose of maintaining strong links to the research community, the Office of Management and Budget, federal research agencies, inspectors general, and the United States Congress.

The members of the committee look forward to substantive consideration of the recommendations offered in both parts of our report.

We are grateful beyond measure to the committee for their tireless efforts, to the staff of the committee: Anne-Marie Mazza, Thomas Rudin, Steven Kendall, Elizabeth O'Hare, Nina Boston, and Karolina Konarzewska, for their dedication and superb work on this project, and to Rebecca Morgan of the National Academies' Research Center, for her invaluable technical assistance.

Larry R. Faulkner, *Chair*
Harriet Rabb, *Vice Chair*

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Academies of Sciences, Engineering, and Medicine's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process.

We wish to thank the following individuals for their review of Part 1 of this report: Bonnie Beaver, Texas A&M University; Arthur Bienenstock, Stanford University; Charles Bowsher, former Comptroller General of the United States; Susan Fiske, Princeton University; John Graham, Indiana University; C.K. Gunsalus, University of Illinois at Urbana-Champaign; Sally Katzen, George Mason University; Michael Lairmore, University of California, Davis; Nancy Lane, University of California,
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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Charles Phelps, University of Rochester and Gordon England, V1 Analytical Solutions. Appointed by the Academies, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Overarching Summary

For nearly 70 years, the American people have considered fundamental research a national imperative. They have contributed, through an investment of federal funds, to a unique government–research university[1] partnership built on the belief that each of the partners would fulfill its roles and obligations with honesty, integrity, and credibility and with the public good always in mind.

Through this partnership, research institutions, with federal government support, have been the principal source of a world-class labor force that has made fundamental discoveries that enhance our lives and the lives of others around the world. Research institutions help to create an educated citizenry capable of making informed and critical choices as engaged citizens in a democratic society. Through teaching, mentoring, research, and scholarship, research institutions train each succeeding generation of researchers, scholars, and leaders and thereby are uniquely responsible for both the creation and the transmission of new knowledge.

The result of this unique government–academic research partnership is a system of education, mentorship, and discovery that is renowned internationally, consistently attracts the best talent from around the world, and serves as a model for other nations determined to advance their leadership in science and engineering in pursuit of economic and social progress and prosperity.

Regrettably, the partnership is under stress. Concerns have been raised repeatedly that federal laws, regulations, rules, policies, guidances, and reporting requirements, while essential to a well-functioning, responsible system of research, have led over time to an environment wherein a significant percentage of an investigator's time is spent complying with regulations,[2] taking valuable time away from research, education, and scholarship.

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[1]The terms *research universities* and *research institutions*, used interchangeably throughout this report, encompass not only research-focused universities but also other entities such as teaching hospitals (e.g., Massachusetts General Hospital) and other academic research institutes (e.g., The Scripps Research Institute) conducting federally funded research.

[2]Throughout this report, the term *regulation* is used not only to encompass laws, but also the "general and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government" ["About the CFR," *National Archives*, accessed September 9, 2015, http://www.archives.gov/federal-register/cfr/about.html], agency policies, and policy guidance (including answers to FAQs), and executive actions.

When effective and well-coordinated, federal regulation protects the government, universities, investigators, and the public and helps prevent fraud, waste, and abuse. Today, however, there is growing concern that the unintended cumulative effect of federal regulations undercuts the productivity of the research enterprise and diminishes the return on the federal investment in research. Consequently, Congress called upon the National Academy of Sciences to examine the regulations and policies of all federal agencies that support basic and applied research and to recommend actions to: (1) assess the effectiveness of current regulations to achieve their intended purposes and modify those that are currently ineffective; (2) decrease redundancies of effort due to different government agencies utilizing different formats and requirements for receipt of similar information; and (3) develop new mechanisms for government agencies and academia to develop joint recommendations that best achieve regulatory intent and optimize the federal investment in research.

Although the study was originally planned for 18 months, 3 months after the committee's first meeting, Senator Lamar Alexander, Chair, Senate Committee on Health, Education, Labor and Pensions, asked the committee to deliver an expedited report by summer's end, 2015. As he explained in his remarks at the committee's July 2015 meeting, Senator Alexander believed that fall 2015 presented a unique opportunity to reconsider, in a bipartisan manner, the regulatory environment governing federally funded research, as Congress would be considering several legislative actions involving higher education, research policy, and medical innovation where it would be appropriate to make changes to the current regulatory structure.

Within this new time frame, the committee reviewed extensive background materials and held four meetings and one regional workshop at the University of California, San Francisco, to hear from various stakeholders, including federal research and regulatory agencies, inspectors general, research administrators, accrediting bodies, higher education groups, and principal investigators. In the course of its study, the committee discovered, as have others, little rigorous analysis or supporting data precisely quantifying the total burden and cost to investigators and research institutions of complying with federal regulations specific to the conduct of federally funded research. In addition to the concerns voiced by the academic research community, the committee noted that numerous other organizations (e.g., the President's Council of Advisors on Science and Technology, Congress, the White House, and the National Science Board) had observed that government regulations were directing investigators' time away from research to the detriment of national interests (see Box 1-3). Nevertheless, the committee encountered difficulty finding data calculating the opportunity costs associated with diverting time, expertise, resources, and potential away from the conduct of basic and applied research to meet regulatory demands. This was not unexpected, as it is difficult to collect and synthesize this kind of data.

The committee considered regulations (laws, regulations, rules, policies, guidances, and reporting requirements) along the continuum of research from proposal preparation and the conduct of research through to the final accounting of research funds and achievements (see Chapters 4–6). The committee directed detailed attention to those issues (see Box 1-2) repeatedly identified in presentations to the committee and in recent reports as encumbering the research enterprise, recognizing nevertheless the many attempts to address such issues at both the congressional and the agency level. It should be noted that because requirements are placed on research institutions through various means (e.g., laws, regulations, policies, guidance, FAQs, etc.), a "single fix" (e.g., deleting a single phrase in a particular piece of legislation) is generally not possible, as requirements are conveyed by various agencies using diverse mechanisms.

The committee's expedited report was issued in September 2015 as *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1*. That report was published as a standalone volume and forms Chapters 1–7 and Appendixes A, D, E, F, G and the first part of Appendix C of this volume.[3] It was published with the understanding that the committee would continue its assessment, seek additional data regarding the effects of regulations on the conduct of research, hold additional meetings (including a regional meeting at Rice University), and issue an addendum report addressing outstanding items from its charge not captured in the expedited report (e.g., assess a subset of regulations against the new proposed framework and identify regulations needing further analysis), and address other regulations (e.g., export controls and dual-use research of concern) that it had been unable to address comprehensively under the expedited time line.

Chapters 8–13 of this volume represent Part 2 of the committee's review.[4] In these chapters, the committee continues its discussion of human subjects research.[5] The committee noted in Part 1 that it believed that a consideration of regulations governing human subjects research is critically important. As Part 1 of the committee's report was going to press, the Department of Health and Human Services issued a Notice of Proposed Rulemaking (NPRM) that seeks to revise the Common Rule governing human subjects research. The committee had made initial comments on human subjects research regulations in its September 2015 report (see Chapter 5), but postponed additional analysis and recommendations so as to be able to incorporate a consideration of and response to the expected NPRM. It provides this analysis and additional recommendations

[3]In addition, the 2015 report is the source of the majority of the text in this summary and the first part of the text in the preface.

[4]The material in these chapters will not be published as an independent report.

[5]Throughout the report, the committee uses the traditional phrase *human subject*, as this is the phrasing typically used in regulatory language. The committee is, however, cognizant and appreciative of the shift from the use of the word *subject* to the use of the word *participant*.

on human subjects research in Chapter 9 of the current volume. Part 2 also discusses the impact of federal regulations on university technology transfer (see Chapter 10), select agent research (see Chapter 11), and access to and use of technology (export controls) (see Chapter 12); and in Chapter 13, the committee illustrates how the new regulatory framework articulated in the 2015 report might be operationalized in the future. Appendix B contains a table of the committee's recommendations from Part 1 and Part 2 of its report.

> ***Over the course of its study, the committee found that prior recommendations by others, though grounded in reality and practicality, had gained little traction. From stakeholders at every level and perspective, the committee heard how increasing federal regulations hinder the output of the remarkable research enterprise that arose from the government-academic partnership. Describing how and why this growth of regulations occurred, why a course correction is needed, and how the government-academic research partnership can be recalibrated and reinvigorated to best serve the nation in the 21st century are the objectives of this report.***

> ***Having benefited from the opportunity to brief numerous groups on Part 1 of our report, the committee has become even more convinced that the nation is far from optimizing its investment in academic research. We continue to believe that the only clear path to strengthening the U.S. research enterprise and preparing it for continued leadership in the 21st century is through the creation of a Research Policy Board as an analytical, anticipatory, and coordinating forum on research regulatory policy. We continue to believe further that the health of the academic research enterprise requires creation of a permanent position within the White House Office of Science Technology Policy established for the primary purpose of maintaining strong links to the research community, the Office of Management and Budget, federal research agencies, inspectors general, and the United States Congress.***

OVERARCHING FINDINGS

The research performed at research institutions by individual investigators and research teams, selected on the basis of scientific merit and capability, fuels economic growth; strengthens national security; enhances the overall health, education, and well-being of U.S. citizens, and often, of all humanity; and greatly contributes to U.S. leadership in science, technology, and social and behavioral sciences. Thus, federal investment in such research serves the interests of the nation. With the importance of this investment to the well-being of the nation as its backdrop, the committee noted nine overarching findings that characterize the current climate for federal support of research at academic research institutions:

1. Effective regulation is essential to the overall health of the research enterprise, protecting both national investment and the various parties in the partnership (research participants, investigators, universities, and agencies).
2. Continuing expansion of the federal regulatory system and its ever-growing requirements are diminishing the effectiveness of the nation's research investment by directing investigators' time away from research and training toward overlapping and incongruent administrative matters that do not take into consideration the environment under which research is conducted at academic institutions today. Our understanding of the cumulative effect of regulations is, however, constrained by a lack of empirical data.[6]
3. Most federal regulations, policies, and guidance, in and of themselves, are efforts to address important issues of accountability and performance associated with scientific integrity, the stewardship of federal funds, and the well-being of the people and animals involved in research. But these well-intended efforts often result in unintended consequences that needlessly encumber the nation's investment in research.
4. Many regulations fail to recognize the significant diversity of academic research institutions (e.g., in geographic location, public or private, size, legal structure, missions, financial and physical resources, and research capability). This diversity translates into widely varying capabilities to respond to increasing and overlapping research regulations.
5. When regulations are inconsistent, duplicative, or unclear, universities may place additional requirements on research investigators, thereby diminishing the effectiveness of the national investment in research.
6. Academic research institutions often receive research funding from multiple federal agencies, but approaches to similar shared goals and requirements (formats of grant proposals and biosketches, animal care, financial conflicts of interest, etc.) are not harmonized across these agencies. Consequently, investigators and administrative staff spend unnecessary time, energy, and resources complying with different sets of rules, regulations, and policies that address common core issues and concerns.
7. Some academic research institutions have failed to respond appropriately to investigators' transgressions or failed to use effectively the range of tools available to create an environment that strongly discourages, at both the institutional and the individual level, behaviors in conflict with the standards and norms of the scientific community.
8. Academic research institutions may be audited by any agency's Office of Inspector General, many of which have very different ap-

[6]Particularly quantitative data.

proaches that in some cases are incongruent with stated policies of their agency.

9. The relationship between federal research funding agencies and academic research institutions has for the past seven decades been considered a partnership. Yet, there exists no formal entity, mechanism, or process by which senior stakeholders from both partners, dedicated to fostering, sustaining, and strengthening our nation's unique research partnership, can consider the effectiveness of existing research policies and review proposed new policies needed to sustain a maximally dynamic, efficient, and effective research enterprise. Further, no entity exists that can collect the data necessary to provide a true measure of the effectiveness and unintended consequence of existing research regulations.

As the committee learned, stresses in the federal-academic partnership have diminished the effectiveness of the nation's investment in academic research. To restore the health of the enterprise, the committee offers the following overarching recommendations and a new framework for the regulation of research at academic institutions. Recognizing the importance of regulation to the overall health of the research enterprise, the recommendations and framework are intended to achieve a more sensible regulatory structure that harmonizes and streamlines, where appropriate, federal regulations and policies addressing the same concerns and eliminates regulations that no longer benefit the nation's investment in research. The goal of the framework is not to increase bureaucracy but rather to make the federal regulatory regime simpler and more effective for all those involved in the partnership. Additionally, moving forward, the recommendations, principles, and framework offer a chance to conduct analyses in advance of new regulations and to undertake retrospective review so that we adopt an evidence-based approach to future regulations.

Academic research is funded by diverse agencies with different missions and with different approaches to the implementation of regulations. Thus, the committee offers a number of recommendations directed at Congress with the expectation that Congress will work in concert with the various agencies to harmonize regulations affecting the academic research enterprise. When a recommendation is directed to a single federal agency, that is noted.

RECOMMENDATIONS[7]

RECOMMENDATION ONE: The regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated.

[7]Analyses and support for the committee's recommendations are found in Chapters 4–7 and 9–12 along with additional details on the specifics of each recommendation.

Specifically, the committee recommends that *Congress* take the following actions:

1. In concert with the White House Office of Management and Budget (OMB), conduct a transparent and comprehensive review of agency research grant proposal documents for the purpose of developing a uniform format to be used by all research funding agencies (Recommendation 4.1).
2. Task a single agency with overseeing and unifying efforts to develop a central database of investigator information (Recommendation 4.4).
3. In concert with the White House Office of Science and Technology Policy (OSTP), and in partnership with research institutions, develop, within the upcoming fiscal year, a federal-wide financial conflicts-of-interest policy to be used by all research funding agencies (Recommendation 5.1).
4. Direct federal agencies following the Common Rule to institute a risk-stratified system of human subjects protections that substantially reduces regulatory burden on minimal-risk research while reserving more intensive regulatory oversight for higher-risk research (Recommendation 5.2).
5. Direct federal agencies following the Common Rule to require, for multisite research studies, that a single institutional review board (IRB) with the necessary staff and infrastructure serve as the IRB of record for all domestic sites (Recommendation 5.3).
6. Direct agencies, within a designated period of time, to align and harmonize their regulations (and definitions) concerning the protection of human subjects (Recommendation 5.4).
7. In instances of minimal-risk research where requiring informed consent would make the research impracticable, amend the Food and Drug Administration's (FDA) authority so as to allow the FDA to develop criteria for waiver or modification of the requirement of informed consent for minimal-risk research (Recommendation 5.5).
8. Instruct the Department of Health and Human Services to work with other agencies to ensure that research involving biospecimens is eligible for a waiver or modification of informed consent, so long as the proposed research meets the conditions for waiver or modification of informed consent as specified in the Common Rule (Recommendation 5.6).
9. Instruct the White House OSTP to convene within one fiscal year representatives from federal agencies that fund animal research and representatives from the research community to assess and report back to Congress on the feasibility and utility of developing a unified federal approach for the development, promulgation, and management of policies and regulations pertaining to the care and use of research animals (Recommendation 5.7).

10. Require inspectors general to:
    - Resolve issues regarding their interpretation of agency policies and priorities with the agency before conducting formal audits of research institutions; this should not apply in those situations in which the audit itself is directed toward inconsistent agency policy interpretations.
    - Include in their semiannual reports, publish on their websites, and highlight in their presentations to Congress examples of effective, innovative, and cost-saving initiatives undertaken by research institutions and federal research agencies that both advance and protect the research enterprise.
    - Provide to Congress and make publicly available information generated each year on the total costs (agency and institutional) of inspectors general audits of research institutions, the total amounts of initial findings, the total amounts paid by institutions after audit resolution, and any significant management, technology, personnel, and accountability steps taken by research institutions as the result of a completed audit.
    - Reexamine the risk-based methodology in identifying institutions as candidates for Offices of Inspectors General audits to take into account the existing compliance environment and oversight on campuses, recognizing that many research institutions have clean Single Audits, are well managed, and have had long-standing relationships with the federal government.
    - Encourage all federal inspectors general to report only final audit resolution findings on their websites and in their semiannual reports to Congress (Recommendation 6.1).
11. In concert with the White House OMB, affirm that research institutions may take advantage of the flexibility provided by the Uniform Guidance[8] for the documentation of personnel expenses (Recommendation 6.2).
12. Transfer responsibility for the operation of the invention report system (currently iEdison) to the Department of Commerce (DOC) and allocate appropriate resources to the department for upgrading the invention reporting system so as to create a user-friendly interface for the input of data on inventions (Recommendation 10.1).
13. Authorize the DOC to require that the invention data-reporting obligations imposed on recipients of federal funding by all agencies are aligned with agreed-upon reporting requirements (Recommendation 10.3).

[8]For a discussion of the Uniform Guidance, see Box 4-2.

Specifically, the committee recommends that the *White House Office of Management and Budget* take the following actions:

1. Conduct a transparent and comprehensive review of agency research grant proposal documents for the purpose of developing a uniform format to be used by all agencies (Recommendation 4.1).
2. Require that research funding agencies use a uniform format for research progress reporting (Recommendation 4.5).
3. Amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education only to the extent necessary for prudent project and performance monitoring, and do not require more extensive monitoring of subrecipients' institutional compliance with all federal statutes, regulations, policies, and institution-wide business practices.

   Permit, as an immediate, interim measure, research institutions to use subrecipients' publicly available Single Audit Reports to verify that subrecipients have not been otherwise debarred or suspended with respect to the receipt of federal funds. For those with a clean Single Audit Report, the prime institution should be allowed to rely on the Single Audit Act oversight process as an alternative to conducting a review of the adequacy of the subrecipient's institutional systems and business practices (Recommendation 4.6).
4. Amend the Uniform Guidance to establish a mandatory 120-day timetable for the submission of all financial reports for all federal research funding agencies (Recommendation 6.4).
5. Amend the Uniform Guidance so that research universities are not required to submit a revised Cost Accounting Disclosure Statement (DS-2) each time they change their accounting practices, as long as those practices are in compliance with the Uniform Guidance and are posted promptly on the universities' websites. Rather, the initial disclosure statement and revisions to it should be submitted to the research institution's cognizant agency in coordination with the institution's Facilities and Administrative proposal (Recommendation 6.5).
6. Further amend the Uniform Guidance as follows:
   - Amend Section 200.329 to read: Procurement by micro-purchases. Procurement by micro-purchase is the acquisition of supplies or services on a purchase order from a single vendor, the aggregate dollar amount of which does not exceed $10,000 (or $2,000 in the case of acquisitions for construction subject to the Davis-Bacon Act).[9]

[9]Reporting on Real Property, 2 CFR § 200.329 (2014). The Uniform Guidance currently reads, "Procurement by micro-purchases. Procurement by micro-purchase is the acquisition of supplies or services, the aggregate dollar amount of which does not exceed the micro-purchase threshold (§ 200.67 Micro-purchase)."

OMB shall periodically revisit and adjust the $10,000 threshold to account for escalating costs of supplies and services.

- Amend the list of criteria for the permissible purchase of supplies and services through noncompetitive bids in Section 200.320 to include: "The procurement is necessary for research, scientific, or other programmatic reasons, such as instances where the purchase is for a specialized service or of a necessary quality that is available only from a single vendor or if only one vendor can deliver in the required time frame" (Recommendation 6.3).[10]

Specifically, the committee recommends that *Congress* and the *Administration* take the following actions:

1. Congress should authorize, and the President should appoint, an independent, free-standing national commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. This commission was authorized by Congress under Public Law 95-622 in 1978, appointed by the President in 1979, and existed outside the structure of federal departments and agencies. The commission had a direct line-item appropriation from Congress, appointed its own staff, and set its own agenda.
   Congress should charge the proposed commission with examining and updating as necessary the ethical, legal, and institutional frameworks governing human subjects research. The commission should make recommendations to the President, Congress, and relevant federal agencies regarding how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts.
   The commission should have two broad charges:

   - Recommend to the President and Congress ethically sound regulatory approaches for unresolved questions in human subjects research; and

[10]This criterion should be added as an additional item in Methods of Procurement to be Followed, 2 CFR § 200.320(f) (2014), which currently reads as follows:

"Procurement by noncompetitive proposals. Procurement by noncompetitive proposals is procurement through solicitation of a proposal from only one source and may be used only when one or more of the following circumstances apply:

(1) The item is available only from a single source;

(2) The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation;

(3) The Federal awarding agency or pass-through entity expressly authorizes noncompetitive proposals in response to a written request from the non-Federal entity; or

(4) After solicitation of a number of sources, competition is determined inadequate."

- Recommend to the President and Congress revisions in the legal and institutional structures for regulating research with human subjects (Recommendation 9.1).

2. To ensure that the proposed national commission can address the full range of unanswered questions regarding the protection of human subjects in federally funded research, the committee recommends that the executive branch withdraw the Notice of Proposed Rulemaking on the Federal Policy for the Protection of Human Subjects. The committee further recommends that the regulatory structure protecting human research subjects not be revised until the national commission has issued its report and the research community, patient groups, the public, and others have had an opportunity to consider and respond to the commission's recommendations (Recommendation 9.2).
3. Support a robust continuation and renewal of the Export Control Reform Initiative. Even under current statutes, the initiative has the potential to make further, marked improvements (e.g., to the regulations, oversight process, and ease of compliance) that would bring significant benefits to national security, to commerce, and to the economy, as well as to federally funded university research. The lessons learned in the initiative over the past 5 years could help participants in the process accelerate the rate at which needed regulatory revisions are proposed and adopted (Recommendation 12.1).

Specifically, the committee recommends that the *Administration* take the following action:

1. The President should assign the responsibility for regulating all microbes and toxins on the select agents and toxins list to a single agency (Recommendation 11.3).[11]

Specifically, the committee recommends that *federal research agencies* take the following actions:

1. Limit research proposals to the minimal information necessary to permit peer evaluation of the merit of the scientific questions being asked, the feasibility of answering those questions, and the ability of the researcher or research team to carry out that research. For proposals demonstrating these characteristics, any supplementary information should, if requested, be provided *just-in-time* (Recommendation 4.2).

[11]The proposed Research Policy Board could take a leadership role in discussions about which agency should have responsibility for the regulation of the microbes and toxins on the select agents and toxins list.

2. Develop a central repository to house assurances similar to the Single Audit Clearinghouse of the Federal Demonstration Partnership (Recommendation 4.3).
3. Reporting, assurances, and verifications to agencies should be reduced and streamlined. Requirements for reporting should be adjusted such that animal-related noncompliance reports are tiered to the level of significance or impact on animals and included in an annual report rather than submitted on an individual event basis. Annual reports to individual agencies about animal care programs should be replaced by a single annual report under the proposed Federalwide Assurance mechanism. Processes that are redundant to the institutional animal care and use committee approval process, such as the Vertebrate Animal section of Public Health Service grant applications and the Department of Defense central administrative protocol review, should be eliminated (Recommendation 5.8).

Specifically, the committee recommends that *other federal agencies* take the following actions:

1. The Department of Commerce, in consultation with the proposed Research Policy Board, should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act (Recommendation 10.2).
2. The Federal Select Agent Program should develop and promulgate a reasonable inventory management system for biological select agents and toxins that takes account of the living, self-replicating nature of biological agents (Recommendation 11.2).
3. The regulations[12] governing select agents and toxins should be amended to:
   - Allow researchers to more readily access relevant select agents in times of public health emergencies;
   - Increase the number of lower-virulence strains of select biological agents available to researchers; and
   - Make more transparent the process by which materials are added to and removed from the select agents and toxins list (Recommendation 11.3).
4. The Export Control Reform Initiative should seek university input at all stages of the process. The Research Policy Board proposed in Part 1 of

[12]Possession, Use and Transfer of Select Agents and Toxins, 7 CFR 331 (2005); Possession, Use and Transfer of Select Agents and Toxins, 9 CFR 121 (2005); and Select Agents and Toxins, 42 CFR 73 (2005).

this committee's report would be an ideal vehicle for providing such input (Recommendation 12.2).

5. The Export Control Reform Initiative should work closely with universities and other stakeholders to specifically address the deemed export provisions[13] and vigorously support the spirit and letter of the fundamental research exclusion (Recommendation 12.3).

Specifically, the committee recommends that *research institutions* take the following actions:

1. Assess their own regulatory processes to determine where their compliance activities can be streamlined to ensure effective use of indirect research recovery costs, while still meeting the requirements of federal regulations (Recommendation 5.9).
2. Conduct a review of institutional policies developed to comply with federal regulations of research to determine whether the institution itself has created excessive or unnecessary self-imposed burden. For example, research institutions should assess their own regulatory processes to determine where their compliance activities can be streamlined to ensure effective use of indirect research recovery costs, while still meeting the requirements of federal regulations (Chapter 7).
3. Revise self-imposed burdensome institutional policies that go beyond those *necessary and sufficient* to comply with federal, state, and local requirements (Chapter 7).

RECOMMENDATION TWO: To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, postdoctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community. Universities that deviate from or fail to enforce the norms of behavior should be sanctioned. The committee recommends that a newly established Research Policy Board[14] should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions (see Chapter 7).

RECOMMENDATION THREE: Inspectors general responsibilities should be rebalanced so that appropriate consideration is given both to uncovering

[13]As recommended by the report *The Deemed Export Rule in the Era of Globalization* [U.S. Deemed Export Advisory Committee, *The Deemed Export Rule in the Era of Globalization* (Washington, DC: Department of Commerce, 2007)].

[14]See Recommendation Four below.

waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness. The relationship between inspectors general and research institutions should be based on a shared commitment to advancing the nation's interest through a dynamic and productive research enterprise (see Chapter 6).

RECOMMENDATION FOUR: The committee recommends the creation of a new mechanism, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies (see Chapters 7 and 13).

Specifically, the committee recommends that *Congress* take the following actions:[15]

1. Establish a new entity, a Research Policy Board. The Research Policy Board would be a self-funded, government-linked entity serving as the primary policy forum for discussions relating to the regulation of federally funded research programs in academic research institutions
2. Establish a new Associate Director, Academic Research Enterprise, in the White House OSTP, having responsibilities to (a) serve as one of two principal federal contact points for the Research Policy Board; (b) oversee and facilitate the general health of the government–academic research partnership; (c) work in partnership with the Office of Information and Regulatory Affairs (OIRA) of the White House OMB to manage the overall regulatory burden; and (d) jointly with the Administrator of OIRA issue an annual report to Congress on regulatory issues and actions affecting the research partnership (Recommendation 7.1).

Specifically, the committee recommends that *participants in the government–academic research partnership* adopt a set of operational principles as a part of the new regulatory framework for federally funded academic research:

1. Regulations should reflect the shared commitment of academic research institutions and federal agencies to the effective and efficient conduct of research and the maintenance of research integrity.
2. Regulations should be harmonized across all federal research funding agencies. To the extent that agency-specific missions require agencies to depart from a uniform approach, agency-based deviations should be reviewed and approved by OIRA in consultation with the Associate Director, Academic Research Enterprise, OSTP.

[15]A detailed discussion of the recommended Research Policy Board and OSTP Associate Director, Academic Research Enterprise, is provided in Chapter 7.

3. Regulations should be written with the input of the Research Policy Board.
4. Regulations and their enforcement should take into account the risk of malfeasance and the overall cost of compliance. Before proposing any new regulation, an agency should determine whether the problem that the regulation is intended to address is systemic. Actions need to be targeted where transgressions occur. Minor issues should not become cause for disproportionate regulatory response. Egregious transgressions that are found to be isolated events should not trigger disproportionate responses.
5. Regulations should be framed with the recognition that risk levels will never be reduced to zero.
6. Regulations should be reviewed periodically to determine their effectiveness. If a regulation is deemed to be ineffective or excessively burdensome, it should be repealed or reformed.
7. Wherever practical and appropriate, new regulations should be piloted at a small number of institutions to determine whether they efficiently accomplish the intent of regulation, and funds should be provided to pilot institutions for related personnel expenses.
8. Academic research institutions must take timely and appropriate action against members of their communities who violate the values of trust and integrity to which community standards and federal funding of research, as well as academic responsibilities, require strict adherence. (Recommendation 7.2).

For nearly 70 years, research universities in partnership with the federal government have advanced fundamental and applied research to improve the health, economic well-being, and security of our citizens. This partnership has yielded tremendous benefit for the American people. It behooves us to be watchful and to make every reasonable effort to ensure that the partnership continues to flourish. Targeted revisions to regulations affecting research institutions, combined with a new framework of structures and principles to coordinate and nurture the government–academic research partnership, will serve the nation as it confronts the scientific and technological challenges of the 21st century.

Part 1

1

Introduction

Research universities[1] are critical contributors to our national research enterprise.[2] They are the principal source of a world-class labor force and fundamental discoveries that enhance our lives and the lives of others around the world. These institutions help to create an educated citizenry capable of making informed and crucial choices as participants in a democratic society. Through teaching, mentoring, research, and scholarship, research universities train each succeeding generation of investigators, scholars, and leaders and thereby are uniquely responsible for both the creation and transmission of new knowledge.

For over half a century, the American people have seen fundamental research as a national imperative. They have contributed, through the allocation of federal funds, to a unique government-academic research partnership that fosters innovative research at universities. The result of this partnership is a system of internationally renowned institutions that is focused on higher education and discovery that consistently attracts the best talent from around the world and serves as a model for other nations determined to advance their leadership and contributions in science, health care, technology, and engineering.

This unique government-academic research partnership is under stress. Concerns have been raised by numerous organizations[3] that federal regulations[4]

[1]The terms *research universities* and *research institutions*, used interchangeably throughout this report, encompass not only research universities but also other entities such as teaching hospitals (e.g., Massachusetts General Hospital) and academic research institutes (e.g., The Scripps Research Institute) conducting federally funded research.

[2]The national research enterprise comprises the federal government, national laboratories, universities, and industry. Within this enterprise the federal government provides funds to universities to conduct the majority of U.S. basic research. Christine M. Matthews, *Federal Support for Academic Research* (CRS Report No. R41895) (Washington, DC: Congressional Research Service, 2012), 7, https://www.fas.org/sgp/crs/misc/R41895.pdf.

[3]Federation of American Societies for Experimental Biologists, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.

Robert S. Decker, Leslie Wimsatt, Andrea G. Trice, and Joseph A. Konstan, *A Profile of Federal–Grant Administrative Burden Among Federal Demonstration Partnership Faculty:*

and reporting requirements have led to an environment wherein an increasing percentage of scientists' time is spent complying with regulations, rather than on the conduct of research, the education of students, and the pursuit of scholarship. The result is that the federal investment in research is no longer delivering the optimal return on the nation's investment.

From its inception, the partnership between the federal government and research universities has appropriately included federal oversight of research. Research must be conducted with integrity, and the expenditure of taxpayer funds makes full accounting and transparency compulsory. Further, as some research carries significant risk, careful oversight is necessary to ensure the safety of human research participants, the appropriate care of research animals, and the protection of the public. Developed effectively, regulations provide a framework for the conduct of research that embodies the shared values of the federal government, research institutions, and the public. Unfortunately, federal regulations and reporting requirements have grown to such an extent that they also encumber the research enterprise, hamper innovation, divert time and expertise from research to administrative matters, and discourage the next generation of investigators.

The increase in federal regulations is well recognized and has many sources. In part, it may be due to the momentum and inertia of a regulatory process that provides little opportunity to review, evaluate, and eliminate unneeded regulations. This is a concern far beyond the research enterprise, as is manifested by decades of initiatives to reduce paperwork and streamline regulation across the federal system.[5] A growing public interest in reducing the cost of government and in increas-

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A Report of the Faculty Standing Committee of the Federal Demonstration Partnership (2007), http://www.iscintelligence.com/archivos_subidos/usfacultyburden_5.pdf.

National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

Mo Brooks (Congressman, Chairman, Subcommittee on Research and Science Education). Letter to Gene Dodaro (Comptroller General of the United States, U.S. Government Accountability Office, Washington, DC) October 13, 2012, https://science.house.gov/sites/republicans.science.house.gov/files/documents/Letters/100312_brooks_GAO.pdf.

[4]Throughout this report, the term *regulation* is used not only to encompass laws but also the "general and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government" ["About the CFR," *National Archives*, accessed September 9, 2015, http://www.archives.gov/federal-register/cfr/about.html], agency policies and policy guidance (including answers to FAQs), and executive actions.

[5]See, e.g., Exec. Order No. 12,291, 46 FR 13193, 3 CFR (1981), Federal Regulatory Review aimed "to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations," February 17, 1981; Exec. Order No. 12,866, 58 FR 51735 (1993) Regulatory

ing accountability has simultaneously led to increased budgetary vigilance and auditing across the federal government. In the particular case of scientific research, the increase in regulation stems, in part, from specific research concerns. Public perception of the risks of some research procedures, materials, or outcomes motivates the accretion of regulations. Episodic investigator misconduct, sometimes associated with investigator or institutional conflicts of interest[6]—and the real and perceived failure of some research institutions to prevent, investigate, or respond sufficiently—have also led to new regulations.

It is appropriate to review the regulatory framework as it currently exists, to consider specific regulations that have placed undue and often unanticipated burdens on the research enterprise, and to reassess the process by which these regulations are created, reviewed, and retired. This review is critical to strengthen the partnership between the federal government and research institutions, to maximize the creation of new knowledge and products, to provide for the effective training and education of the next generation of scholars and workers, and to optimize the return on the federal investment in research for the benefit of the American people.

CONGRESSIONAL CONCERN

Concerned that the unintended cumulative effect of federal regulations undercuts the productivity of the research enterprise and diminishes the return on the federal investment in research, Congress has commissioned a number of reports to examine the federal regulation of higher education. In the fall of 2013, for example, Senators Lamar Alexander, Barbara Mikulski, Michael Bennet, and Richard Burr tasked higher education leaders to examine the federal regulation of higher education. That task force, co-chaired by William Kirwan, chancellor of the University System of Maryland, and Nicholas Zeppos, chancellor of Vanderbilt University, focused on those regulations promulgated and enforced by the U.S. Department of Education (DoED). The task force developed "recommendations for consolidating, streamlining, and eliminating redundant and burdensome Federal regulations and reporting affecting institutions of higher education." Its report, *Recalibrating Regulation of Colleges and Universities*, was published by the American Council on Education in February 2015 and addresses DoED regulations. The report provides a valuable complement to the current report.

Planning and Review, September 30, 1993; Exec. Order No. 13,563, 76 FR 3821 (2011) Improving Regulation and Regulatory Review, January 18, 2011; Exec. Order No. 13,579, 76 FR 41587 (2011) Regulation and Independent Regulatory Agencies, July 11, 2011; and Exec. Order No. 13,610, 77 FR 28469 (2012) Executive Order 13610, Identifying and Reducing Regulatory Burdens, May 10, 2012.

[6]For the purposes of this report, the phrase *conflicts of interest* generally refers to financial conflicts of interest.

CHARGE TO THE COMMITTEE

In January 2014, Congress called upon the National Academy of Sciences to examine the regulations and policies of all federal agencies that support basic and applied research at universities. In response to this call, in late 2014 the National Academies of Sciences, Engineering, and Medicine appointed an ad hoc committee under the auspices of the Committee on Science, Technology, and Law and the Board on Higher Education and Workforce. The committee's charge is set forth below.

The committee will:

conduct a study of Federal regulations and reporting requirements with specific attention to those directed at research universities. In conducting its analyses, the committee will be aware of: (a) the context and intended benefits and circumstances under which a particular regulation was issued and may have evolved, and (b) whether those contexts or circumstances still remain of public concern. The committee will develop a new framework for Federal regulation of research universities in the 21st century that addresses the needs of Congress, Federal agencies, and the broader public while advancing to the maximum extent feasible the missions of research universities.

Specifically, the committee will:

1. Identify by research agency and statutory authority the Federal regulations with significant impact, and the reporting requirements with which research universities must comply;
2. Work with research universities and associations to gather and review information on personnel time and costs of compliance with Federal regulations and reporting requirements;
3. Work with research universities and associations to gather and review information on methodologies for most efficiently and effectively estimating time, costs, and resulting benefits;
4. Work with federal research agencies to identify regulations and requirements with significant impact that the committee should review;
5. Work with professional staff of congressional committees with jurisdictional responsibility for regulatory oversight and research funding;
6. Work with the stakeholders such as the Federal Demonstration Partnership to demonstrate methodologies for estimating the personnel time and costs of compliance for a subset of regulations and reporting requirements specific to research universities;
7. Develop a framework and supporting principles for the Federal regulation of research universities in the 21st century, taking into account:

(a) the purposes, costs, benefits, and reporting requirements of regulation, (b) the processes used to promulgate regulations and reporting requirements, (c) the roles of Congress, Offices of Inspectors General and Federal agencies, including the Office of Science and Technology Policy and the Office of Management and Budget, and (d) the missions of research universities;

8. Recommend steps needed to implement the framework;
9. Assess how a subset of regulations and reporting requirements fit within the framework, and offer suggestions for evaluating those regulations and reporting requirements that are outdated or redundant, or where compliance burdens have become disproportionate with expected benefits; and
10. Identify regulations and reporting requirements that will require additional analysis in order to assess their fit with the framework and to develop improved approaches.

The ad hoc committee, now named the Committee on Federal Regulations and Reporting Requirements: A New Framework for Research Universities in the 21st Century, was to conduct its work over an 18-month period. However, 3 months after the committee was convened, Senator Lamar Alexander, Chair, Senate Committee on Health, Education, Labor and Pensions, asked the committee to deliver an expedited report by the end of summer 2015. As he explained in his remarks at the committee's July 2015 meeting, Senator Alexander believed that fall 2015 presented a unique opportunity to reconsider, in a bipartisan manner, the regulatory environment governing federally funded research, as Congress would be considering several legislative actions involving higher education, research policy, and medical innovation where it would be appropriate to make changes to the current regulatory structure. "Here's what I suggest you do. Make an interim report in September to Congress, especially the Senate, on the specific recommendations that you would like us to put into law, or make changes to existing regulations that would simplify and reduce the cost of federal regulations on university-based research."[7]

Within this new time frame, the committee reviewed extensive background materials and held four meetings and a regional workshop at the University of California, San Francisco to hear from stakeholders. The committee sought input from a number of individuals and organizations (see Acknowledgments, p. xi)

[7]Senator Lamar Alexander, before the committee, July 22, 2015, Washington, D.C. See Jeffrey Mervis, "Senator Offers Tantalizing Prospect of Regulatory Relief for Biomedical Researchers," *ScienceInsider*, (2015), DOI: 10.1126/science.aac8892.

deeply engaged in the issues addressed in this report. In addition, the committee reviewed numerous background papers and studies (see Box 1-1), including many that documented: (1) the reasons for and growth in regulations governing research at academic institutions; (2) the increased time that scientists devote to administrative activities; (3) the erosion of the robustness of the research enterprise; and (4) recommendations put forth over past decades to address these problems.

The committee considered regulations along the continuum of research from proposal preparation and the conduct of research through to the final accounting of research funds. It identified important areas for improvement along three main tracks: (1) regulations governing research project management; (2) regulations governing the conduct of research; and (3) regulations governing research financial accounting (see Box 1-2). As it is impossible for the committee to consider all regulations and related policy and guidance associated with these tracks, the committee elected to direct detailed attention to those issues repeatedly identified in presentations to the committee and in past reports as encumbering the research enterprise. Throughout its review and deliberations, the committee remained mindful of both the history of the U.S. research enterprise and the current fast-paced, hypercompetitive global research environment in which the enterprise now operates.

Over the course of its study, the committee discovered, as have others, little rigorous analysis or supporting data precisely quantifying the total burden and cost to investigators and research institutions of complying with federal regulations specific to the conduct of federally funded research. Many of the reports available are surveys of faculty and administrators who may have biases.[8] The committee, however, identified numerous reports from outside the academic research community (e.g., from the President's Council of Advisors on Science and Technology, Congress, the White House, and the National Science Board) that expressed interest in rethinking government policies in light of concerns that regulations were directing investigator time away from research to the detriment of the nation's investment (see Box 1-3).

[8]The Federal Demonstration Partnership has issued two reports: Robert Decker, Leslie Wimsatt, Andrea Trice, and Joseph Konstan, *A Profile of Federal-Grant Administrative Burden Among Federal Demonstration Partnership Faculty,* (Washington, DC: Federal Demonstration Partnership, 2007) and Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, and Randy Brutkiewicz, *2012 Faculty Workload Survey: Research Report*, (Washington, DC: Federal Demonstration Partnership, 2014), indicating that faculty conducting federally funded research spend 42 percent of their time on "pre and post-award administrative activities" and "meeting requirements" rather than conducting active research. These reports represent an important effort to collect data on this issue. Work that identifies appropriate methodologies and study design for data collections of this type should proceed.

BOX 1-1 Significant Background Documents Informing the Committee's Deliberations

Promoting Objectivity in Research, 42 C.F.R. § 50.6 (f) (2000)

Protection of Human Subjects, 45 C.F.R. 46 (2009)

Federal Select Agent Program, Centers for Disease Control and Prevention and U.S. Department of Agriculture, 2014, accessed August 13, 2015, http://www.selectagents.gov/

National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf

Scope of the Export Administration Regulations (Part 734) (Washington, DC: Bureau of Industry and Security, 2015), https://www.bis.doc.gov/index.php/forms-documents/doc_view/412-part-734-scope-of-the-export-administration-regulations

Federation of American Societies for Experimental Biology, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Bethesda, MD: National Institutes of Health, Office of Biotechnology Activities, 2013), http://osp.od.nih.gov/sites/default/files/Synthetic_FAQs_April_2013.pdf

"Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf

National Research Council, *Research Universities and the Future of America: Ten Breakthrough Actions Vital to our Nation's Prosperity and Security* (Washington, DC: The National Academies Press, 2002)

National Institutes of Health, Office of Science Policy, "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," accessed August 13, 2015, http://osp.od.nih.gov/office-biotechnology-activities/dual-use-reasearch-concern-policy-information-national-science-advisory-board-biosecurity-nsabb/united-states-government-policy-oversight-life-sciences-dual-use-research-concern

Report to the President: Transformation and Opportunity: The Future of the U.S. Research Enterprise (Washington, DC: Executive Office of the President, President's Council of Advisors on Science and Technology, 2012), https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf

(Continued)

BOX 1-1 Continued

Improving Regulation and Regulatory Review, Executive Order No. 13610, 2012

Regulation and Independent Regulatory Agencies, Executive Order No. 13579, 2011

"Payroll Certifications: A Proposed Alternative to Effort Reporting," The Federal Demonstration Partnership, January 3, 2011, accessed August 24, 2015, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_055994.pdf

Federation of American Societies for Experimental Biology (FASEB). Letter to A-21 Task Force (July 2011), https://www.faseb.org/Portals/2/PDFs/opa/7.28.11%20FASEB%20A-21%20letter.pdf

David Kennedy, *COGR Attachment to NIH RFI Input on Reduction of Cost and Burden Associated with OMB Circular A-21* (Washington, DC: Council on Governmental Relations, An Association of Research Universities, 2011), http://rbm.nih.gov/cogr_cost_burden.pdf

University Research: Policies for the Reimbursement of Indirect Costs Needs to Be Updated (GAO-10-937) (Washington, DC: U.S. Government Accountability Office, 2010), http://www.gao.gov/products/GAO-10-937

Investing in the Future: NSF Cost Sharing Policies for a Robust Federal Research Enterprise (NSB-09-20) (Arlington, VA: National Science Foundation, National Science Board, 2009), http://www.nsf.gov/pubs/2009/nsb0920/nsb0920_1.pdf

Public Health Service Policy on Humane Care and Use of Laboratory Animals (Washington, DC: U.S. Department of Health and Human Services; Bethesda, MD: National Institutes of Health, 2002)

Implementation of the NSTC Presidential Review Directive-4: Renewing the Federal Government-University Research Partnership for the 21st Century (Washington, DC: Executive Office of the President of the United States, Office of Science and Technology Policy, 2001), http://fas.org/irp/offdocs/prd/prd-4-report.pdf

William J. Clinton, *Memorandum on Renewing the Federal Government-University Research Partnership for the 21st Century* (Washington, DC: U.S. Government Printing Office, April 27, 1999), http://www.gpo.gov/fdsys/pkg/WCPD-1999-05-03/pdf/WCPD-1999-05-03-Pg753.pdf

The Regulatory Environment for Science – A Technical Memorandum (OTA-TM-SET-34)(Washington, DC: U.S. Government Printing Office, February 1986), https://www.princeton.edu/~ota/disk2/1986/8621/8621.pdf

BOX 1-2 Significant Laws, Rules, Policies, and Guidance, and Executive Memoranda Considered by the Committee in Its Analysis

Laws

The Animal Welfare Act. Pub. L. No. 89-544 (1966)

National Research Act of 1974. Pub. L. No. 93-348 (1974)

Inspector General Act of 1978. Pub. L. No. 95-452, 5 U.S.C. App. (1978), amended through Pub. L. No. 113-126 (2014)

Bayh-Dole Patent and Trademark Act Amendments Act of 1980. Pub. L. No. 96-517 (1980)

Single Audit Act of 1984. Pub. L. No. 98-502 (1984)

Health Research Extension Act of 1985. Pub. L. No. 99-158 (1985)

Paperwork Reduction Act of 1995. Pub. L. No. 104-13 (1995)

Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 104-191 (1996)

American COMPETES Act. Pub. L. No. 110-69 (2007)

Inspector General Reform Act of 2008. Pub. L. No. 110-409 (2008)

Leahy–Smith America Invents Act (AIA). Pub. L. No. 112-29 (2011)

Federal Agency Responsibilities. 44 U.S.C. § 3506 (2012)

Rules

Protection of Human Subjects. 21 CFR 50 (1980)

Institutional Review Boards. 21 CFR 56 (1981)

The Public Health and Welfare. 42 U.S.C. (1981)

Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. 42 CFR 50(f) (2000)

Responsibilities of Institutions Regarding Investigator Financial Conflicts of Interest. 42 CFR 50.604 (e)(1) (2015)

What are the Review Criteria for Grants? 42 CFR 52(h)(8) (2004)

Protection of Human Subjects. 42 CFR 46(b-d) (2009)

(Continued)

BOX 1-2 Continued

Possession, Use and Transfer of Select Agents and Toxins. 7 CFR 331 (2005)

Possession, Use and Transfer of Select Agents and Toxins. 9 CFR 121 (2005)

Select Agents and Toxins. 42 CFR 73 (2005)

International Traffic in Arms Regulations. 22 CFR §§120-130 (2011)

Export Administration Regulations. 15 CFR §§730-774 (2012)

"Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590

Requirements for Pass-Through Entities. 2 CFR 200.331 (2014)

Audit Requirements. 2 CFR 200.501(f) (2014)

Monitoring and Reporting Program Performance. 2 CFR 215.51(a) (2010)

Policies and Guidance

"The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," *Federal Register* 50, no. 97 (May 20, 1985): 85-12059

U.S. Public Health Service

Grant Application (OMB No. 0925-0001, PHS 398) (Washington, DC: U.S. Department of Health and Human Services, U.S. Public Health Services, 2012), http://grants.nih.gov/grants/funding/phs398/fp1.pdf

U.S. Department of Defense

Funding Opportunity Announcement: Fiscal Year 2015 Department of Defense Multidisciplinary Research Program of the University Research Initiative (ONRFOA 14-012) (Washington, DC: U.S. Department of Defense, 2015), http://www.arl.army.mil/www/pages/8/2015_MURI_FOA_ONR_FOA_14-012_FINAL_EGS.pdf

U.S. Environmental Protection Agency

"EPA's Interim Financial Assistance Conflict of Interest Policy," U.S. Environmental Protection Agency, accessed September 2, 2015, http://www.epa.gov/ogd/epa_interim_financial_assistance_coi_policy.htm

(Continued)

BOX 1-2 Continued

National Institutes of Health

"Frequently Asked Questions from Applicants: Human Subject Research – Assurances," National Institutes of Health, Office of Extramural Research, 2010, http://grants.nih.gov/grants/policy/hs/faqs_aps_assurances.htm#271

"Just-in-Time Procedures for First and Career Awards," NIH Guide 25, no. 10 (1996) http://grants.nih.gov/grants/guide/notice-files/not96-081.html

NIH Grants Policy Statement (Washington, DC: U.S. Department of Health and Human Services, Bethesda, MD: National Institutes of Health, 2003), http://grants.nih.gov/archive/grants/policy/nihgps_2003/nihgps_2003.pdf

NIH Grants Policy Statement (Washington, DC: U.S. Department of Health and Human Services, Bethesda, MD: National Institutes of Health, 2015), http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

Notice of Requirement for Electronic Submission of Just-in-Time Information and Related Business Process Changes Beginning April 20, 2012 (NOT-OD-12-101) (Bethesda, MD: National Institutes of Health, 2012), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-101.html

"Office of Laboratory Animal Welfare: Obtaining Assurance," National Institutes of Health, Office of Extramural Research, 2015, http://grants.nih.gov/grants/olaw/obtain_assurance.htm

National Science Foundation

"Final Format: Research Performance Progress Report," The National Science Foundation, 2010, https://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf

Grant Policy Manual: Chapter V – Grantee Standards: 510 Conflict of Interest Policies (NSF 05-131) (Arlington, VA: National Science Foundation, 2005), http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

Executive Memoranda

National Security Decision Directive 189 (NSDD 189): National Policy on the Transfer of Scientific, Technical and Engineering Information (Sept. 21, 1985)

Peter R. Orszag and John P. Holdren (2010) Policy on Research Performance Progress Report (RPPR) [Memorandum]. Washington, DC: The White House, http://www.nsf.gov/bfa/dias/policy/rppr/policyletter.pdf

BOX 1-3 Concern About Regulation and Research

Universities "stand at the central locus of the new innovation ecosystem." "They require special attention in the area of regulatory and policy reform." "The Federal Government should identify and achieve regulatory policy reforms, particularly relating to regulatory burdens on research universities."

Report to the President: Transformation and Opportunity: The Future of the U.S. Research Enterprise (Washington, DC: Executive Office of the President, President's Council of Advisors on Science and Technology, 2012), https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf

"I am concerned with the amount of time and resources being spent on duplicative and burdensome paperwork and red tape in the conduct of federally funded scientific research."

Mo Brooks (Congressman, Chairman, Subcommittee on Research and Science Education). Letter to: Gene Dodaro (Comptroller General of the United States, U.S. Government Accountability Office, Washington, DC) October 13, 2012., requesting that the GAO review the current regulatory and reporting requirements October 3, 2012.

"It is the sense of Congress that – (1) high and increasing administrative burdens and costs in Federal research administration, particularly in the higher education sector…are eroding funds available to carry out basic scientific research…"

Research and Development Efficiency Act, H.R. 1119, 114th Cong., (2015-2016) Introduced by Mrs. Barbara Comstock, Committee on Science, Space, and Technology

"Regulatory requirements are essential to ensuring accountability, transparency, and safety in the conduct of federally funded research. Excess regulations, differing agency requirements, and requirements and delays resulting from institutional concerns about liability, however, slow the pace of research without improving scientific or regulatory outcomes. Requirements that result in the unnecessary loss of valuable research time must be addressed to fully realize returns on Federal investments in scientific research. A higher level of oversight and authority is necessary to effectively coordinate Federal research agency requirements, their implementation, and efforts to ensure compliance. Active stakeholder participation is also necessary for the development and implementation of sound policy. Investigator time and institutional costs should be weighed when developing and implementing new legislation and regulatory requirements."

National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf

(Continued)

BOX 1-3 Continued

"The Federal Government's partnership with America's colleges and universities through a variety of research grant programs remains strong but perhaps not as efficient and beneficial for American taxpayers as it could be. University management of Federal contracts, grants, and other awards requires several layers of reporting to multiple agencies, and the costs of unnecessary duplication within and across colleges and universities can be substantial. Resources that should be going to education and research are thereby diverted to less productive activities. Some of this duplication and inefficiency results from a lack of clear compliance standards, while in other cases the burdens result from accrued legacy requirements and processes that need to be reviewed and updated. Removal of unnecessary reporting burdens could free universities to further focus their resources on vital research and educational missions; to achieve this objective we need your help and engagement."

Howard Shelanski, David Mader, and Anne Rung, "National Dialogue: Driving Efficiency for America's Colleges & Universities," *The White House*, August 14, 2015, https://www.whitehouse.gov/blog/2015/08/14/national-dialogue-driving-efficiency-america%E2%80%99s-colleges-universities-0

The committee had difficulty finding data calculating the opportunity costs associated with diverting time, expertise, resources, and potential away from the conduct of basic and applied research to meet regulatory demands. Noting the lack of empirical data, former Office of Information and Regulatory Affairs administrator Cass Sunstein identifies several questions that need to be asked: "What do we actually know about the likely effects of proposed rules? What would be the human consequences? What are the costs and benefits? How can government avoid reliance on guesses and hunches? What do we know about what existing rules are actually doing for—or to—the American people? How can we make things simpler? … We have started to incorporate the resulting findings [of economic and social science], and we need to do far more."[9]

The committee found that prior recommendations by others, though grounded in reality and practicality, had gained little traction. From stakeholders at every level and perspective, the committee heard how increasing regulations hinder the output of the remarkable research enterprise that arose from the government-academic research partnership. Describing how and why this growth of regulations occurred, why a course correction is needed, and how the government-academic research partnership can be recalibrated to best serve the nation in the 21st century are the objectives of this report.

[9]Cass Sunstein, *Simpler: The Future of Government* (New York, NY: Simon & Schuster, 2013), p. 5.

Following the release of this expedited report, the committee will continue its assessment, seek additional data regarding the effects of regulations on the conduct of research, hold additional meetings (including a regional meeting at Rice University) and issue in spring 2016 an addendum report addressing any outstanding items from its charge not captured in the current report and address other regulations (e.g., export controls and dual-use research of concern), that it has been unable to address comprehensively under the expedited time line.

ORGANIZATION OF PART 1 OF THIS REPORT

To enable full consideration of the impact of federal regulations on the research enterprise, Chapter 2 describes the previously strong government-academic research partnership and the developing erosion of that relationship as reflected in the growth of the regulatory regime. Chapter 3 provides an overview of the process for securing a federal research grant. Drawing on presentations to the committee, numerous prior reports and studies, and committee analysis, Chapters 4, 5, and 6 examine significant regulations and policies that are interfering with the effectiveness of the decades-old research partnership and offer detailed findings and recommendations to rationalize them. Chapter 7 provides the committee's overarching findings and offers a framework for a national strategy to renew the partnership between the government and academic research institutions for the 21st century.

2

Partners in Research and Oversight

The United States maintains a research enterprise that is world renowned for its productivity, innovation, and dynamism. A core part of this enterprise is the well-established partnership between the federal government and research institutions. Research institutions perform fundamental and applied research while also educating and training the next generation of researchers, scholars, and leaders. This partnership, which was deliberately established, has been extraordinarily successful, and is internationally recognized for achieving significant advances in scientific and engineering research for the benefit of society. However, the regulation of this partnership, while longstanding, necessary, and constructive, has grown to such an extent that it may now impede the advance of discovery and diminish returns on the public investment.

CHARACTER AND OUTCOMES OF THE PARTNERSHIP

The partnership between the federal government and research institutions emerged in the aftermath of World War II,[1] when national leaders recognized the importance of the contribution of basic and applied research to the war effort, comprehended its significance to national prosperity and strength, and deliberately established a means to maintain it. Upon extensive reflection, and with visionary institutional thinking and considerable debate, a partnership was forged that was decentralized (rather than embedded, for example, within a single ministry of science and technology), merit based (awarding research funds on the basis of peer evaluation and determination of scientific quality and significance rather than, for example, on geographical dispersion or seniority of applicants), and overseen by federal agencies, primarily to ensure accountability in

[1]The advancement of the scientific enterprise has, however, been a national aspiration since the nation's founding. This aspiration is stated explicitly in United States Constitution in Article 1, Section 8, Clause 8. The clause gives Congress the specific power "to promote the Progress of Science and useful Arts" by providing intellectual property protections for authors and inventors.

the use of public funds.[2] Implicit in the formulation of the partnership was the presumption that research institutions would accept primary responsibility to enable, administer, and oversee faculty conduct of research.

Within the partnership, research universities continue to exercise autonomy in providing their faculties with the freedom to decide what and how they teach and the research questions they choose to pursue. At the institutional level, governing boards with substantial independence guide institutions. That said, research institutions are nonetheless accountable to the taxpayers and other funders (e.g., foundations, industry)[3] supporting their research.

The partnership is without precedent. It has resulted in the most preeminent and productive research universities in the world. These institutions are the product of an extraordinary confluence of factors: "…the right values and social structures, exceptionally talented people, enlightened and bold leadership, a commitment to the ideal of free inquiry and institutional autonomy from the state, a strong belief in competition among universities for talent, and unprecedented, vast resources directed at building excellence to create an unparalleled system of higher learning."[4]

A 2014 study evaluating 500 of the world's universities largely on research performance identified 16 of the top 20 as U.S. institutions, and 32 U.S. institutions in the top 50.[5] U.S. universities where fundamental research is pursued with federal funding also have been the home institutions of more Nobel Prize winners in the sciences than universities in any other country. The array of Nobel Prize recipients also demonstrates how effectively U.S. research universities attract top talent from elsewhere: 32 percent of laureates who won their Nobel Prizes while at a U.S. research university were foreign born.[6]

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[2]On the origins of the partnership, see Jonathan R. Cole, *The Great American University: Its Rise to Preeminence, Its Indispensable National Role, Why It Must be Protected* (New York: Public Affairs, 2012); James J. Duderstadt, *A University for the 21st Century* (Ann Arbor: University of Michigan Press, 2000); and Homer A. Neal, Tobin L. Smith, and Jennifer B. McCormick, "Beyond Sputnik: U.S. Science Policy in the 21st Century," *Review of Policy Research* 26, no. 3 (2009): 345-346.

[3]Robert M. Berdhal, "Research Universities: Their Value to Society Extends Well Beyond Research," Association of American Universities, April 2009, https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=8740.

[4]Jonathan R. Cole, *The Great American University: Its Rise to Preeminence, Its Indispensable National Role, Why It Must be Protected* (New York: Public Affairs, 2012).

[5]"Academic Ranking of World Universities 2014," Center for World-Class Universities at Shanghai Jiao Tong University, 2015, http://www.shanghairanking.com/ARWU2014.html.

[6]"The United States is also unique in the scale on which it attracts human capital: of the 314 laureates who won their Nobel prize while working in the U.S., 102 (or 32%) were foreign born, including 15 Germans, 12 Canadians, 10 British, 6 Russians and 6 Chinese (twice as many as have received the award while working in China). Compare that to Germany, where just 11 out of 65 Nobel laureates (or 17%) were born outside of Germany (or, while it still existed, Prussia). Or to Japan, which counts no foreigners at all

The partnership has been remarkably productive, whether measured in direct scientific output, in the expertise and capabilities of each generation of researchers and scholars they train, or in economic impact.[7] Over several decades, the partnership has yielded discoveries and knowledge that have had an immense effect and impact—from the Internet to genomics, from barcodes to the understanding of black holes, from breakthrough accomplishments in major scientific fields to the creation of entirely new fields of study. The contributions of the U.S. research enterprise are unparalleled.[8]

But the research enterprise yields much more than knowledge. It has given the nation a system of higher education that consistently attracts to its faculties and student bodies top talent from around the world. U.S. research universities provide a trained workforce with direct experience in research—devising new lines of inquiry, conducting experiments, analyzing outcomes, generating new knowledge—that equips graduates not only for careers in science and engineering but also in the rapidly changing knowledge industries, and indeed for leadership in any field.[9]

The success of the research enterprise can be conveyed by its effect on U.S. economic performance. Based on work initiated by Robert Solow and since pursued in an extended body of economic literature, economists attribute as

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among its nine Nobel laureates." Jon Bruner, "American Leadership in Science, Measured in Nobel Prizes [Infographic]," *Forbes*, October 5, 2011, http://www.forbes.com/sites/jonbruner/2011/10/05/nobel-prizes-and-american-leadership-in-science-infographic/.

[7]Institute of Medicine, National Academy of Sciences, and National Academy of Engineering, "Why Are Science and Technology Critical to America's Prosperity in the 21st Century?" in *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future* (Washington, DC: The National Academies Press, 2007), pp. 41–67.

[8]The accomplishments of federally funded research at U.S. research universities are far too numerous to convey in a single note. For some displays of the impressive outcomes of federally funded research, see "Nifty 50," National Science Foundation, accessed August 11, 2015, http://nsf.gov/about/history/nifty50/index.jsp.

National Academy of Sciences, *Beyond Discovery: The Path from Research to Human Benefit*, accessed August 11, 2015, http://www.nasonline.org/publications/beyond-discovery.

University-Discoveries.com, "Discoveries & Innovation that Changed the World," accessed August 11, 2015, http://university-discoveries.com/.

National Institutes of Health, "NIH…Turning Discovery into Health," August 15, 2012, http://nih.gov/about/discovery/index.htm.

See also Institute of Medicine, National Academy of Sciences, and National Academy of Engineering, *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future* (Washington, DC: The National Academies Press, 2007).

[9]Keith Yamamoto, Vice Chancellor for Research, Executive Vice Dean of the School of Medicine, and Professor of Cellular and Molecular Pharmacology, University of California, San Francisco, Presentation to the Committee, May 28, 2015.

much as half of U.S. economic growth over the past 50 years to scientific advances and technical innovations.[10]

The means by which university research contributes to the economy are many. They include not only the translation of knowledge into products and applications and the employment that stems from such results but also the training of scientists and engineers for industry and the creation of entirely new areas of economic activity.

Atkinson and Pelfrey indicate that approximately 80 percent of leading industries today are the result of research conducted at academic institutions.[11] For example, federally supported research in fiber optics and lasers helped create the telecommunications and information technology industries that now account for one-seventh of the U.S. economy.[12] Research in fundamental molecular biology and in chemistry, sustained for decades with federal financing, led to the development of biotechnology and made possible the multibillion dollar pharmaceutical and biotechnology industries that have contributed to the health and well-being of individuals around the world.[13] Further, research institutions across the nation have contributed immensely to the economies of their regions, creating hubs of innovation and employment in high-technology and knowledge-intensive industries.[14]

DIVERSITY OF EACH PARTNER

The members of the research partnership are generally identified as the fed-

[10]For discussion and references, see Homer A. Neal, Tobin L. Smith, and Jennifer B. McCormick, "Beyond Sputnik: U.S. Science Policy in the 21st Century," *Review of Policy Research* 26, no. 3 (2009): 345–346.

[11]Richard C. Atkinson and Patricia A. Pelfrey, "Science and the Entrepreneurial University," *Issues in Science and Technology* XXVI, no. 4 (Summer 2010).

[12]Homer A. Neal, Tobin L. Smith, and Jennifer B. McCormick, "Beyond Sputnik: U.S. Science Policy in the 21st Century," *Review of Policy Research* 26, no. 3 (2009): 345–346.

[13]The existence of the biotechnology industry provides a powerful and compelling example of the measurable contributions of fundamental research to the economy. A recent study of the economic impact of licensing resulting from academic biotechnology research suggests contributions to gross domestic product ranging from $130 billion to $518 billion in the period from 1996 to 2013 (in constant 2009 U.S. dollars). In the same time period, the study estimates that sales of products licensed from U.S. universities, hospitals, and research institutes supported between 1.1 and 3.8 million "person years of employment." Lori Pressman, David Roessner, Jennifer Bond, Sumiye Okubo, and Mark Planting. *The Economic Contribution of University/ Nonprofit Inventions in the United States: 1996–2013* (Washington, DC: Biotechnology Industry Organization), https://www.bio.org/sites/default/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf.

[14]See Iryna Lendel, "The Impact of Research Universities on Regional Economies: The Concept of University Products," *Economic Development Quarterly* 24, no. 3 (2010): 210-230.

eral government and research institutions, as though each were a single entity. In fact, the "halves" of this partnership are composed of many diverse entities.

The involvement of the federal government in the research enterprise is not overseen by a single office. Unlike in some countries, the U.S. government does not confine its funding of research within a single ministry. Rather, it supports and oversees research via a diverse and decentralized array of agencies and offices with different missions, mandates, budgets, and institutional profiles. These include cabinet-level entities, such as the Departments of Defense (DOD), Energy, and Health and Human Services (HHS), and other agencies such as the National Science Foundation (NSF) and the National Aeronautics and Space Administration. There are also many offices and institutes within individual agencies (e.g., the National Oceanic and Atmospheric Administration within the Department of Commerce). The National Institutes of Health (NIH), itself located within HHS, houses 27 institutes and centers. In addition to funding research at universities, some of these entities conduct their own mission-related scientific research and maintain their own laboratories.

U.S. research universities may engage with more than 20 different agencies when seeking federal research support (see Box 2-1). This multiplicity is both a boon to researchers (as the decentralization provides diversity in research priorities) and a hindrance (due to inconsistencies in agency policies and requirements).

Because of their relationships with federal research funding agencies, research institutions interact with a host of other government entities (e.g., Congress, the auditing community, and national laboratories) involved in the support, oversight, or conduct of federally funded research.

Research universities include private and public institutions of varying sizes. Some have enviable endowments, others depend on shifting state budgets, and others are strongly dependent on tuition income and other revenue sources.[15] Some include prominent medical schools and hospitals; others excel at engineering or agriculture. Some have a single campus; others represent an affiliation of many independent campuses. Some are able to provide extensive administrative assistance to faculty engaged in research; others can provide only limited support.

By some measures, research institutions are a special few. Among nearly 5,000 institutions of higher education in the United States, 108 are classified as research institutions with very high research activity. Another 99 institutions are classified as research universities with high research activity.[16] While federal

[15]See *Finances of Research Universities* (Washington, DC: Council on Government Relations An Association of Research Universities, 2008), http://www.cogr.edu/viewDoc.cfm?DocID=151534.

[16]"The Carnegie Classification of Institutions of Higher Education," *About Carnegie Classification*, accessed August 12, 2015, http://carnegieclassifications.iu.edu//.

funds for research are distributed to universities across the nation,[17] the top 100 institutions receive approximately 80 percent of all federal funding for research at universities. The diversity of these top 100 universities (see Appendix D) shapes the regulatory landscape. They engage with different agencies supporting diverse portfolios of research, many of which have different approaches and policies regarding common concerns. And these diverse institutions must respond to federal funding levels that can vary from year to year in terms of both the levels of support and the focus of funding opportunities.

BOX 2-1 Examples of Federal Agencies That Provide Research Support

Department of Agriculture (USDA)
- Agricultural Research Service (ARS)
- National Institute of Food and Agriculture (NIFA)
- Animal and Plant Health Inspection Service (APHIS)

Department of Commerce (DOC)
- U.S. Census Bureau (Census)
- Economic Development Administration (EDA)
- National Institute of Standards and Technology (NIST)
- National Oceanic and Atmospheric Administration (NOAA)

Department of Defense (DOD)
- Defense Advanced Research Projects Agency (DARPA)
- Department of the Navy (Office of Naval Research – ONR)
- Department of the Air Force (Air Force Office of Scientific Research – AFOSR)
- Department of the Army (Army Research Office – ARO)

Department of Education (DoED)
- Institute of Education Sciences (IES)

Department of Energy (DOE)
- Office of Science
- Advanced Research Projects Agency – Energy (ARPA-E)

Department of Health and Human Services (HHS)
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Agency for Healthcare Research and Quality (AHRQ)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Department of Homeland Security (DHS)
- Science and Technology Directorate (STD)

Department of Housing and Urban Development (HUD)

Department of the Interior (DOI)

(Continued)

[17]For a map of the distribution, see "Federal Science Funding Information Factsheets," Federation of American Societies for Experimental Biology, 2014, accessed August 12, 2015, http://www.faseb.org/Policy-and-Government-Affairs/Become-an-Advocate/Federal-Science-Funding-Information-Factsheets.aspx.

BOX 2-1 Continued

- U.S. Geological Survey (USGS)
- U.S. Fish and Wildlife Service (FWS)

Department of Justice (DOJ)

- National Institute of Justice (NIJ)

Department of Labor (DOL)
Department of State (DOS)
Department of Transportation (DOT)
Department of Veterans Affairs (VA)
Environmental Protection Agency (EPA)
National Aeronautics and Space Administration (NASA)
National Science Foundation (NSF)
United States Agency for International Development (USAID)

PATTERNS IN FEDERAL INVESTMENT IN RESEARCH

Today, the President's overall FY 2016 budget provides $146 billion for federal research and development (R&D), including the conduct of R&D and investments in R&D facilities and equipment.[18] Proposed FY 2016 funding for basic research is $32.7 billion and $34.2 billion for applied research (see Appendix F).[19]

Historical trends reveal significant shifts in the scale and composition of federal support. Over the many decades that the federal government has invested in research, priorities have changed. During the Cold War and particularly after the Soviet launch of Sputnik, federal support of research increased substantially. During this time, a significant portion of funding was devoted to space-related research. In the 1990s, congressional focus shifted to health research and provided additional support to research that might offer cures for disease.[20]

HHS, primarily through NIH, channels more funding to research universities than any other federal agency (see Figure 2-1). DOD has consistently been the largest supporter of academic engineering research. NSF is the only federal agency with responsibility for basic research and education across all areas of science and technology. While it does not fund biomedical research, it does fund basic biological sciences research. It also supports science and math education programs from kindergarten, through high school, and into college.

[18] *Fiscal Year 2016 Analytical Perspectives of the U.S. Government* (Washington, DC: U.S. Government Accountability Office, 2015), p. 293, https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/spec.pdf. The amount of $146 billion represents a 5.5 percent increase over the 2015 enacted level of $138 billion (which may change as agency operating plans are finalized).

[19] Ibid, p. 298.

[20] As the largest funder of research at universities, NIH's budget reflected increases of 14 to 16 percent from FY 1998 to 2003, but has declined in constant dollars by about 25 percent since 2003.

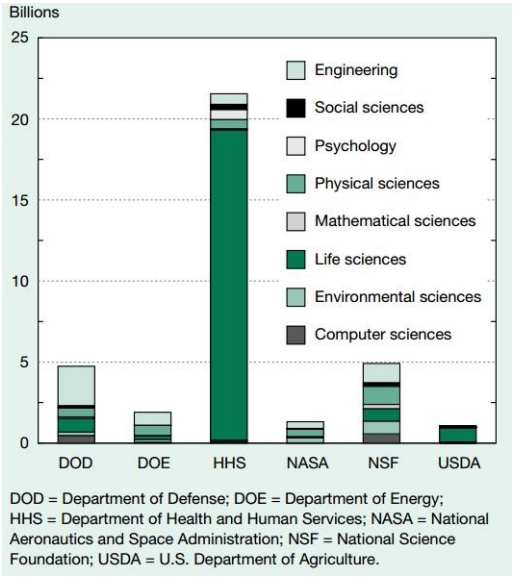

FIGURE 2-1 Federal funding of university research by agency.

SOURCE: National Science Foundation, National Center for Science and Engineering Statistics, Higher Education Research and Development Survey, FY 2012. See appendix table 5-4.

While the federal government has been the major funder of research at universities since the government-university partnership was established, it is not the only source of support (see Figure 2-2). State and local governments also provide funding, as do foundations and industry (although the latter generally supports applied research and development rather than basic research). As Figure 2-2 illustrates, universities are increasingly redirecting their own funds (whether from state appropriations, tuition, gifts, endowments, or other sources) to support research. NSF data indicate that over the past 20 years, the university share of support for research has grown faster than any other sector. Universities are the second leading sponsor of university research, providing nearly 20 percent of the total funding. This exceeds the combined total of state, industry, and foundation support by 10 percent.[21] University support has become more necessary, as the limit on federal reimbursement for administration (capped at 26 percent since the early 1990s)[22] does not permit universities to recoup the full cost

[21]National Center for Science and Engineering Statistics, National Science Foundation, 2014, accessed August 12, 2015, http://www.nsf.gov/statistics/.

[22]The 26 percent cap applies to the administration portion of Facilities and Administrative (F&A) costs.

of complying with federal regulations on research (the only class of recipient organizations so restricted).

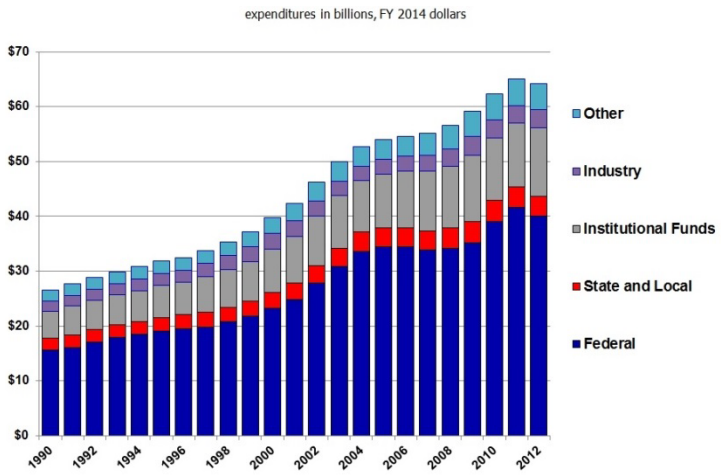

FIGURE 2-2 Funders of research at universities.
SOURCE: National Science Foundation, National Center for Science and Engineering Statistics, *Higher Education R&D* series, based on national survey data. Includes Recovery Act Funding. ©2014, AAAS.

THE IMPORTANCE OF REGULATIONS TO FEDERALLY FUNDED RESEARCH

Increases in funding for academic research have been accompanied by consistently increasing federal oversight. Given the significant investment of taxpayer dollars and the potential risks to study participants, the public, and researchers themselves, the need for federal oversight is clear. Indeed, federal oversight is recognized by research universities as being in their own interest. When an individual case of research malfeasance occurs—whether in the form of misuse of funds, research misconduct, mishandling of materials, or harm to research participants—universities and the federal government are also among the victims. When exercised well, oversight protects the government, universities, research participants, investigators, and the public.

Federal regulations address financial accountability for federal funds, the conduct of research, and public welfare. Regulations directed at financial accountability seek to ensure that federal research funds are suitably charged, properly expended, and wisely used. Regulations seek to promote the efficient and effective use of federal funds while preventing theft, fraud, or abuse. Financial accountability is required throughout the research funding process, from the submission of preliminary budgets in initial research proposals to the final close-out of an award and continuing through subsequent audits.

Federal regulations also address the conduct of research, particularly the safety, rights, and welfare of human subjects and the welfare of animals. Federal oversight of human participants concerns not only human welfare and safety but also the process of obtaining acknowledgment that the participant is aware of the risks involved in the research, is cognizant of privacy issues that might arise, and, understanding these facts, knowingly consents to participate in the research. Any risk to human participants must be deemed proportionate to the potential benefits of the research. Vulnerable populations (such as minors and prisoners) are protected by additional safeguards. At the level of the institution, oversight of the use of human participants in scientific research is accomplished through institutional review boards. Any institution that uses animals in federally funded research is required to have an institutional animal care and use committee to inspect facilities and review research protocols. Those protocols must include the rationale for using animals, provide an account of procedures that will be used in the research, and describe the techniques that will be used to minimize animal discomfort. Accrediting organizations[23] assist institutions with the development of measures and procedures designed to ensure that human and animal research participants are treated appropriately.

Research universities are partners in ensuring research integrity and the safety of all involved. Because some research is risky, research institutions implement their own standards and policies that are designed to ensure safe practices. Because research misconduct and careless science harm the entire research enterprise, universities also have an interest in sanctioning abuses. Funding agencies can impose a range of sanctions on researchers found guilty of misconduct. These include removal from research projects, debarment from participation in agency review panels, and temporary or permanent prohibitions on receipt of federal research funding. Institutions also can impose sanctions that include dismissal of transgressors. Although institutional personnel policies generally prevent incidents of malfeasance from becoming public, universities do reprimand and can dismiss investigators deemed culpable of research misconduct or other transgressions. Moreover, the U.S. Public Health Service (PHS) Office of Research Integrity, which receives and reviews the institutional files and actions in all cases of scientific misconduct in research funded by a PHS agency, publishes its findings whenever it finds a researcher guilty of scientific misconduct.

Federal oversight of scientific research extends to public safety. This broad category includes regulations regarding the handling of materials such as toxic

[23]Accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Inc. demonstrates that an institution has rigorous standards in place for the protection of human research subjects. Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International demonstrates that an institution has rigorous standards in place to ensure the humane treatment of research animals.

chemicals or radioactive reagents that could be harmful to the researchers and the public if released into the environment. This category also includes controls on materials, technology, or information deemed "dual use"—that is, that could be used to do harm if misapplied. Export Controls, International Traffic in Arms Regulations, Select Agent Rules, and Dual Use Research of Concern policies are all examples of regulations designed to address public safety concerns.

Expenditures of taxpayer dollars should not occur without adequate accountability. Research universities are partners in this effort. Although research grants are often identified with their principal investigator, legally a research grant received by a faculty member at a university is a grant to that institution and not to the individual. Every proposal to a federal funding agency must therefore be reviewed and approved by the university before submission. Review entails determining that planned expenditures are appropriate and allowable, listed salaries are correct, proper costs will be charged for facilities and administration, and necessary research protocols have been reviewed and approved.

HOW THE GOVERNMENT FUNDS ACADEMIC RESEARCH

Since the beginning of the partnership, the federal government funded both the "direct" costs of research (i.e., the costs of personnel, supplies, and equipment needed to conduct research) plus the "indirect" costs (or Facilities and Administrative [F&A] costs)[24] (i.e., those costs associated with maintaining research facilities, managing hazardous and radioactive waste, and supporting administrative oversight and management of federal research awards.) Indirect costs are costs for activities that benefit more than one project and which are difficult to ascribe to an individual project. An institution's F&A rate is awarded by the federal government to each university on the basis of a proposal that each institution submits every 3 to 5 years following review and negotiation with the institution's cognizant federal agency.

In 1991, regulations changed. Following publicity of allegations of violations at one institution that were perceived to be widespread, the federal government imposed a 26 percent cap[25] on the federal reimbursement of the admin-

[24]"F&A costs are shared expenses related to university facilities and administration. Facilities costs are defined as allowances for depreciation and use of buildings and equipment; interest on debt associated with buildings and equipment placed into service after 1982; operation and maintenance expenses, and library expenses. Administrative Costs are defined as general administration and general expenses such as the central office of the university president, financial management, general counsel, and management information systems; departmental administration; sponsored-projects administration; and student administration and services that are excluded or limited when computing rates for research." *Analysis of Facilities and Administrative Costs at Universities* (Washington, DC: Office of Science and Technology Policy, 2000), p. 3, https://www.whitehouse.gov/files/documents/ostp/NSTC%20Reports/Analysis%20of%20Facilities%202000.pdf.

[25]Via a 1991 revision of Circular A-21.

istrative component of a university's indirect costs. Even though federal regulations and other administrative requirements have increased over the proceeding decades, the administrative component of the indirect cost rates has remained unchanged at 26 percent. As a consequence, universities have been required to increase their use of institutional funds to pay for the administrative component of the indirect costs of research. While some universities may have the resources to cover these unreimbursed costs for the present, an increasing number of both private and public universities may not. [26]

THE GROWTH AND COST OF REGULATION

Although regulation and oversight are essential elements of the research enterprise, they have increased dramatically in recent decades (see Figure 2-3). The regulations, policies, and guidance issued by many different federal agencies, and sometimes by Congress itself, are at times duplicative, conflicting, or ineffective in meeting goals of improved accountability, efficiency, or perhaps even safety. Further, incomplete and conflicting guidance on how to comply, as well as audit practices that depart from stated agency policies, have created uncertainty and confusion for researchers and universities.[27]

Regardless of whether the data indicates a dramatic escalation in the number of regulatory changes or whether it is consistent with a long-term trend, the pattern is concerning. The increase in just this time period has been dramatic. "In the 1990s, the federal government promulgated approximately 1.5 new or substantially changed federal regulations and policies per year that 'directly affect[ed] the conduct and management of research under Federal grants and contracts.' In the

[26]See *Finances of Research Universities* (Washington, DC: Council on Government Relations An Association of Research Universities, 2008), http://www.cogr.edu/viewDoc.cfm?DocID=151534.

[27]The challenges of complying with duplicative and conflicting regulations have not been lost on federal sponsors of academic research. Agencies have frequently undertaken efforts to reduce regulatory burden. As far back as 1999, NIH undertook "an initiative to improve the effectiveness and efficiency of its overall research mission by reducing regulatory burden being experienced by the research community" and sought "potential solutions for the issues that emerged." See *NIH Initiative to Reduce Regulatory Burden: Identification of Issues and Potential Solutions*, Bethesda, MD: National Institutes of Health, Office of Extramural Research, 1999, accessed August 12, 2015, http://grants.nih.gov/archive/grants/policy/regulatoryburden/.

More recently, the U.S. Department of Agriculture issued a proposed rule as part of the agency's review of its regulations and information collections. The proposed rule invites "public comment to assist in analyzing…existing significant [USDA] regulations to determine whether any should be modified, streamlined, expanded, or repealed." See "Identifying and Reducing Regulatory Burdens," *Federal Register* 80, no. 51 (March 17, 2015): 13789, https://www.federalregister.gov/articles/2015/03/17/2015-05742/identifying-and-reducing-regulatory-burdens.

past decade (2003-2012), this number has increased to 5.8 per year." See "Sustaining Discovery in Biological and Medical Sciences: A Discussion Framework," *Federation of American Societies for Experimental Biology,* 2015, accessed September 9, 2015, http://www.faseb.org/SustainingDiscovery/Home.aspx.

Regulations add cost to the research enterprise, particularly as they accumulate over time. The cost of regulation has been estimated in many ways. In recent testimony before the Senate Committee on Health, Education, Labor, and Pensions, Vanderbilt Chancellor Nicholas Zeppos, stated that Vanderbilt spends "approximately $146 million annually on federal compliance," which represents about "11 percent of our non-clinical expenses." Dr. Zeppos further noted that "as a major research institution with nearly $500 million annually in federally supported research, a significant share of this cost is in complying with research-related regulations."[28]

[28]*Recalibrating Regulation of Colleges and Universities: A Report from the Task Force on Government Regulation of Higher Education: Hearing Before the Committee on Health, Education, Labor, and Pensions, United States Senate*, 114th Cong. (2015) (statement of Nicholas S. Zeppos, Chancellor, Vanderbilt University). These figures have come under scrutiny. See, e.g., G. Blumenstyk, "The Search for Vanderbilt's Elusive Red-Tape Study," *The Chronicle of Higher Education*, July 22, 2015.

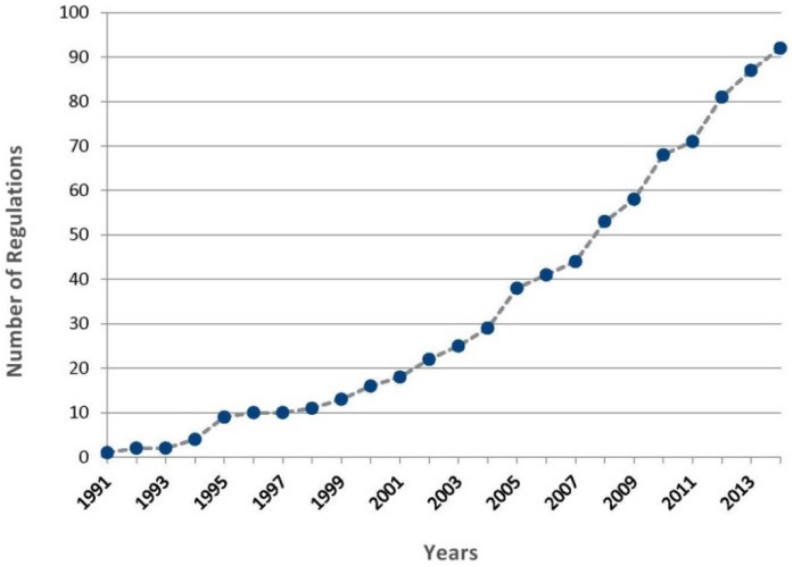

FIGURE 2-3 Cumulative number of regulatory changes applicable to research institutions (since 1991[a]).
SOURCE: Courtesy of the Federal of American Societies for Experimental Biology, 2015. Based upon data selected by the Council on Government Relations.

[a]The year of the implementation of the 26 percent cap on administrative costs in the F&A Cost stipulated under OMB Circular A-21 (Cost Principles for Education Institutions). This graph should not be read as implying that there were zero regulations prior to 1991. Compilation of this data began in response to the implementation of the cap. It would be difficult to collect a complete list for years prior to 1991, as some regulatory changes might have affected only a small segment of research and therefore, may be easily overlooked. Regardless of whether the data indicates a dramatic escalation in the number of regulatory changes or whether it is consistent with a long-term trend, the pattern is concerning. The increase in just this time period has been dramatic. "in the 1990s, the federal government promulgated approximately 1.5 new or substantially changed federal regulations and policies per year that "directly affect[ed] the conduct and management of research under Federal grants and contracts.' In the past decade (2003-2012), this number has increased to 5.8 year." See "Sustaining Discovery in Biological and Medical Sciences: A Discussion Framework," Federation of American Societies for Experimental Biology, 2015, accessed September 9, 2015, http://www.faseb.org/Sustaining Discovery/Home.aspx.

The specific regulatory changes referred to in the graph are as follows:

Year	Federal Regulatory Change
1991	Federal Policy for the Protection of Human Subjects (Common Rule, 1991)
1992	Nonindigenous Aquatic Nuisance Prevention & Control Act of 1990 (Implemented, 1992)
1994	Deemed Exports (1994, EAR & ITAR)
	NIH Guidelines for Research Involving Recombinant DNA Molecules (1994)
1995	Conflict of Interest, NSF Financial Disclosure Policy (1995)
	Conflict of Interest, Public Health Service/NIH Objectivity in Research (1995; Amendments Proposed 2010)
	Cost Accounting Standards (CAS) in OMB Circular A-21 (1995)
	Executive Order 13224, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit or Support Terrorism (September 2001, also EO 12947, 1995)
	Lobbying Disclosure Act of 1995 (Amended 2007)
1996	Health Insurance Portability & Accountability Act of 1996 (HIPAA) Privacy Rule
1998	OMB Elimination of Utility Cost Adjustment (UCA) (1998)
1999	Data Access/Shelby Amendment (FY 1999 Omnibus Appropriations Act);
	Policy on Sharing of Biomedical Research Resources (NIH, 1999)
2000	HHS Centers for Medicare and Medicaid Services (CMS) National Coverage Determination for Routine Clinical Trials (Clinical Trials Policy), 2000
	Misconduct in Science (Federalwide Policy, 2000)
	Health and Human Services/FDA Clinical Trials Registry (2000, Food and Drug Administration Amendments Act of 2007; Mandated Reporting, 2008)
2001	Executive Order 13224, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit or Support Terrorism (September 2001, also EO 12947, 1995)
	NEH, 2001, Misconduct in Science (Federalwide Policy, 2000)
2002	CIPSEA Confidential Information Protection and Statistical Efficiency Act (OMB Implementation Guidance 2007, Title V, E Government Act of 2002)
	FISMA Federal Information Security Management Act (Title III, E Government Act of 2002) OMB Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automated Information Systems

(Continued)

Continued

Year	Federal Regulatory Change
	NSF, 2002, Misconduct in Science (Federalwide Policy, 2000)
	Select Agents & Toxins (under CDC and USDA/APHIS) Public Health Security & Bioterrorism Preparedness & Response Act of 2002; companion to the USA PATRIOT Act (2001)
2003	Consolidation of Agencies' Governmentwide Debarment & Suspension Common Rule (2003). Office of Management & Budget Guidance for Governmentwide Debarment and Suspension [Nonprocurement] (2CFR Part 180, 2006)
	Data Sharing Policy (NIH, 2003)
	EPA, Directive, 2003, Misconduct in Science (Federalwide Policy, 2000)
2004	Higher Education Act, Section 117 Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)
	Homeland Security Presidential Directive (HSPD) – 12, Common Identification Standards for Federal Employees and Contractors (2004)
	Labor, 2004, Misconduct in Science (Federalwide Policy, 2000)
	Model Organism Sharing Policy (NIH, 2004)
2005	Constitution & Citizenship Day (2005, Consolidated Appropriations Act FY 2005)
	Education, 2005, Misconduct in Science (Federalwide Policy, 2000)
	Energy, 2005, Misconduct in Science (Federalwide Policy, 2000)
	Genomic Inventions Best Practices (2005)
	HHS/PHS, 2005, Misconduct in Science (Federalwide Policy, 2000)
	NASA, 2005, Misconduct in Science (Federalwide Policy, 2000)
	Transportation, 2005, Misconduct in Science (Federalwide Policy, 2000)
	Veterans Affairs, 2005, Misconduct in Science (Federalwide Policy, 2000)
	Nuclear Regulatory Commission Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials (Feb 2008, Section 652, Energy Policy Act of 2005)

2006	America COMPETES Act 2006
	Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006)
	Office of Management & Budget Guidance for Governmentwide Debarment and Suspension [Nonprocurement] (2 CFR Part 180, 2006)
2007	CIPSEA Confidential Information Protection and Statistical Efficiency Act (OMB Implementation Guidance 2007, Title V, E Government Act of 2002)
	Lobbying Disclosure Act of 1995 (Amended 2007)
	Health and Human Services/FDA Clinical Trials Registry (2000, Food and Drug Administration Amendments Act of 2007; Mandated Reporting, 2008)
2008	Certification of Filing and Payment of Federal Taxes (Labor, HHS, Education and Related Agencies Appropriations Act of 2008, Division G, Title V, Section 523)
	Code of Business Ethics & Conduct (FAR) 2008
	Combating Trafficking in Persons (2008)
	Health and Human Services/FDA Clinical Trials Registry (2000, Food and Drug Administration Amendments Act of 2007; Mandated Reporting, 2008)
	Homeland Security Chemical Facilities Anti-Terrorism Standards (CFATS) 2008
	Military Recruiting and ROTC Program Access (2008, Solomon Amendment, National Defense Authorization Act for FY 2005)
	National Institutes of Health Public Access Policy (2008, Consolidated Appropriations Act of 2008, Division G, Title II Section 218)
	Nuclear Regulatory Commission Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials (February 2008, Section 652, Energy Policy Act of 2005)
	National Institutes of Health Policy for Genome-Wide Association Studies (GWAS, 2008)
2009	E-Verify 2009
	Executive Order 13513, Federal Leadership on Reducing Text Messaging While Driving (October 2009)
	National Institutes of Health Guidelines for Human Stem Cell Research (2009)
	National Science Foundation Post-Doctoral Fellows Mentoring (America COMPETES Act 2006; implemented 2009)
	USAID Partners Vetting System (re: EO 13224 et al. re: terrorist financing 2009)
2010	OMB Open Government Directive, April 2010); Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006)

(Continued)

Continued

Year	Federal Regulatory Change
2010	OMB Open Government Directive, April 2010); Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006)
	(Compliance with § 872, National Defense Authorization Act of 2009, PL 110-417; as amended, 2010); Federal Acquisition Regulations (FAR) and Office of Management & Budget Federal Awardee Performance and Integrity Information System (FAPIIS) and Guidance for Reporting and Use of Information Concerning Recipient Integrity and Performance (2010)
	DFARS Export Control Compliance Clauses (2010) - Deemed Exports (1994, EAR & ITAR)
	FAR, July 2010; Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and Subrecipient Reporting (2006)
	Federal Acquisition Regulations (FAR) and Office of Management & Budget Federal Awardee Performance and Integrity Information System (FAPIIS) and Guidance for Reporting and Use of Information Concerning Recipient Integrity and Performance (2010) (Compliance with § 872, National Defense Authorization Act of 2009, PL 110-417; as amended, 2010)
	Federal Acquisition Regulations [FAR] Flowdown of Debarment/Suspension to Lower Tier Subcontractors (December 2010; amendment to FAR Subpart 9.4), Office of Management & Budget Guidance for Governmentwide Debarment and Suspension [Nonprocurement] (2CFR Part 180, 2006)
	National Institutes of Health, Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts (2010)
	National Science Foundation Public Outcomes Reporting (America COMPETES Act 2006; implemented 2010)
	National Science Foundation Responsible Conduct of Research Training (America COMPETES Act 2006; implemented 2010)
	USDA, 2010, Misconduct in Science (Federalwide Policy, 2000)
2011	Homeland Security/Citizenship & Immigration Services I129 Deemed Export Certification for H1B Visitors (November 2010; implementation postponed to February 2011)
	Nuclear Regulatory Commission - Statement concerning the Security and Continued Use of Cesium-137 Chloride Sources (July 2011)
	America Invents Act 2011 Patent Regulatory Changes (2012): Implementation of First Inventor to File System
2012	Select Agents & Toxins (under CDC and USDA/APHIS) Public Health Security & Bioterrorism Preparedness & Response Act of 2002; companion to the USA PATRIOT Act (2001); revised October 2012
	USAID Partners Vetting System (re: EO 13224 et al. re: terrorist financing 2009; Extension to Acquisitions, 2012)
	Federal Acquisition Regulations (FAR) and Office of Management & Budget Federal Awardee Performance and Integrity Information System (FAPIIS) and Guidance for Reporting and Use of Information Concerning Recipient Integrity and Performance (2010; 2012) (Compliance with § 872, National Defense Authorization Act of 2009, PL 110-417; as amended, 2010)

	America Invents Act 2011 Patent Regulatory Changes (2012): Implementation of First Inventor to File System
	NASA/OSTP China Funding Restrictions (2012, Under PL 112-10 1340(2) and PL 112-55 539)
	US Government Policy for the Oversight of Life Science Dual Use Research of Concern (March 2012)
	Food and Drug Administration Reporting Information Regarding Falsification of Data (April 2012)
	National Science Foundation Career-Life Balance Initiatives (2012)
	Gun Control, Prohibition on Advocacy & Promotion (Consolidated Appropriations Act of 2012 - PL 112-74, Sec 218)
	Conflicts of Interest, Public Health Service/NIH Objectivity in Research (1995; Amendments August 2012)
2013	Health Insurance Portability & Accountability Act of 1996 (HIPAA) Privacy Rule (Amendments January 2013)
2013	Lobbying Disclosure Act of 1995 (Amended 2007; 2013)
	NIH, Mitigating Risks of Life Science Dual Use Research Concern (2013) - US Government Policy for the Oversight of Life Science Dual Use Research of Concern (March 2012)
	Office of Science and Technology Policy (OSTP), Increasing Access to the Results of Federally Funded Scientific Research (February 2013)
	Executive Order 13642 Making Open and Machine Readable the New Default for Government Information (May 2013)
	Defense/DFAR Safeguarding of Unclassified Controlled Technical Information (November 2013)
2014	The Digital Accountability and Transparency (DATA) Act (OMB; May 2014)
	National Institutes of Health, Genomic Data Sharing Policy (August 2014)
	OMB/COFAR Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (December 2014)
	OSTP US Governmental Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014)
	Public Health Service, The Newborn Screening Saves Lives Reauthorization Act of 2014 (December 2014)

SOURCE: Courtesy of the Federation of American Societies for Experimental Biology, 2015. Based upon data collected by the Council on Governmental Relations. The list "lists federal regulatory changes that affect 'the conduct and management of research under Federal grants and contracts' in chronological order. In some instances, regulations were instituted and/or amended more than once; in these cases, all relevant changes were tallied. Also, when legislation required additional agency-based regulation, both the date of the legislation and the date of the agency regulation(s) were used. Regulations associated with the American Recovery and Reinvestment Act (ARRA) of 2009 are not included." See "Sustaining Discovery in Biological and Medical Sciences: A Discussion Framework," *Federation of American Societies for Experimental Biology,* 2015, accessed September 9, 2015, http://www.faseb.org/Sustaining Discovery/Home.aspx.

The costs of regulation may also be measured by administrative costs borne by research universities that are not reimbursed by funding agencies because of the 26 percent cap[29] on the administrative component of F&A costs.

Some have sought to estimate the amount of time individual investigators divert from research to track information, gather administrative data, and prepare proposals and reports.[30] As investigators typically receive research funding from multiple federal agencies, they and their administrative staff often spend unnecessary time, energy, and resources complying with agency rules, regulations, and policies that address common core issues and concerns but with different sets of requirements. As noted in the 2014 National Science Board report, "This overall lack of harmonization often comes at a high cost to investigators and institutions in the form of lost productivity and cost of administrative personnel."[31] This is a diversion not only of time and effort but also of expertise.

Others have recognized the opportunity costs associated with a potential decline in interest from future researchers, as students wary of a complex and adversarial regulatory environment pursue other careers.[32] Opportunity costs also include foregone benefits from research that is not conducted while investigators spend time on regulatory compliance. Regardless of how the specific costs of compliance are computed, there are also the uncalculated costs as less time, expertise, resources, and potential is directed at the conduct of basic and translational research.

[29]The 26 percent cap on administrative costs refers to the amount of administrative costs associated with a particular project that can be reimbursed to a university.

[30]Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, and Randy Brutkiewicz, *2012 Faculty Workload Survey: Research Report*, (Washington, DC: Federal Demonstration Partnership, 2014).

[31]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research*, p. 16, (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[32]Bruce Alberts, Marc W. Kirschner, Shirley Tilghman, and Harold Varmus, "Rescuing US Biomedical Research from its Systemic Flaws," *Proceedings of the National Academy of Sciences of the United States of America (PNAS)* 111, no. 16 (2014): 5773-5777.

3

Federally Funded Research at Universities

Federal assistance is awarded to individual scientists through their respective institutions to support meritorious projects that deepen understanding and stimulate innovation in basic and applied research. Scientists are expected, in turn, to contribute to the corpus of scientific knowledge through publications, presentations at scientific meetings, the education and training of the next generation of scientists, and data and materials sharing. While it is true that investigator-initiated discoveries generate intellectual property that may be patented and licensed for commercialization by the respective institutions, an essential aim of research is to advance scientific understanding for the public good. [1]

Over the past decade, there has been a significant decline in the level of federal funds allocated to research support, as measured in constant dollars.[2] As a result, many in Congress, at federal agencies, and at research institutions are seeking ways to optimize the use of federal funds by reducing administrative and regulatory costs associated with the receipt of federal research funding. There is significant concern that the scope of the current regulations and requirements diminishes the returns on the nation's investment in research and

[1]As the National Research Council previously observed, "Discovery, learning, and societal engagement are mutually supportive core missions of the research university. Transfer of knowledge to those in society who can make use of it for the general good contributes to each of these missions. These transfers occur through publications, training and education of students, employment of graduates, conferences, consultations, and collaboration as well as by obtaining rights to inventions and discoveries that qualify for patent protection (intellectual property, or IP) and licensing them to private enterprises. All of these means of knowledge sharing have contributed to a long history of mutually beneficial relations among U.S. public and private universities, the private sector, and society at large." National Research Council, *Managing University Intellectual Property in the Public Interest* (Washington, DC: The National Academies Press, 2010).

[2]It is projected that between FY 2006 and FY 2016, total federal investment in research and development will have fallen (in constant 2015 dollars) by 9.2 percent or $15.1 billion. See "Historical R&D Data," American Association for the Advancement of Science (AAAS), 2015, accessed August 12, 2015, http://www.aaas.org/page/historical-rd-data.

that the burdens imposed by the existing regulatory framework reduce our ability to meet the research needs of the 21st century.

Four general constructs describe the environment in which the government-university research partnership operates:

1. Federal research agencies and research institutions are partners in the U.S. scientific enterprise.
2. Though federal research agencies and universities share the costs of research, an increasing and significant portion of these costs is now borne by research institutions.
3. The primary goal of the federal sponsorship of scientific research is to promote discovery in basic and applied research for the public good.
4. There is a shared obligation to produce science of the highest quality under the highest ethical and scientific standards, with special concern for the well-being of human and animal research participants, the integrity of results, and the safety of investigators and the public.

THE PROCESS FOR ACQUIRING AND USING FEDERAL RESEARCH FUNDS

The predominant form of government support of science since World War II is the grant in aid,[3] which is awarded as assistance to a research institution in support of a research team's meritorious scientific research. The scientific questions and approach are typically proposed by an investigator; the quality of a proposal is usually reviewed and evaluated by anonymous peers;[4] and agencies generally sponsor research based upon a proposal's quality and likelihood of

[3]That is, money given to a local government, an institution, or a particular scholar.

[4]What Are the Review Criteria for Grants? 42 CFR § 52h.8 (2004) states that, in carrying out its review of a grant, a "scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent factors:

(a) The significance of the goals of the proposed research, from a scientific or technical standpoint;

(b) The adequacy of the approach and methodology proposed to carry out the research;

(c) The innovativeness and originality of the proposed research;

(d) The qualifications and experience of the principal investigator and proposed staff;

(e) The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

contributing to the corpus of scientific knowledge and/or the overall scientific enterprise. Support for science must recognize that the significance of discoveries may be realized decades later (see Box 3-1).

The process of securing a grant involves many steps (see Box 3-2). In general, after identifying appropriate funding sources, an investigator creates a research proposal. The development of the research proposal provides researchers with an opportunity to articulate the importance of a particular scientific question and to offer a strategy for addressing that question. In collaboration with his or her institution, an applicant assembles and submits application materials to the relevant funding body. Compliant proposal packages are reviewed for scientific merit, and applications clearing merit review undergo final administrative review. Award terms and conditions are negotiated with the applicant's institution and an award is issued to that institution on behalf of the applicant. During the course of his or her research and for the duration of the award period, the grantee and the institution are responsible for providing periodic financial, compliance, and progress reports to the awarding agency via his or her institution's sponsored projects office.

While some proposals are contracted to support specific government initiatives or projects and other awards are made to support research through institutional capacity building (i.e., to purchase shared instrumentation needed for research) or other mechanisms,[5] research grants from federal agencies have, over time, become the predominant form of federal support of the academic scientific enterprise.

Federal awards are not full-cost reimbursement mechanisms. Total award amounts are "fixed." Federal funders do not reimburse for costs or expenditures in excess of an award amount. There are limitations on costs that may be charged to federal awards, including, for example, limitation on faculty salaries charged during the academic year or limitations on indirect costs. Consequently, the researcher's institution is responsible for assuming costs in excess of an award amount.

Sponsored research projects are typically dynamic, and the overall effort and use of resources reflects the evolving nature of the scientific activity. The specific aims articulated in a competitive proposal often change over time as science advances within the project and within the scientific community. There is a fundamental understanding that, as the science progresses, the questions,

[5]NIH AREA (Academic Research Enhancement Award) grants, for instance, "support small-scale research projects at educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. The goals of the program are to (1) support meritorious research, (2) expose students to research, and (3) strengthen the research environment of the institution." See "NIH Area Grand Research Objectives," National Institutes of Health, Office of Extramural Research, accessed August 12, 2015, http://grants.nih.gov/grants/funding/area_grant_objectives.htm.

approaches, methodologies, and investigator's capabilities may shift, refocus, and evolve in concert with his or her research discoveries, advances in the field, and/or use of resources. Sponsors generally expect investigators to respond rapidly to unexpected and emerging findings in the area of interest and to refine methodologies and employ new instrumentation as a project develops.

BOX 3-1 Influences on the Direction of Research

Today, Public Health Service[a] applications require a description of the "relevance" of proposed research to public health.[b] Information provided in response to this requirement has the potential to affect both the likelihood of funding and the type of science that is proposed (and ultimately conducted).

Consider, for example, the case of retroviruses. Retroviruses were studied for decades because of their association with certain types of animal cancers. Until as late as 1980, retroviruses had not been isolated as causative agents of human disease.[c]

In 1984, the causative agent of AIDS was identified as a retrovirus [Human Immunodeficiency Virus (HIV)]. In the following decade, tremendous progress was made in the development of therapies to fight HIV infection. Although this progress is often attributed to investments made in HIV research, such progress could not have been made without earlier work on nonhuman retroviruses that had illuminated fundamental aspects of retroviral biology. Many of these studies had been supported by NIH grants. At that time, there was not an emphasis on linking the relevance of a particular research project to current public health concerns. Yet, without the knowledge that resulted from nonhuman retrovirus research, progress against HIV may very well have been slower.

It may be difficult to connect research directly to current public health concerns. However, fundamental research may provide insights that, while bearing indirectly on public health issues in the present, prove to be critically important in addressing future health emergencies. Given NIH's mission, it is reasonable for the agency to give preference to research that addresses a current health concern. However, it is important to recognize that providing overly prescriptive instructions may adversely affect the creative direction of scientific inquiry and deprive the knowledge base of foundational information needed to address future concerns.

There are other contextual considerations to consider in the allocation of research funding. If a funding agency issues an award because it needs to know the answer to a specific question, it is reasonable to expect that, at the end of a study, investigators will deliver the requested information. Similarly, an award to conduct a clinical trial for a certain hypertension medication would be expected to deliver information about how well the drug performed. Imagine, however, that an award is made to study a cellular signaling pathway, and initial investigation reveals a hitherto unknown connection with another signaling pathway that promises new insights into intracellular communication. In that situation, one can argue that exploring the new pathway is more interesting and important than following an objective stated

(Continued)

BOX 3-1 Continued

on an application. There are, of course, instances when following the stated objectives will lead directly to discovery. However, every scientist knows that science can be unpredictable and that scientific progress often results from taking advantage of serendipitous observations and pursuing new leads.

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[a] The Public Health service comprises all agency divisions of the U.S. Department of Health and Human Services (including the National Institutes of Health) and the Public Health Service Commissioned Corps.

[b] See "Application for a Public Health Service Grant PHS 398" (OMB No. 0925-0001) (Washington, DC: U.S. Department of Health and Human Services), http://grants.nih.gov/grants/funding/phs398/phs398.pdf.

[c] Robert C. Gallo reported the successful isolation of the first human retrovirus (human T-cell leukemia virus, now human T-cell lymphotropic virus type I; HTLV-I) in 1980. See B. J. Poiesz, F. W. Ruscetti, A. F. Gazdar, P. A. Bunn, J. D. Minna, and R. C. Gallo, "Detection and Isolation of Type C Retrovirus Particles from Fresh and Cultured Lymphocytes of a Patient with Cutaneous T-Cell Lymphoma," *Proceedings of the National Academy of Sciences of the United States of America* 77, no. 12 (1980): 7415-7419.

BOX 3-2 Steps for Securing and Managing a Federal Research Grant[a]

1. The applicant reviews agency Requests for Applications (RFAs)[b] and/or Requests for Proposals (RFPs)[c] or Funding Opportunity Announcements (FOAs)[d] to identify relevant funding opportunities.

2. In response to an RFA/RFP/FOA,[e] the applicant collects preliminary data and begins to articulate the importance of a particular scientific approach or strategy for addressing a particular scientific question.

3. The applicant drafts the proposal text, assembles and completes required proposal documents (these may include a research plan, information on facilities and personnel, investigator biosketches, budgetary information, etc.),[f] and obtains required assurances,[g] protocol approvals, and so forth.

4. Once all materials have been assembled, reviewed, and approved by the applicant's institution (via the institution's sponsored projects office), the grant proposal package is transmitted to the prospective funding sponsor by the applicant's institution.

5. A compliant proposal is generally assigned to a program officer at the sponsoring agency who, in turn, assigns the proposal to anonymous reviewers who assess the project's scientific merit (merit review). Proposals may be subject to multiple stages of merit review.

6. Proposals that have successfully cleared merit review undergo final administrative review, and award terms and conditions are negotiated with the applicant's institution.

7. An award is issued to the applicant's institution.

(Continued)

BOX 3-2 Continued

8. Once an award is made, the grantee provides required periodic financial, compliance, and progress reports to his or her institution's sponsored projects office and subsequently to the awarding agency in order to continue funding for the duration of the award period.[h]

9. At the conclusion of the award period, the investigator and the investigator's institution provides an overview of the scientific progress during the entire award period, plus final technical and financial reports as established under the terms and conditions of the award.

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[a] The steps listed are meant to provide a general representation of the process of obtaining federally funded research grants. It is particularly applicable to project grants supporting a principal investigator and research group (such as an NIH Research Project Grant R01). There are other funding sources available to investigators; for example, nonfederal grants (available from private industry, foundations, etc.) and research grants funded by an investigator's home institution. Furthermore, funding for research may take several forms (e.g., contracts, cooperative agreements, training grants, and fellowships) and there are numerous other grant types in addition to single project grants such as R01s (e.g., program project grants that support several projects and investigators with a common objective and career development programs that are designed to facilitate career development).

[b] These are stand-alone requests for proposals.

[c] Also known as Program Announcements (PAs), these solicitations "describe new, continuing, or expanded program interests of the sponsor or…announce the availability of a new mechanism of support." See "Identifying Sources of Funding," Johns Hopkins Medicine, accessed August 12, 2015, http://www.hopkinsmedicine.org/Research/ora/handbook/handbook_II.html.

[d] "A publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the agency and type of program." See "Description of the NIH Guide for Grants and Contracts," National Institutes of Health, Office of Extramural Research, accessed August 12, 2015, http://grants.nih.gov/grants/guide/description.htm#foa.

[e] Applicants may also submit unsolicited proposals to potential sponsors.

[f] Each grant proposal must include specific components and information in ordered to be considered. Agencies largely determine what constitutes required information.

[g] An assurance is a documented commitment to comply with certain institutional policies and federal requirements.

[h] Depending on the award type, an award may be eligible for renewal. To obtain a renewal, an investigator must typically reapply for support and undergo initial merit review again. If there is a significant change or expansion of the scope of research, a new application is generally required.

4

Regulations and Policies Related to the Acquisition and Use of Federal Research Grants

In the next three chapters, beginning with the development of a grant proposal and proceeding to the conduct of research and the accounting for research expenditures, the committee provides an assessment of several areas where regulatory requirements and research funding processes are viewed as particularly and needlessly burdensome to the research enterprise. These include proposal preparation, progress reporting, subrecipient monitoring, conflicts of interest, human subjects research, animal research, auditing practices, reporting of compensation for personnel expenses, and aspects of the Uniform Guidance. The committee then analyzes the consequences of these requirements and offers specific findings. The focus of the current chapter is regulatory requirements related to the development and management of a federally funded research project. The specific areas of consideration are proposal preparation, progress reporting, and subrecipient monitoring.

PROPOSAL PREPARATION[1]

At its core, proposal preparation is an act of scholarship, as the creation of a research proposal is fundamentally an intellectual process that provides the investigator with an occasion to articulate the importance of a particular scientific question and to offer a strategy for addressing that question. Ideally, the process provides the investigator with an opportunity to summarize relevant

[1]The discussion in this section applies primarily to grants made in support of discrete, delineated projects to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies ["NIH Research Project Grant Program (R01)," National Institutes of Health, Office of Extramural Research, accessed August 12, 2015, http://grants.nih.gov/grants/funding/r01.htm]. These grants represent a primary source of funding for new and established investigators and form a large percentage of grants awarded by nondefense funding agencies. In agencies where there is an interest in particular deliverables (e.g., defense agencies), competitive contract proposals are commonly employed.

literature, evaluate hypotheses, and describe the scientific merits of the proposed research activity. A critically important feature of the proposal submission process—merit review—provides the agency and applicant with perspectives of other experts about the ideas, proposed research approaches, and the capacity of the applicant and his or her research group to carry out the proposed research.[2] Regrettably, however, a significant portion of the information that must be submitted as part of a grant proposal package has little utility when it comes to evaluating the scientific merit of proposed research or the capabilities of the research team. Proposal preparation has become, in large measure, an administrative activity that dampens scientific ferment and imposes undue burdens on the researcher, his or her institution, and those engaged in proposal review.

Often, investigators apply for grants from multiple agencies to support their research programs. Individual federal agencies generally determine the information required in grant proposals; however, in certain instances, agencies are obligated by statute[3] to obtain particular information resulting in agencies having differing statutory requirements for the acquisition of information. Agencies nevertheless have a great deal of discretion regarding the information that must be submitted as part of a grant proposal package. Items selected for inclusion are often determined by agency mission. If an agency wishes to request additional proposal information, such changes require approval by the White House Office of Management and Budget (OMB) as part of its periodic review of agency forms.

Nature of Concern

Most funding agencies require that applications include responses to all of the categories of requested information on the agency's standard grant application form.[4] For the past decade, funding success rates at the National Institutes

[2]The reviewers of a proposal are typically anonymous so as to enhance the credibility of the review process.

[3]For instance, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (America COMPETES Act) Act, H.R. 2272, 110th Congress (2007), states that the director of the National Science Foundation "shall require that all grant applications that include funding to support postdoctoral researchers include a description of the mentoring activities that will be provided for such individuals, and shall ensure that this part of the application is evaluated under the Foundation's broader impacts merit review criterion."

[4]Some agencies adopt a different approach. In the case of investigators who wish to engage in scientific research funded by the Department of Defense, for instance, the proposal preparation process typically involves two stages. "Prospective awardees are encouraged to submit white papers to minimize the labor and cost associated with the production of detailed full proposals that have very little chance of being selected for funding. Based on an assessment of the white papers, the responsible Research Topic Chief will provide informal feedback notification to the prospective awardees to

of Health (NIH) and the National Science Foundation (NSF), among the largest nondefense funders of scientific research, have been at historic lows,[5] and investigators typically submit many proposals to increase their chances of receiving an award. In the particular case of NIH, the approximate number of awards made by some institutes is less than 10 percent of submitted proposals.[6,7] These discouraging results lead to a highly inefficient process where investigators submit an enormous amount of information as part of a proposal that has a very small chance of success. Assembling and providing unnecessary information adds burden for the investigator, the institution, and those who review proposals at the agencies' behest. Furthermore, an application process may take many months to complete (see Appendix G). As a result, applicants invest an inordinate amount of time updating and revising application packages and spend correspondingly less time conducting research. The amount of administrative burden associated with proposal preparation has been well documented.[8]

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encourage or discourage submission of full proposals. The Research Topic Chief may also on occasion, provide feedback encouraging reteaming to strengthen a proposal. "If an offer is not made an investigator may still submit a full proposal. However, the initial evaluation of the white papers should give prospective awardee some indication of whether a later full proposal would likely result in an award." See, e.g., *Fiscal Year (FY) 2015 Department of Defense Multidisciplinary Research Program of the University Research Initiative* (ONRFOA 14-012), p. 7, http://www.arl.army.mil/www/pages/8/MURI-FY15-14-012-Amendment-0001.pdf.

[5]For NIH success rates over time, see "Table #218, Success Rates of NIH R01 Equivalent and Research Project Grants Applications, Fiscal Years 1970–2014," National Institutes of Health, Office of Extramural Research, Office of Planning, Analysis and Communications, Division of Statistical Analysis & Reporting, 2014, accessed August 12, 2015, http://report.nih.gov/FileLink.aspx?rid=665. For NSF, see National Science Foundation, *Report to the National Science Board on the National Science Foundation's Merit Review Process Fiscal Year 2013* (NSB-14-32) (Arlington, VA, 2014), http://www.nsf.gov/pubs/2014/nsb1432/nsb1432.pdf.

[6]See "Research Project Success Rates by NIH Institute for 2014," National Institutes of Health, Research Portfolio Online Reporting Tools (RePORT), 2014, accessed August 12, 2015, http://report.nih.gov/success_rates/Success_ByIC.cfm.

[7]The success rate for grant funding across NIH was 15.9 percent in FY 2014 [see "Research Project Success Rates by Type and Activity for 2014," National Institutes of Health, Research Portfolio Online Reporting Tools (RePORT), 2014, accessed August 12, 2015, http://report.nih.gov/success_rates/Success_ByActivity.cfm. This figure represents all grants awarded. The percentage of Research Project (R01) grants was slightly lower at 15.4 percent] and 20 percent across NSF in FY 2014 [see National Science Foundation, *Report to the National Science Board on the National Science Foundation's Merit Review Process Fiscal Year 2013* (NSB-14-32) (Arlington, VA, 2014), 20, http://www.nsf.gov/pubs/2014/nsb1432/nsb1432.pdf.]

[8]See, e.g., National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf and Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, Randy Brutkiewicz, *Federal Demonstration Partnership (FDP): 2012 Facul-*

Analysis

Grant proposals typically require the submission of the following components in a format determined by the agency: detailed budgetary information, descriptions of current and pending support, evidence of researcher compliance with required training, disclosure of financial conflicts of interest, post-doctoral research management plans, data management and sharing plans, and when applicable, approvals by institutional review boards (IRBs) and institutional animal care and use committees.[9]

In most instances, granting agencies have long-term relationships with the researcher's academic institution and are well placed to make assessments regarding organizational legitimacy for managing funds and overseeing the conduct of research absent all of the detailed information currently required in proposal packages. Research institutions frequently seek accreditation of their programs and facilities by independent accrediting bodies, maintaining, for example, accredited human research protection and animal care and use programs. In addition, institutions must have valid assurances[10] on file to receive federal funding. For example, NIH requires institutions conducting animal research to have an assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW) in order to receive Public Health Service funding. If the institution does not have a valid assurance, the funding agency will ask OLAW to negotiate an assurance before the grant, contract, or cooperative agreement is awarded.[11] Similarly, an institution must have a valid assurance whenever it engages in nonexempt human subjects research.[12] In addition, most proposals come from institutions that have biosafety committees that report to NIH as well as to local and state authorities. Such institutions must register with the government before they can apply for federal funding. All of these certifications could be relied upon to relieve funding agencies and the investigators of the needless descriptive procedures used to assure the trustworthiness of their relevant activities.

For the relatively few investigators whose grant applications are selected for funding, agencies often require updated information immediately prior to the

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ty Workload Survey Research Report (2014), 19-20, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.

[9]The NIH requirement that grant applications contain extensive animal research protocols for review by study sections, when the same materials are also reviewed by institutional review entities, highlights a burdensome redundancy.

[10]An assurance is a documented commitment to comply with certain institutional policies or federal requirements.

[11]See "Office of Laboratory Animal Welfare: Obtaining Assurance," National Institutes of Health, Office of Extramural Research, 2015, accessed August 12, 2015, http://grants.nih.gov/grants/olaw/obtain_assurance.htm.

[12]See "Frequently Asked Questions from Applicants: Human Subject Research – Assurances," National Institutes of Health, Office of Extramural Research, 2010, accessed August 12, 2015, http://grants.nih.gov/grants/policy/hs/faqs_aps_assurances.htm#271.

time when the application receives tentative approved for funding because, as noted, 8–9 months may elapse between the submission of a grant application and the release of funds. The government understandably wants affirmation that the information previously submitted remains accurate. For agencies and programs that follow such practices, the presence of valid institutional assurances should be sufficient for the purpose of proposal review; detailed information could be submitted later for those proposals that have a reasonable prospect of being funded.

Findings

Much of the information requested by different federal funding agencies is the same. Regrettably, agencies often require the submission of the same information in dissimilar forms and formats. A relatively small portion of the required information may be agency-specific or unique, perhaps as the result of statute or regulation (e.g., the current requirement for NIH to collect information regarding financial conflicts of interest at the time of proposal submission, rather than, for example, after the completion of the merit review process).[13] The burden associated with providing such particular additional information could be reduced or even eliminated by revisions to specific statutes, regulations, or agency policies.

Research agencies and universities have worked diligently through both the Research Business Models Subcommittee of the National Science and Technology Council and the Federal Demonstration Partnership to standardize the forms and formats involved in the grant application process. Yet, despite best efforts, formats still vary widely across agencies, leaving faculty and their institutions to track and respond to very different and burdensome requirements. The lack of harmony and standardization has also frustrated efforts to create standard datasets that can be submitted either uniformly through federal portals (e.g., Grants.gov) or through third-party providers (e.g., SciENcv or My Bibliography).

Currently, each agency application and progress report form is individually reviewed and approved by OMB's Office of Information and Regulatory Affairs (OIRA), under the Paperwork Reduction Act (see Appendix E). Each document is reviewed on a unique cycle for a 3-year period.[14] In the course of that review, the public may have an opportunity to comment on the proposed formats and information collection and on agency estimates of the burden associated with the completion of the forms. A review of the individual estimates of the

[13]See Responsibilities of Institutions Regarding Investigator Financial Conflicts of Interest, 42 CFR 50 § 604 (e) (1) (2015), which requires "that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research."

[14]Or sooner as required by OMB.

time required and the costs to complete the forms indicates a wide variation in burden estimates between and among agencies. This raises questions about the accuracy of the estimates, over and above the variance due to the degree of complexity in completing the forms.[15] In addition, agencies may have concurrent proposal preparation related submissions to OIRA. This makes it difficult for the public to understand the full burden of providing information to funding agencies.

A substantial increase in the use of "just-in-time" procedures could streamline the grant application process. Just-in-time (JIT) refers to information that is sent to a federal funding agency after an application package goes through initial scientific merit peer review and is deemed likely to be funded. Certain NIH programs and award mechanisms currently use JIT procedures for some information, and according to NIH, the "procedure reduces the time to award while ensuring the accuracy and timeliness of information needed to award NIH grants"[16] while decreasing "the administrative burden for the 75-80 percent of the applications that will not receive funding."[17]

If JIT procedures were employed for the submission of all documents that do not bear directly on the scientific merit of a proposal or provide critical assurances and biographical and budgetary information, a grant application might be reduced to the following components:

- Details on the Applying Institution
- Biosketch of Principal Investigator and Key Research Personnel
- Abstract Describing the Proposed Research
- Research Plan
- Total Estimated Budget Amount

and

- If human subjects, animals and/or select agents are involved, the application package would demonstrate that the institution has the necessary

[15]Burden estimates are split between various OMB approval numbers and are inconsistent with regard both to the estimates listed on the forms and approvals. Agencies often seem to require information collections that have not been approved by OMB. Even in instances where estimates are approved and consistent, the estimates do not seem to be related to the actual time expended by the individuals completing these forms. In addition, the burden estimates for the same forms vary widely by agency. These types of issues are not limited to grant proposal forms. Burden estimates for other required forms, for example, progress reporting forms (see Progress Reporting section of this report), exhibit similar problems.

[16]See *Notice of Requirement for Electronic Submission of Just-in-Time Information and Related Business Process Changes Beginning April 20, 2012* (NOT-OD-12-101) (Bethesda, MD: National Institutes of Health, 2012), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-101.html.

[17]See "Just-in-Time Procedures for First and Career Awards," *NIH Guide* 25, no. 10 (1996), http://grants.nih.gov/grants/guide/notice-files/not96-081.html.

> assurances to conduct the research and that appropriate protocol approval documents will be provided in the event of a high likelihood of funding.

Additional researcher and key personnel information [e.g., references, complete curriculum vitae (CV), lists of all publications] could ideally be accessed through a unified, online, third-party database via a unique researcher identifier. A model for such a database exists in the form of ORCID, an open, nonprofit, community-driven effort to create and maintain a registry of unique researcher identifiers that transparently links research activities and outputs to the researcher identifier.[18]

Investigators' biosketch information is routinely collected by agencies, and much of that collected information is identical across funding agencies. For example, NIH, NSF, Department of Defense, and U.S. Department of Agriculture biosketch forms all require the following information: (1) name and address/contact information; (2) professional/employment history; (3) professional activities and/or honors/awards; and (4) relevant publications.[19] Yet, despite the uniformity of the information required, such information must be entered into forms and in formats unique to each agency.[20] The NIH biosketch form also requires a personal statement and a statement regarding how the proposed research contributes to science. While this information is certainly relevant, there is no reason why it should be included as part of a biosketch when it is provided in the component of the application that details the scientific merit of the project (e.g., as part of an abstract) rather than in the revised format that adds substantial investigator burden.

Although agencies have moved towards use of online databases[21] for the collection of data, they make use of diverse databases. In addition, the infor-

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[18]See "ORCID," ORCID, Inc., accessed August 12, 2015, http://orcid.org/.

[19]In January 2015, NIH introduced a new biosketch form (see Biographical Sketch (OMB No. 0925-0001/0002) (Bethesda, MD: National Institutes of Health, 2015) http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx) that substitutes a "Contribution to Science" section for the "Selected Peer-reviewed Publications" section that was part of the earlier formulation. The Contribution to Science section asks applicants to "describe up to five of your most significant contributions to science," and to for each contribution, to "indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work." The Selected Peer-Reviewed Publications section had asked applicants to list selected publications "based on importance to the field, and/or relevance to the proposed research."

[20]In addition, websites used to collect application information vary from agency to agency, and grant applicants applying to multiple agencies must become familiar with the idiosyncrasies of the various interfaces.

[21]The most recent version of the NIH biosketch form, for instance, asks investigators to "provide a URL to a full list of your published work as found in a publicly available

mation contained within these databases may be inaccurate or outdated, which means the investigator may need to invest significant time and effort to make certain that the information in multiple databases is corrected and/or up to date.[22] Furthermore, the information in current databases is generally limited to biological sciences, and this presents challenges for investigators in other disciplines, such as the physical and computing sciences. Moreover, at a time when science is increasingly collaborative and interdisciplinary, use of multiple diverse databases creates difficulties with research proposals that involve researchers from diverse disciplines. Additionally, in some cases, agency funding restrictions preclude administrative staff from assisting with data entry and management and administrative tasks are shifted to faculty and investigators.

When a proposal is deemed likely to be funded, the investigator and his or her institution could be asked to provide any additional documentation just in time. Such documents could include human institutional assurances with protocol numbers and IRB approval, animal institutional assurances with protocol numbers, select agent approval, conflict-of-interest disclosures, detailed budgets, resource requirements (with the exception of specialized equipment necessary to conduct the research), and so forth.

Agencies funding research designed to provide specific deliverables should employ a contract mechanism or cooperative agreement rather than a research award mechanism.

RECOMMENDATIONS

4.1. The committee recommends that Congress, in concert with the White House Office of Management and Budget, conduct a transparent and comprehensive review of agency research grant proposal documents for the purpose of developing a uniform format to be used by all research funding agencies.

- Information collection and formats should be simplified and standardized to take advantage of both federal and third-party portals for submission of information across federal funding agencies.
- In instances where requested information beyond the common standard is deemed as bearing directly on an agency's particular mission, the agency should be required to provide legitimate and credible justification for the collection of such information.

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digital database such as SciENcv or My Bibliography" (See Biographical Sketch (OMB No. 0925-0001/0002) (Bethesda, MD: National Institutes of Health, 2015), http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx).

[22] All NIH grantees must list all their publications in PubMed (a full-text archive of biomedical and life sciences journal literature at NIH's National Library of Medicine).

- Agency-specific information collections should be restricted to a minimal portion of the material contained in an application package.

4.2. The committee recommends that research proposal information should be limited to the minimal information necessary to permit peer evaluation of the merit of the scientific questions being asked, the feasibility of answering those questions, and the ability of the researcher/research team to carry out that research. For proposals demonstrating these characteristics, any supplementary information should, if requested, be provided *just-in-time*.[23]

- Materials provided as part of an initial proposal should be limited to the following:
  1. Details on the Applying Institution and Research Team.
  2. Biosketch of Principal Investigator and other Key Personnel. The information in a biosketch should be limited to
     a. Name and address/contact information;
     b. Professional/employment history;
     c. Professional activities; and
     d. Relevant publications.
  3. Abstract Describing the Proposed Research.
  4. Research Plan.
  5. Total Estimated Budget Amount.
  6. If humans, animals and/or select agents are involved, the application package should demonstrate that the institution has the necessary federal assurance to conduct the research and will provide appropriate institutional approval protocol numbers before funding takes place.

4.3. The committee recommends that research agencies develop a central repository to house assurances similar to the Single Audit Clearinghouse of the Federal Demonstration Partnership (FDP).

4.4. The committee recommends that Congress task a single agency with overseeing and unifying efforts to develop a central database of investigator information.

- Each investigator should be assigned a unique identifier linked to the database and accessible to all federal funding agencies.
- In order to assure the currency of information in the database, information in the database should be maintained by individual investigators.

[23]That is, sent to a sponsor after a proposal package goes through initial peer review and is deemed likely to be funded.

- The database should include each investigator's relevant personally identifiable information,[24] CV, and a list of the investigator's publications or links to a third-party site listing the investigator's publications.

PROGRESS REPORTS

Recipients of federal grants "are responsible for managing and monitoring each project, program, subaward, function or activity supported by the award."[25] For each award, when required, performance reports are to be submitted to the awarding agency. Performance reporting requirements are specified in OMB Circular A-110 "Monitoring and Reporting Program Performance"[26] and the Common Rule implementing OMB Circular A-102. OMB Circular A-110 states that reports "shall generally contain, for each award, brief information on each of the following: (1) A comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs; (2) Reasons why established goals were not met, if appropriate; (3) Other pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs."[27] Awarding agencies prescribe the frequency with which the performance reports must be submitted.[28]

Recognizing that there was "inconsistency in interim research progress reporting among federal agencies," that interdisciplinary and interagency research is increasingly complex, and that "unnecessary variations" in progress reporting requirements "contribute to administrative burdens, take research time from investigators, and increase associated costs involved in the management of research programs, the Research Business Models Subcommittee of the Committee on Science launched an initiative that resulted in the creation of a "uniform Research Performance Progress Report (RPPR) format for use by agencies and awarding offices that support research and research-related activities."[29]

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[24]But not social security numbers or financial information. In establishing such a database, it will be important to ensure that all privacy concerns relating to the collection and amalgamation of any other personally sensitive information are recognized and addressed.

[25]See Monitoring and Reporting Program Performance, 2 CFR 2 § 215.51(a) (2010).

[26]See Monitoring and Reporting Program Performance, 2 CFR 2 § 215.51 (2010).

[27]See Monitoring and Reporting Program Performance, 2 CFR 2 § 215.51(d) (2010).

[28]See Monitoring and Reporting Program Performance, 2 CFR 2 § 215.51(b) (2010).

[29]Peter R. Orszag and John P. Holdren (2010) *Policy on Research Performance Progress Report (RPPR)* [Memorandum]. Washington, DC: The White House, http://www.nsf.gov/bfa/dias/policy/rppr/policyletter.pdf.

The RPPR is to be used by agencies that fund research for the collection of reports submitted by grantees for annual or other interim performance reporting on grants and cooperative agreement awards. The RPPR was expected to replace other performance-reporting formats currently in use by agencies funding research to address progress for the most recently completed period, at the frequency required or designated by the agency. Each category in the RPPR is a separate reporting component that must be filed independently.[30]

In general, information regarding project financial expenditures is provided by recipient institutions as separate reports generated by institutional payment management systems (e.g., the weekly, monthly, or quarterly cash transaction report, and annual and end-of-project financial reports) as required by the terms of the award.

Nature of Concern

While the intent of the RPPR was and is to harmonize progress reporting, funding agencies have the latitude to use the RPPR to collect unneeded information, undermining its objective. They may, for instance, use optional components of the RPPR format to request additional information[31] and provide additional program-specific instructions necessary to clarify a requirement for a particular program. Agencies may also develop additional agency- or program-specific reporting components[32] and use other reporting formats, such as the Performance Progress Report, if those formats are better suited to the agency's reporting requirements, for example, for research centers and institutes, clinical

[30]The RPPR format was implemented under 2 CFR Part 215 [OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (2012)] and the Grants Management Common Rule implementing OMB Circular A-102, Grants and Cooperative Agreements with State and Local Governments (published 1994, amended 1997). See Peter R. Orszag and John P. Holdren (2010) *Policy on Research Performance Progress Report (RPPR)* [Memorandum]. Washington, DC: The White House, http://www.nsf.gov/bfa/dias/policy/rppr/policyletter.pdf.

[31]"Within a particular component, agencies should direct recipients to complete only those questions that are relevant to the award or agency." See "Final Format: Research Performance Progress Report," National Science Foundation, 2010, p.1. Accessed August 12, 2015, https://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf.

[32]"However, to maintain maximum uniformity, agencies are to minimize the degree to which they supplement the standard categories. Such agency- or program-specific requirements require additional OMB review and clearance under the Paperwork Reduction Act." See "Final Format: Research Performance Progress Report," National Science Foundation, 2010, accessed August 12, 2015, https://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf.

trials, or fellowship and training awards or in connection to reporting on program performance.[33]

Analysis

Most federal funders of scientific research have implemented or are in the process of adopting the RPPR to collect progress report data on all federally funded research and research-related awards.[34]

Standard cover page data elements, as well as mandatory and optional components, comprise the complete RPPR format.[35] If an agency elects to collect the complete suite of data for all mandatory and optional components, the information collected may be considerable.

For the cover page alone, the elements are as follows:

- Federal Agency and Organization Element to Which Report is Submitted
- Federal Grant or Other Identifying Number Assigned by Agency
- Project Title
- Program Director/Principal Investigator Name, Title and Contact Information (e-mail address and phone number)
- Name of Submitting Official, Title, and Contact Information (e-mail address and phone number), if other than Program Director/Principal Investigator
- Submission Date
- DUNS[36] and EIN[37] Numbers

[33]See Peter R. Orszag and John P. Holdren (2010) *Policy on Research Performance Progress Report (RPPR)* [Memorandum]. Washington, DC: The White House, http://www.nsf.gov/bfa/dias/policy/rppr/policyletter.pdf.

[34]The Department of Energy, for example, implemented the Research Performance Progress Report format on November 22, 2010. While all Department of Defense components awarding grants and cooperative agreements for research activities are subject to the implementation of the RPPR, it is not clear that the RPPR is used uniformly by the Department of Defense. At NIH, the RPPR has replaced all interim performance reports used by grantees to report on research and research-related activities. The Department of Homeland Security continues to work with the DHS Component program and awarding offices that administer research awards and intends to implement the RPPR no later than the end of fiscal year 2016. Information on agency implementation plans may be found at "Research Performance Progress Report (RPPR)," National Science Foundation, accessed August 12, 2015, http://www.nsf.gov/bfa/dias/policy/rppr/.

[35]See "Final Format: Research Performance Progress Report," National Science Foundation, 2010, accessed August 12, 2015, https://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf.

[36]Data Universal Numbering System. A DUNS number is a unique nine-digit identification number that identifies business entities on a location-specific basis.

- Recipient Organization (Name and Address)
- Recipient Identifying Number or Account Number, if any
- Project/Grant Period (Start Date, End Date)
- Reporting Period End Date
- Report Term or Frequency (annual, semiannual, quarterly, other)
- Signature of Submitting Official (signature shall be submitted in accordance with agency specific instructions)[38]

In addition to cover page information, the only mandatory reporting component is "Accomplishments." The information provided in this section allows the agency to assess whether satisfactory progress has been made during the reporting period. Respondents are responsible for answering the following questions:

- What are the major goals and objectives of the project?
- What was accomplished under these goals?
- What opportunities for training and professional development has the project provided?
- How have the results been disseminated to communities of interest?
- What do you plan to do during the next reporting period to accomplish the goals and objectives?[39]

Optional reporting components of the RPPR are (1) Products (designed to enable agencies to evaluate what the project-related publications demonstrate about the excellence and significance of the research and the efficacy with which the results are being communicated to colleagues, potential users, and the public); (2) Participants and Other Collaborating Organizations (designed to inform agencies regarding who has worked on the project to gauge and report performance in promoting partnerships and collaborations); (3) Impact (designed to assess how knowledge, techniques, people, and infrastructure are drawn upon again and again for application to commercial technology and the economy, to health and safety, to cost-efficient environmental protection, to the solution of social problems, to numerous other aspects of the public welfare, and to other fields of endeavor); (4) Changes [for instances where changes were not previously reported in writing, the section allows the investigator to provide the following additional information, if applicable: (a) changes in approach and reasons for change, (b) actual or anticipated problems or delays and actions or plans

[37]Employer Identification Number. An EIN number is also known as a Federal Tax Identification Number. It is used to identify a business entity.

[38]See "Final Format: Research Performance Progress Report," National Science Foundation, 2010, accessed August 12, 2015, https://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf.

[39]Ibid.

to resolve them, (c) changes that have a significant impact on expenditures, (d) significant changes in use or care of animals, human subjects, and/or biohazards]; (5) Self Reporting Requirements (allowing investigators to respond to any special reporting requirements specified in the award terms and conditions, as well as any award-specific reporting requirements); and (6) Budgetary Information (used to collect budgetary data from the recipient organization for use in the conduct of periodic administrative and budgetary reviews).[40]

NIH requires grant recipients to provide information for all six "optional" sections. In many cases, such as the "Products" (publications) section, the information required of respondents is extensive. The amount of information collected by other agencies is significantly less (see Box 4-1).

Findings

The RPPR requires more work than previous progress reports, and each section of the report must be uploaded independently. The frequency with which reports are required may interrupt research productivity and discourage research on difficult, long-term problems. In addition, at the early phase of a grant period, there is little tangible output (e.g., publications) to provide metrics for assessing investigator progress.

The purpose of progress reporting is to demonstrate to the funding agency that the research is progressing. While a standard interagency RPPR is desirable, the reality is that there is a great deal of flexibility with regard to agency implementation of the RPPR, as agencies selectively request that grantees include or exclude data from the common dataset encapsulated by the RPPR. Additional

[40]Ibid. On July 23, 2015, the National Science Foundation issued a request for public comment on a proposed update to the RPPR. Proposed changes include the use of "one report format for both interim and final reports" and the addition of a seventh optional report category: "Project Outcomes: What were the outcomes of the award?" According to the draft format for the proposed updated RPPR, "This component is used to provide information regarding the cumulative outcomes or findings of the project." Those completing this section would be required, for the final project RPPR, to "provide a concise summary of the outcomes or findings of the award (no more than 8,000 characters) that:

- is written for the general public in clear, concise, and comprehensible language;
- is suitable for dissemination to the general public, as the information may be available electronically;
- does not include proprietary, confidential information or trade secrets; and
- includes up to six images (images are optional)."

See "Components and Significant Changes," National Science Foundation, accessed August 12, 2015, http://nsf.gov/bfa/dias/policy/rppr/frppr_sigchanges.pdf, and "Draft Format For Use in Submission of Interim and Final Research Performance Progress Reports," National Science Foundation, accessed August 12, 2015, http://nsf.gov/bfa/dias/policy/rppr/frpprformat_fedreg.pdf.

award-specific requirements can be added, and multiple systems can (and are) used for RPPR submission. Unfortunately, the ease of electronic data collection may have inadvertently stimulated overzealous agency information collection.

BOX 4-1 Research Performance Progress Reporting for the National Institutes of Health, National Science Foundation, and the Department of Energy

There are significant differences in how three federal research funding agencies, NIH, NSF, and DoE, currently employ the Research Performance Progress Report (RPPR) to collect data. The length of the three agencies' RPPR instructional documents provides an indication of the relative scope of their progress reporting information requirements:

> "NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instruction Guide"[a] – 115 pages
>
> "Research Performance Progress Report (RPPR) Screenshots and Instructions" (NSF)[b] – 27 pages
>
> "Federal Assistance Reporting Checklist and Instructions for RD&D Projects" (DoE)[c] – 10 pages[d]

RPPRs are submitted to the three agencies via three different web interfaces. NIH RPPRs are submitted via eRA Commons, NSF RPPRs are submitted via Research.gov, and DoE RPPRs are submitted through the DoE Office of Science Portfolio Analysis and Management System (PAMS).

In general, NSF and DoE limit their information collection to the standard set of questions established by the RPPR format. NIH, however, requires information well beyond the standard question set. To the standard question set for the "Accomplishments" section, for example, NIH has added a number of sub-questions:

> Under the standard question "What are the major goals and objectives of the project?," NIH has added the following sub-question: "Have the major goals changed since the initial competing award or previous report?" The agency further states that, if "the major goals/specific aims have changed since the initial competing award or previous report," "a revised description of major goals/specific aims is required." NIH also notes that "written prior approval from the awarding agency grants official is required for significant changes in the project or its direction" and that "the RPPR is not an appropriate vehicle to request such a change."
>
> Under the question "What opportunities for training and professional development has the project provided?," NIH asks that, "For all projects reporting graduate students and/or postdoctoral participants," grant recipients describe whether their respective institution "has established Individual Development Plans (IDPs) for those participants" and to "include information to describe how IDPs are used, if they are used, to help manage the training for those individuals."

(Continued)

BOX 4-1 Continued

And under the question, "What do you plan to do during the next reporting period to accomplish the goals and objectives?," NIH requires the inclusion of "any important modifications to the original plans" and "a scientific justification for any changes involving research with human subjects or vertebrate animals." Detailed descriptions of such changes must also be provided.

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[a] Available at http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf.
[b] Available at https://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&_pageLabel=research_node_display&_nodePath=/researchGov/Service/Desktop/PublicOutcomesReport.html.
[c] Available at http://energy.gov/management/downloads/federal-assistance-reporting-checklist-and-instructions-rdd-projects.
[d] Inclusive of the "DOE F 4600.2, Financial Assistance Reporting Checklist for RD and D" and "Attachment 1, Research Performance Progress Report."

In addition, by asking pointed questions regarding the direction research is taking or has taken, funding agencies may affect the course of scientific discovery, as investigators may feel the need to adhere strictly to the goals of the proposal rather than pursue promising avenues of inquiry as they appear. An investigator may feel safer reporting that the major goals and objectives of the project have not changed rather than providing an explanation for new directions given uncertainties as to how deviations from stated objectives might be viewed by the funder. Agencies with a focus on discovery-based science, such as NIH, or other agencies seeking to support discovery science should make it clear that investigators have the latitude to explore diverse avenues of research if promising leads emerge during the course of research.

RECOMMENDATION

4.5. The committee recommends that the White House Office of Management and Budget require that research funding agencies use a uniform format for research progress reporting.

- All investigator progress reports should be limited to performance outcomes, submitted no more frequently than annually, and commensurate with both the size of the award and use made of the report by the recipient agency.
- Requests for additional data should be restricted to information that is essential for the assessment of compliance and performance.
- If additional information is to be requested, agencies must provide legitimate and credible justification for the collection of such information.

SUBRECIPIENT MONITORING

A subrecipient relationship exists when an institution, as a pass-through entity, disburses funds from a federal award to another entity for the performance of a portion of the work or to accomplish certain objectives specified in the award.[41] Institution A, wishing to collaborate on a research project with Institution B, might, for example, enter into an agreement with Institution B wherein Institution A disburses funds from a federal grant to pay researchers at Institution B to perform a certain task. Organizations acting as pass-through entities (in the above example, Institution A) are tasked with monitoring the programmatic and financial activities of subrecipients (Institution B in the above example) so as to ensure proper stewardship of federal funds. Organizations are further charged, in addition to achieving performance goals, with ensuring that subrecipients are in compliance with federal laws and regulations and with provisions of agreements that govern the subaward.

Subrecipient relationships at research institutions occur frequently as researchers from one institution collaborate with researchers at another. In such cases, a research institution receiving the initial (or prime) award from a federal research agency issues a subaward for that portion of the research activity that will be carried out at another institution. Such collaborations may occur for a variety of purposes (e.g., to obtain additional scientific expertise or resources, to incorporate a specialized methodology, to build multi-institutional teams, to enhance patient recruitment for clinical studies). Historically, if a subrecipient was a research institution, the pass-through entity was responsible for oversight of the work performed by the subrecipient, and the subrecipient institution was responsible for other aspects of its institutional conduct (e.g., business practices, investigator conduct, research subject participant protections).

Subrecipient monitoring requirements are found in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, hereafter the *Uniform Guidance*.[42] The Uniform Guidance (see Box 4-2) is cur-

[41] A subrecipient "is an entity that expends awards received from a pass-through entity to carry out a project." A "pass-through entity means a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program." See Pass-Through Entity, 2 CFR 2 § 200.74 (2014).

[42] These requirements originated in the Single Audit Act of 1984. This act standardized audit requirements for states, local governments, and Indian tribal governments receiving and using federal financial assistance. It provides audit requirements to ensure that federal grants to nonfederal entities "are expended properly." "A single audit is intended to provide a cost-effective audit for non-Federal entities in that one audit is conducted in lieu of multiple audits of individual programs." See "Office of Federal Financial Management Single Audit," *The White House, Office of Federal Financial Management Single* Audit, accessed September 9, 2015, https://www.whitehouse.gov/omb/financial_fin_single_audit. In 1985, the United States Office of Management and Budget (OMB) issued OMB Circular A-128 (Audits of State and Local Governments) to assist with the implementation of the

rently the principal document governing the administrative, financial management, and audit requirements for federal awards.

Nature of the Concern

The Uniform Guidance[43] specifies two kinds of responsibilities for pass-through entities when making subawards to other organizations. The first set of responsibilities involves providing administrative information to ensure that every subaward is clearly identified to the subrecipient as a subaward.[44] The requirements of this section are relatively clear and limited in scope to the specific subaward.

The second set of requirements[45] is significantly more burdensome. These requirements intermix responsibilities that may be viewed as appropriate and limited to the performance of a specific subaward with provisions that may be viewed as putting the pass-through entity in a position to review the subrecipient's business systems and standing in the context of federal audit requirements. The following examples are requirements that, if misapplied or misinterpreted, put the pass-through entity in an untenable position:

> The pass-through is responsible for evaluating each subrecipient's risk of noncompliance with Federal statues, regulations, and the terms and conditions of the subaward…which may include consideration of such factors as:

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new single audit, and in 1990, administratively extended the Single Audit process to non-profit organizations with the issuance of OMB Circular A-133 (Audits of States, Local Governments and Non-Profit Organizations). These changes were subsequently incurporated into the Single Audit Act Amendments of 1996.

[43]Requirements for Pass-Through Entities, 2 CFR 2 § 200.331 (a) (2014).

[44]Required information includes: "(1) Federal award identification…; (2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award; (3) Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the Federal awarding agency including identification of any required financial and performance reports; (4) An approved federally recognized indirect cost rate negotiated between the subrecipient and the Federal government or, if no such rate exists, either a rate negotiated between the pass-through entity and the subrecipient…or a de minimis indirect cost rate…; (5) A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this […section]; (6) Appropriate terms and conditions concerning closeout of the subaward." See Requirements for Pass-Through Entities, 2 CFR § 2.200.331 (2014).

[45]These are delineated in Requirements for Pass-Through Entities, 2 CFR 2 § 200.331 (b–h) (2014).

1) the results of previous audits;
2) whether the subrecipient has new personnel or new or substantially changed systems; and

BOX 4-2 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance)

"To deliver on the promise of a 21st-Century government that is more efficient, effective and transparent," the Office of Management and Budget issued the Uniform Guidance in an effort to streamline the federal government's guidance on administrative requirements, cost principles, and audit requirements for federal awards.[a] The guidance supersedes and streamlines requirements from eight earlier OMB circulars.[b] The goal of this reform was to deliver on President Obama's directives to: "(1) streamline "guidance for Federal awards to ease administrative burden; and (2) strengthen oversight over Federal funds to reduce risks of waste, fraud, and abuse" by:

- Eliminating Duplicative and Conflicting Guidance;
- Focusing on Performance over Compliance for Accountability;
- Encouraging Efficient Use of Information Technology and Shared Services;
- Providing For Consistent and Transparent Treatment of Costs;
- Limiting Allowable Costs to Make Best Use of Federal Resources;
- Setting Standard Business Processes Using Data Definitions;
- Encouraging Non-Federal Entities to Have Family-Friendly Policies;
- Strengthening Oversight; and
- Targeting Audit Requirements on Risk of Waste, Fraud, and Abuse[c]

Federal agencies each developed agency-specific Uniform Guidance implementation plans. Research institutions, as federal grantees, expended significant resources in reviewing the guidance and in developing and implementing policies and procedures to comply with the guidance. The Uniform Guidance went into effect on December 26, 2014.

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[a] See *Federal Register* 78, no. 248 (December 26, 2013): 78590, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/html/2013-30465.htm.

[b] Circulars A–21 (Cost Principles for Educational Institutions), A–87 (Cost Principles for State, Local and Indian Tribal Governments), A–110 (Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations), and A–122 (Cost Principles for Non-Profit Organizations), which have been placed in OMB guidances; Circulars A–89 (Catalog of Federal Domestic Assistance), A–102 (Grants and Cooperative Agreements with State and Local Governments), and A–133 (Cost Principles for Non-Profit Organizations); and the guidance in Circular A–50 (Audit Followup) on Single Audit Act follow-up.

[c] See *Federal Register* 78, no. 248 (December 26, 2013): 78590-93, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/html/2013-30465.htm.

> 3) the extent and results of Federal awarding agency monitoring (e.g., if the subrecipient also receives Federal awards directly from a Federal awarding agency).
>
> Depending upon the pass-through entity's assessment of risk posed by the subrecipient…monitoring tools may be […used] by the pass-through entity to ensure proper accountability and compliance with program requirements and achievement of performance goals:
>
> (1) verify that every subrecipient is audited as required by Subpart F [of the Uniform Guidance] – Audit Requirements;[46]
> (2) consider whether the results of the subrecipient's audits…or other monitoring indicate conditions that necessitate adjustments to the pass-through entity's own records; and
> (3) consider taking enforcement action against noncompliant subrecipients.[47, 48]

If these requirements are interpreted literally, they require institutions to evaluate subrecipients' compliance with *all* federal statues without qualification. [49]

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[46]Audit Requirements, 2 CFR § 200.501 (f) (2014), "sets forth standards for obtaining consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards." For example, "a non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year" [2 CFR 2 § 200.501(a) (2014)] and "a non-Federal entity that expends less than $750,000 during the non-Federal entity's fiscal year in Federal awards is exempt from Federal audit requirements for that year, except…in...relation to other audit requirements [Audit Requirements, 2 CFR § 200.501 (d) (2014)].

[47]If "a pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the…pass-through entity may…

(a) Temporarily withhold cash payments pending correction of the deficiency by the non-Federal entity or more severe enforcement action by the Federal awarding agency or pass-through entity.

(b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.

(c) Wholly or partly suspend or terminate the Federal award.

(d) Recommend that [suspension or debarment] proceeding[s] be initiated by a Federal awarding agency.

(e) Withhold further Federal awards for the project or program.

(f) Take other remedies that may be legally available."

See Remedies for Noncompliance, 2 CFR § 200.338 (2014).

[48]The complete list appears at Audit Requirements, 2 CFR § 200.501 (b-h) (2014).

[49]The expansion of subrecipient monitoring is not limited to financial practices. For instance, with regard to the use of animals in research performed by a subrecipient, a previous NIH grants policy statement stated that the prime institution "must ensure that all

The ambiguity of the requirements is at odds with the intent of the Single Audit Act and inappropriately transfers what is essentially the federal responsibility of auditing institutional compliance from the government to research institutions. Research institutions are not equipped to meet this requirement.

Analysis

Requirements for subrecipient monitoring were originally enacted to monitor state governments receiving large federal block grants. Such assistance programs were and continue to be very large,[50] and subawards are disbursed to multiple subrecipients of varying size, sophistication, and organizational experience. Funds generally flow down from the state in a "one-to-many" relationship to agencies and to local and nonprofit organizations within the state. Often, pro-

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sites engaged in research involving the use of live, vertebrate animals have an appropriate animal welfare assurance." (See "Administrative and Other Requirements," *NIH Grants Policy Statement*, December 1, 2003, p. 226, http://grants.nih.gov/archive/grants/policy/nihgps_2003/nihgps_2003.pdf). The 2015 *NIH Grants Policy Statement* is more prescriptive and states that the primary recipient is responsible for including in its agreements with collaborating organizations requirements of accountability for the performance of the project and the appropriate expenditure of grant funds by all parties (as well as other specified obligations) and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved animal welfare assurance and that the activity has valid IACUC approval." (See *NIH Grants Policy Statement* (Washington, DC: U.S. Department of Health and Human Services, Bethesda, MD: National Institutes of Health, 2015), IIA-13, http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf). Similar language exists with respect to the monitoring of subrecipient human subject research: "In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites, and for ensuring that an FWA and certification of IRB review and approval exists for each site before human subjects research may begin." (See *NIH Grants Policy Statement* (Washington, DC: U.S. Department of Health and Human Services, Bethesda, MD: National Institutes of Health, 2015), IIA-27, http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf). In both examples, the implication is that prime recipients are responsible for monitoring subrecipient institutions for *any* noncompliance.

[50]The Congressional Research Service identified 23 block grant programs for FY 2014 with budgets totaling $50,843,354,662 [Robert J. Dilger and Eugene Boyd, *Block Grants: Perspectives and Controversies* (CRS Report No. R40486) (Washington, DC: Congressional Research Service, 2014), https://fas.org/sgp/crs/misc/R40486.pdf.] FY 2015 allocations to states for one such program—Social Services Block Grants (SSBG)—totaled $1,575,246,254, and allocations to individual states ranged from $2,888,318 (Wyoming) to $190,019,689 (California). See "Fiscal Year 2015 SSBG Allocations," Administration for Children and Families and U.S. Department of Health and Human Services, 2015, accessed August 24, 2015, http://www.acf.hhs.gov/sites/default/files/ocs/ssbg_fy2015_3rd_quarter_allocations_0.pdf.

posals are received and funds awarded only once or a few times a year. State organizations are frequently in a hierarchical relationship with subrecipient organizations, and accordingly in a position to conduct subrecipient monitoring, including with regard to the ability to make determinations of competency and to take action against noncompliant subrecipients. What may be appropriate for state agencies when monitoring the expenditure of federal funds in the context of a generally hierarchal relationship is not appropriate for research institutions when managing research awards, 80 percent of which are awarded to 100 institutions.[51]

While the extension of subrecipient monitoring requirements to research institutions may have, at one time, seemed logical and commonsensible, subrecipient relationships among research institutions differ fundamentally from those between states and constituent organizations. Researchers engage in collaborative research activities with many institutions, and such collaboration has only increased as science has become increasingly interdisciplinary, interinstitutional, and team based. Relationships are more typically "many to many," and the funds for such collaborations may be received from multiple funding agencies and awarded throughout the year. Further, one institution may be both a "prime" recipient of multiple grants from federal research agencies and simultaneously a "subrecipient" collaborating on many research projects. Given that the vast majority of federally funded research takes place within the top 100 institutions that receive such funding, this means that the majority of subrecipient activity takes place between and among peer institutions that are subject to the same single audit requirements.[52] In fact, in FY 2013, research institutions reported awarding approximately $5.7 billion in grants as prime recipients[53] and receiving about $6.6 billion as subrecipients.[54] These peer research institutions are placed in an unsupportable position when providing appropriate oversight of the compliance of subrecipients with federal statutes, regulations, and financial accounting systems.

Implementation of the Uniform Guidance creates a chaotic situation wherein universities and research institutions are potentially required to review one another's business practices (e.g., procurement, property management). Yale

[51]"Higher Education Research and Development Survey, Fiscal Year 2013: Table 21 Ranked by all Federal R&D expenditures, by R&D field: FY 2013," National Science Foundation, 2013, accessed August 24, 2015, http://ncsesdata.nsf.gov/herd/2013/.

[52]Ibid.

[53]"Higher Education Research and Development Survey, Fiscal Year 2013: Table 71 Total and Federally Financed, by Highest Degree Granted and Institutional Control, Passed through to Subrecipients," National Science Foundation, 2013, accessed August 24, 2015, http://ncsesdata.nsf.gov/herd/2013/.

[54]"Higher Education Research and Development Survey, Fiscal Year 2013: Table 70 Total and Federally Financed, by Highest Degree Granted and Institutional Control, Received as a Subrecipient," National Science Foundation, 2013, accessed August 24, 2015, http://ncsesdata.nsf.gov/herd/2013/.

University reports, for example, that it served as a prime recipient and issued approximately 750 new and modified subawards in FY 2014 to approximately 250 different institutions. The university was a subrecipient on approximately 1,100 subawards from approximately 295 unique, prime organizations during FY 2014–2015 to date (federal awards only).[55] These numbers provide some indication of the enormity of the task that falls upon institutions as they comply with the subrecipient monitoring requirements mandated by the Uniform Guidance.

In a recent survey by the Council on Governmental Relations, 51 institutions reported engaging in approximately 12,000 subawards, an average of 235 subawards per institution. These institutions reported that it takes on average 2.8 FTEs[56] to manage this level of subrecipient activity at an estimated total cost of over $7.5 million dollars independent of the time investment by faculty or departmental level staff.[57]

Further, in addition to the administrative burden that increased subrecipient monitoring imposes on research entities, institutions serving as partners in research will inevitably face conflicts by virtue of their position as both overseers and collaborators.

Findings

One of the purposes of the Single Audit Act was to reduce burdens on nonprofit organizations by promoting sound financial management of federal awards "administered by non-Federal entities." Research institutions are not administering federal awards per se. Rather, they are collaborating in scientific research supported largely by grants or other funding mechanisms.

The new Uniform Guidance, rather than reducing regulatory burden, has increased the prescriptiveness of subrecipient monitoring, and placed institutions in a position of reviewing one another's audit standing and the compliance of their organizational business systems without evidence that the new guidelines will reduce the risk of fraud, waste, or abuse.

Research institutions judiciously engage in ad hoc institutional risk assessment and oversight, particularly with new recipients under the authority of the Uniform Guidance,[58] that allows the prime recipient to impose specific terms and conditions for the management of subawards in order to meet the require-

[55]Staff of the Office of Sponsored Projects, Yale University, Personal Communication to Committee Member Geoff Grant, President, Research Advocates, July 30, 2015.

[56]Full-time Equivalent. The number of total hours worked divided by the maximum number of compensable hours in a full-time schedule as defined by law. An FTE of 1.0 is equivalent to a full-time worker or student.

[57]"Initial Findings and Recommendations of the AAU-COGR-Yale Review of Compliance Costs," (Presentation, Council on Governmental Relations, June 4-5 2015).

[58]See Requirements for Pass-Through Entities, 2 CFR 2 § 200.331 (2014).

ments of the federal award (including ensuring access, as necessary, to the subrecipient's records and financial statements). However, this form of oversight appropriately focuses on project-specific requirements, that is, financial monitoring, supervision of the terms on the award, and so forth. This oversight does not require that institutions engage in inappropriate reviews of other institutions' business systems.

Institutions also engage in substantial oversight of the "programmatic" aspects of subrecipient agreements in accordance with the Uniform Guidance,[59] most importantly by reviewing scientific progress and managing other essential programmatic terms and conditions. These terms often address the use of scientific data developed in the course of the agreement; the potential transfer of research materials developed during the project; specific issues with respect to the conduct of overseas activity, if any, and so forth. To this end, research institutions and research funding agencies have successfully worked together for years through FDP to refine standard subagreement terms and conditions that address essential programmatic issues in a substantive yet streamlined fashion. While these issues represent a significant burden for faculty and administrators to negotiate at the time of the agreement, they are far more germane to the process of monitoring subrecipient conduct than the prescriptive, institutional monitoring requirements imposed on research institutions by the Uniform Guidance.

It is crucial to clarify the role of research institutions with respect to subrecipient monitoring as stewards of federally sponsored projects, both programmatically and financially. Recipient institutions monitor and review the programmatic and financial activities of subrecipients so as to ensure appropriate performance of specified research. If a subrecipient is a research institution, it is not appropriate for another research institution to act as auditor by overseeing subrecipients' compliance with federal statutes and regulations, the competence of their institution-wide business systems, or to oversee the resolution of outstanding audit findings.

RECOMMENDATIONS

4.6. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education only to the extent necessary for prudent project and performance monitoring, and do not require more extensive monitoring of subrecipients' institutional compliance with all federal statues, regulations, policies, and institution-wide business practices.

[59] See Requirements for Pass-Through Entities, 2 CFR 2 § 200.331 (a) (2014).

As an immediate, interim measure, the committee recommends that the Office of Management and Budget permit research institutions to use subrecipients' publicly available Single Audit Reports to verify that subrecipients have not been otherwise debarred or suspended with respect to the receipt of federal funds. For those with a clean Single Audit Report, the prime institution should be allowed to rely on the Single Audit Act oversight process as an alternative to conducting a review of the adequacy of the subrecipient's institutional systems and business practices.

5

Regulations and Policies Related to the Conduct of Research

The focus of this chapter is regulatory requirements related to the conduct of research, specifically those regulations and policies that protect the well-being of research participants (both human and animal) and ensure the integrity and credibility of research findings. The specific areas of consideration are conflict of interest (COI), human subjects research, and animal subjects research.

CONFLICT OF INTEREST

A number of organizations have defined COIs in research and medicine. The Institute of Medicine has defined COI broadly as a set of circumstances resulting in a risk that a person's professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.[1] The Public Health Service (PHS) has taken a narrower view and specifically defined financial conflict of interest (FCOI) as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research, but has extended required oversight to the researcher's other institutional responsibilities.[2]

COIs are common in all professions, and the professions have over time developed normative behavioral and transactional processes to prevent or mitigate the undue influence of these conflicts on professional judgments, choices, and decisions.[3] Secondary interests that may produce conflicts are diverse, but financial gain has been the major focus of federal policies. In the research context, the question is whether the financial interest might have an effect on the design, conduct, or reporting of research being directed or performed by the researcher. Federal policies also often define monetary thresholds for financial

[1]Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice* (Washington, DC: The National Academies Press, 2009), p. 46.

[2]"Grants & Funding: Financial Conflict of Interest," National Institutes of Health, accessed August 24, 2015, http://grants.nih.gov/grants/policy/coi/.

[3]David Korn, "Conflicts of Interest in Biomedical Research," *JAMA* 284, no. 17 (2000).

interests of concern. COIs are inevitable at research institutions, whose missions include the promotion of the public good by both creating new knowledge and facilitating the transfer of that knowledge to the private sector. Research universities, and the scientific profession itself, encourage faculty to engage in activities that fulfill this mission not only through publications but also by outside speaking engagements at conferences and professional meetings, consulting with commercial and nonprofit entities, and the commercialization of technologies derived from their basic research through university technology licensing offices. While it is appropriate for faculty to be rewarded for their activities that are part of the university's mission to benefit the larger society, the individual and the university must closely monitor these activities for COIs to ensure that an individual's decisions or actions are not unduly influenced by considerations of personal financial gain.[4]

Outside professional activities allow researchers to provide their expertise to commercial and nonprofit organizations beyond their institution and compensation for this work is appropriate; consequently, it is critical to note that having FCOIs is not research misconduct. The federal definition of research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting results.[5] FCOIs have accompanied instances of research misconduct, thus contributing to conflation of the two in the minds of the public, the media, and legislators. Research misconduct is by definition a severe threat to the research enterprise and is addressed by federal and institutional policies. In marked contrast, most circumstances where an investigator's financial interests are related to her or his research responsibilities can be evaluated and managed to ensure that the individual's professional decisions are not unduly influenced by potential financial gain.

Nature of Concern

Beginning in the mid-1970s and continuing through the 1980s, a series of widely publicized episodes of scientific misconduct and of harm to human re-

[4]Institutions also have financial interests (e.g., patent income) that must be managed to avoid impact on university research, but this section focuses on COIs of individual investigators and related federal COI policies. Research institutions also have institutional COI policies. In the late 1990s, reports from the HHS OIG and the Government Accountability Office, among others, raised questions about the effectiveness of institutional review boards (IRBs) and how well the safety of human research subjects was being protected. These reports raised the question of institutional COIs: that is, IRBs are institutional committees, and if the institutions themselves had financial interests in research outcomes, would that not necessarily bias the IRBs' reviews? Between 1998 and 2001, the deaths of three research subjects led to substantial media attention, further enhancing the publics' and legislators' concerns about the effectiveness of IRBs.

[5]Office of Research Integrity, Department of Health and Human Services, accessed August 24, 2015, https://ori.hhs.gov/.

search subjects, some accompanied by FCOIs, aroused congressional ire and resulted in highly contentious hearings in both the House and Senate, culminating in the 1990 report from the House Committee on Government Operations entitled *Are Scientific Misconduct and Conflicts of Interest Hazardous to Your Health?* In the 1985 reauthorization of the Public Health Act, Congress directed the PHS to regulate scientific misconduct (the regulation was issued in 1989). In acrimonious hearings in 1988 of the House Subcommittee on Oversight and Investigations, Chairman Dingell first raised the matter of ordering the Department of Health and Human Services (HHS) to issue a regulation addressing FCOIs, and the HHS began this effort even though formal authorizing language would not appear until 1993.

The FCOI regulation was issued in 1995. It defined FCOIs in research, and required research institutions to implement and enforce their own COI policies. It also required institutions, whenever they discovered that a grant recipient had a conflicting financial interest, to address the problem by eliminating, mitigating, or managing the conflict. No details or information had to be reported to the agency.

During the first decade of the 2000s, the Office of the Inspector General (OIG) in HHS issued regular reports expressing its concerns about the management of FCOIs in research institutions and the effectiveness of National Institutes of Health (NIH) oversight. In 2008, the OIG issued a report[6] that was critical of the NIH's oversight of FCOIs in awardee institutions, describing them as "grossly inadequate." That report called for modification of the 1995 regulation to require institutions to provide NIH with details of their investigator's COIs and their management plans. In 2009, the OIG further criticized research institutions' oversight and management of faculty COIs.[7] Among other things, the report criticized institutions for trusting their faculty members' reports of financial interests possibly related to their research, and it recommended that NIH require grantee institutions to "develop and disseminate guidance on methods to verify researchers' financial interests."

Under continuing heavy pressure from the OIG, in the spring of 2009 the NIH issued an Advanced Notice of Proposed Rulemaking (ANPRM) that incorporated most of the OIG's recommendations. The ANPRM elicited a flood of critical comments from the research community, though these comments were not reflected in the Notice of Proposed Rulemaking (NPRM) issued a year later, nor in the final rule issued in August 2011, to become effective in August 2012. The PHS COI policy is scheduled for a formal review in August 2015. Major

[6] *National Institutes of Health: Conflict of Interest in Extramural Research* (OEI-03-06-00460) (Washington, DC: Office of the Inspector General, U.S. Department of Health and Human Services, 2008), https://oig.hhs.gov/oei/reports/oei-03-07-00700.pdf.

[7] Daniel R. Levinson, *How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health (*OEI-03-07-00700) (Washington, DC: Office of the Inspector General, U.S. Department of Health and Human Services, 2009), https://oig.hhs.gov/oei/reports/oei-03-07-00700.pdf.

elements of the new regulation are shown in Box 5-1. This reissuance of the PHS regulation failed to acknowledge that institutions were aware of deficiencies in implementing the previous regulation and had taken steps to address these deficiencies—as outlined in their public comments to the agency during the negotiated rulemaking process.[8]

Many investigators and institutions also must conform to the National Science Foundation's (NSF) COI policy. NSF, which had essentially adopted the 1995 PHS regulation soon after it was issued, did not adopt the new 2011 PHS regulation or revise its existing policy. NSF requires that investigators disclose all significant financial interests that "would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF."[9] This contrasts with the PHS policy that expands disclosures to any significant financial interests that "would reasonably appear to be related to the investigator's institutional responsibilities which include: research and other scholarly activities; clinical care activities; teaching or educational activities; and administrative activities."[10]

The Uniform Guidance directs all federal agencies to create COI policies and requires award recipients to disclose any *potential* conflicts of interest.[11] This is a significant departure from the PHS and NSF policies that focus on existing significant financial interests, not *potential* conflicts of interest. Furthermore, despite an attempt to have uniform guidance across all federal agencies, the regulation as currently written gives wide latitude to each agency to create its own COI policies—thereby creating the possibility that investigators and institutions would have to comply with multiple different policies issued by different funding agencies, adding substantially to the burden associated with COI compliance. For example, the Environmental Protection Agency (EPA) has defined COI as "an actual or potential situation that undermines, or may undermine, the *impartiality* of an individual or non-Federal entity because their self-interest conflicts, or may conflict, with their duty and obligations to EPA and the public in performing an EPA financial assistance agreement" (italics added).[12,13]

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[8]Carol Blum, *COGR Comment on RIN 0925-AA53; NIH-2010-0001, Promoting Objectivity in Research for which PHS Funding is Sought* (Washington, DC: Council on Governmental Relations, An Association of Research Universities, 2008), http://www.cogr.edu/viewDoc.cfm?DocID=151760.

[9]"Grant Policy Manual: NSF 05-131," National Science Foundation, July 2005, accessed August 24, 2015, http://www.nsf.gov/pubs/manuals/gpm05_131/index.jsp?org=EF.

[10]Promoting Objectivity in Research, 42 CFR 50 (f) (2000).

[11]"Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf.

[12]"EPA's Revised Interim Financial Assistance Conflict of Interest Policy," U.S. Environmental Protection Agency, 2015, accessed August 24, 2015, http://www.epa.gov/ogd/epa_revised_interim_financial_assistance_coi_policy_5_22_15.htm.

[13]While assessments of impartiality may be relevant in the context of procurement, agency COI policies should recognize the difference between COIs related to an

No other agency has introduced the notion of impartiality to definitions of COIs. This new EPA definition is yet another troubling departure from the PHS and NSF policies that focus on significant FCOIs.

BOX 5-1 Changes in Public Health Service Financial Conflict of Interest Regulations Implemented in 2012[a]

- Expanded disclosure and review of researchers' financial interests beyond those related to their funded research to any that related to their academic responsibilities, including those for education, administration, and clinical care.
- Changed from annual to transaction-based disclosure and review by the institution.
- Required that investigators disclose *all* financial interests meeting certain criteria to their institutions, and transferred responsibility for judging whether those interests were related to the investigators' ongoing research from the investigator to the institution.
- Extended review of financial interests to include compensation received from nonprofit entities and organizations not under the purview of the Public Health Service (PHS).
- Reduced the threshold for related financial interests requiring disclosure and review from $10,000 to $5,000 (defined as "Significant Financial Interest").
- Added travel reimbursement to the calculation of the threshold for financial conflicts of interest (FCOIs) from companies, as well as travel payments from nonprofit entities.
- Added reporting of some FCOIs (depending on the monetary extent of the researcher's financial interest) and the details of their mitigation, management, or elimination to NIH for the agency's review.
- Added oversight of conflicts of interest at subaward recipient institutions to the responsibilities of the institution receiving the grant (the prime institution).
- Added review of institutional financial interests when research involves human subjects.
- Added mandatory conflict of interest training with retraining required every 4 years.
- Added a requirement that institutions make details of their faculty members' FCOIs that are related to their PHS-funded research or other institutional responsibilities available on a publicly accessible website, or by written response to a requesting individual within 5 business days.

[a] See Promoting Objectivity in Research, 42 CFR 50, Subpart F (2011).

investigator's personal financial interests that have the potential to bias research, and institutional procurement issues.

The scientific research community recognizes the necessity of appropriately managing FCOIs to ensure the integrity and credibility of scientific findings and the protection of research subjects, and it supports rigorous management approaches. However, several major elements that were included in the expanded scope of the current PHS COI regulation impose undue, and in the committee's opinion, unnecessary, time and cost burdens on investigators and their institutions (as described below), with no benefit to the integrity of the scientific enterprise and research subjects. The lack of harmonization of COI requirements among different federal research funding agencies emerging from the Uniform Guidance threatens to further and substantially increase these burdens.

Analysis

Three recent surveys have attempted to characterize and quantify the costs and benefits associated with the new 2011 PHS FCOI regulation. As noted, the new regulation is far more than a "revision" of the 1995 regulation. It is a new regulation. The Association of American Medical Colleges (AAMC) Conflict of Interest Metrics Policy Project surveyed AAMC member institutions in the year before and the year after implementation of the new regulation.[14] As reported in a March 2015 letter, the Council on Governmental Relations (COGR), an association of more than 190 research universities and affiliated medical centers, also surveyed its members regarding changes at their institutions in FCOI disclosures and associated costs to administer the new rule.[15] Finally, the National Science Board's (NSB) Task Force on Administrative Burden in 2013–2014 conducted a large qualitative survey of federally funded researchers at colleges, universities, and nonprofit institutions.[16]

AAMC invited all of its member medical schools and teaching hospitals to participate in the study and collected data on institutional COI policies, the number of full-time equivalent employees who oversaw the administration of COI policies, the number of significant financial interests (SFIs) disclosed to the institution, and the number of FCOIs reported to the NIH (or other PHS funding agency) during two 12-month periods (the year prior to implementation and the year after implementation). FCOIs are those that meet the threshold for SFI and

[14]Heather H. Pierce, Anurupa Dev, and Daria Grayer, "Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project," *AAMC Analysis in Brief* 15, no. 4 (2015).

[15]Lisa Nichols, *NIH Request for 3-year Extension of Reporting Requirements Associated with Revised FCOI Requirements* (Washington, DC: Council on Governmental Relations, An Association of Research Universities, 2015), http://www.cogr.edu/viewDoc.cfm?DocID=152147.

[16]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

are then deemed to have the potential to affect the individual's conduct of her or his institutional responsibilities.

Among the 74 AAMC member institutions that responded, more than 79 percent reported an increase in the number of disclosed SFIs after implementation of the revised rule, which lowered the definition of SFI from $10,000 to $5,000. However, there was only a 13 percent increase in the number of FCOIs reported to a PHS funding agency. Perhaps most important, the percentage of SFIs found to be FCOIs decreased from 4.8 percent to 1.4 percent after implementation of the regulation.

In its 2011 Notice of Proposed Rule Making, the NIH estimated annualized burden hours for compliance with the regulation to be 676,130 hours at an estimated cost of $23 million across roughly 2,000 awardee institutions.[17] However, the AAMC survey indicated that just 70 institutions spent $22.6 million to implement the rule.[18,19] COGR also reported that, among its 34 member institutions that provided data on compliance costs, there was a combined additional cost of approximately $2 million (for a total of $10 million) to implement the new regulation, relative to combined costs of approximately $8 million during the year prior to implementation (although these costs do not include the ongoing incremental expense of meeting the expanded regulations).[20] Finally, like the AAMC survey project, COGR observed that while institutions reported a 110 percent increase in the number of SFI disclosures made in the year subsequent to the implementation of the new rule, these did not lead to concomitant increases in FCOIs that needed to be managed by the institution or reported to the funding agency. The NSB survey also concluded that the new regulations resulted in substantial increases in administrative burden and financial costs, but limited perceived benefit in terms of increased protections against FCOIs.[21]

Together, the results of the AAMC, COGR, and NSB surveys indicate that implementation of the new 2011 PHS FCOI regulation resulted in an increase in the number of SFIs that had to be reviewed by institutions, but without a proportional increase in the number of FCOIs that warranted reporting to PHS funding

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[17]Lisa Nichols, *NIH Request for 3-year Extension of Reporting Requirements Associated with Revised FCOI Requirements* (Washington, DC: Council on Governmental Relations, An Association of Research Universities, 2015), http://www.cogr.edu/viewDoc.cfm?DocID=152147.

[18]Ibid.

[19]Heather H. Pierce, Anurupa Dev, and Daria Grayer, "Implementing the Regulations on Financial Conflicts of Interest: Results from the AAMC Conflict of Interest Metrics Project," *AAMC Analysis in Brief* 15, no. 4 (2015).

[20]Lisa Nichols, *NIH Request for 3-year Extension of Reporting Requirements Associated with Revised FCOI Requirements* (Washington, DC: Council on Governmental Relations, An Association of Research Universities, 2015), http://www.cogr.edu/viewDoc.cfm?DocID=152147.

[21]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

agencies. These observations call into question whether the new COI rule is accomplishing its intended goal of protecting the integrity of the scientific process and the welfare of research subjects, especially given the documented increases in administrative burden to institutions and investigators in the year following implementation of the rule. Put differently, the new regulation led to a substantially bigger haystack without significantly increasing the number of needles found.

Findings

COIs are common and expected in all professions, and the scientific community, like other professions, has over time developed normative behavioral and transactional processes to prevent or mitigate the effects of conflicts that might influence or bias professional judgments, choices, and decisions.

It is critical that research institutions appropriately identify and manage FCOIs related to research in order to ensure the protection of research subjects and the integrity and credibility of scientific findings. Institutional management of faculty COIs is also essential to protect the interests of trainees from constraints on the scope and direction of their research or use of their time and expertise for personal financial gain of the research supervisor, as may occur, for example, when the faculty advisor is involved in a start-up company.

The 2011 revision of the PHS FCOI regulation has resulted in increased time and cost burdens to investigators and institutions that are disproportionate to any resulting benefit to the scientific enterprise and research subjects.

The 2013 Uniform Guidance, which directs all federal agencies to create COI policies, includes troublesome provisions and nonspecific language that may result in multiple COI policies across the federal government. This lack of harmonization across the agencies will result in substantial increases in burden to investigators and institutions.

Centralized clearinghouses, or databases, allow individual investigators to document that they are in compliance with PHS and other agency FCOI policies and allow organizations interested in certifying this compliance (for funding or other purposes) the ability to access this information via a web-based portal (see Box 5-2). They can substantially mitigate the administrative burdens associated with oversight and the reporting of COIs.

RECOMMENDATION

5.1. The committee recommends that Congress, in concert with the White House Office of Science and Technology Policy and in partnership with research institutions, develop, within the upcoming fiscal year, a federal-wide financial conflicts of interest policy to be used by all research funding agencies.

BOX 5-2 Examples of Centralized Databases for Documenting Conflict of Interest Policy Compliance

The FDP Clearinghouse

The Federal Demonstration Partnership maintains a web-based clearinghouse[a] that provides a central location for research institutions and other entities to document their compliance with the Public Health Service (PHS) financial conflict of interest rules and regulations. It is incumbent upon individual institutions to add their certifications. The clearinghouse also can be used by institutions receiving PHS funding to verify compliance on the part of any potential subrecipients. As of June 2015, 16 federal agencies and 12 nonfederal entities have registered with the clearinghouse as using the PHS regulations in their grant award terms. There are currently 928 research institutions listed as compliant in the clearinghouse.

Association of American Medical Colleges' Convey Project

Convey is a web-based portal[b] that serves as a repository where individual researchers can enter and maintain records of their financial interests. The Convey database was developed in response to a recommendation from the 2009 Institute of Medicine report *Conflict of Interest in Medical Research, Education, and Practice.*[c] Organizations (research institutions, journals, professional societies, funding agencies) can subscribe to the system to access disclosure information for specific investigators, in an effort to comply with the PHS COI policy.

[a] FDP Institutional Clearinghouse, Federal Demonstration Partnership, accessed August 24, 2015, http://sites.nationalacademies.org/PGA/fdp/PGA_070596.
[b] Convey, Association of American Medical Colleges, accessed August 24, 2015, https://www.aamc.org/initiatives/research/coi/404084/convey-disclosuredatabase.html.
[c] Institute of Medicine, Conflict of Interest in Medical Research, Education, and Practice (Washington, DC: The National Academies Press, 2009).

The policy should incorporate the following elements:

- The policy should return to research institutions accountability for review and management of significant financial interests that might reasonably appear to be related to the design, conduct, or reporting of the funded research. Investigator disclosures should be limited to all financial interests related to the investigator's federally funded research responsibilities rather than to "academic responsibilities" that involve education, clinical care, institutional administrative responsibilities, and institutional and public service. Institutions, at their discretion, may set different standards for disclosure. Institutional accountability includes responsibility for imposing sanctions when individuals fail to adhere to COI policies.
- The policy should not require information and reporting on the details of investigator-provided disclosures of financial interests and subse-

quent institutional responses. If an institution requires disclosure of interests related to an aspect of the individual's institutional responsibilities but unrelated to the funded research, the institution should not be required to report this information to an agency.

- The policy should differentiate requirements for financial interest disclosure and management for research that does and does not involve human subjects, and among human subjects studies based on the level of risk as determined by the institutional review board (IRB), and should raise the monetary thresholds used to define significant financial interests above those established in the 2011 regulation. Institutions should also be able to elect, at their discretion, to require investigators to disclose all financial interests regardless of the threshold without requiring additional reporting by the institution. The policy should prohibit enrollment of subjects in the research study unless the significant financial interest is eliminated, or a plan for mitigating potential harm to subjects or threat to the integrity of the research has been approved and will be overseen by the institution.
- The policy should not require disclosure and management when income is provided in return for services to nonprofit entities (e.g., professional societies, conferences, journals) that are not created or overseen by, or otherwise related to, a company or other for-profit entity.
- The policy should streamline training requirements to limit repetitive training sessions when there has been no change in COI policies.
- The policy should make individual researchers responsible for disclosures of all related financial interests in publications and public presentations. Institutional policies should state that this responsibility lies with individual investigators and failure to comply is subject to sanctions.

HUMAN SUBJECTS RESEARCH

Research involving human subjects that is conducted using federal funding, or that falls under the jurisdiction of the U.S. Food and Drug Administration (FDA), is subject to a comprehensive regimen of regulatory oversight. Eighteen federal agencies have signed on to the Common Rule, the federal policy for the protection of human subjects in research studies.[22] Statutory authority for the Common Rule derives from the National Research Act of 1974. Regulations governing research that falls under the jurisdiction of the FDA[23] are similar, but,

[22]The Common Rule is codified at Protection of Human Subjects, 45 CFR 46 (2009). Additional subparts apply to research involving pregnant women, human fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D).

[23]Protection of Human Subjects, 21 CFR 50 (2011) and Institutional Review Boards, 21 CFR 56 (2009).

importantly, not identical, to the Common Rule. Finally, the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA) of 1996[24] mandates additional requirements related to the privacy and confidentiality of protected health information used in research. Compliance enforcement rests with offices established within each department or funding agency. For example, the HHS Office of Human Research Protections (OHRP) enforces compliance of HHS-sponsored research with the Common Rule.

The Common Rule creates two layers of procedural protections for human subjects. Applicable human subjects research must be approved by an IRB before investigators are permitted to initiate research. Before approving a protocol, the IRB must find that the protocol meets specified criteria related to risk and benefit, equitable subject selection, confidentiality, and informed consent, as well as criteria designed to ensure participant safety. In addition, the IRB must continue to review the research and provide approvals at least annually. The IRB must approve all protocol amendments except those necessary to eliminate immediate hazards to participants and be notified of unanticipated problems involving risks to participants or others or of any serious or continuing noncompliance with policy. Second, before they are enrolled in research, candidate study participants or their legal proxies must give informed consent to participate in the study. The Common Rule requires that investigators make a specified set of disclosures, typically in writing, prior to obtaining the potential participant's or proxy's informed consent. In limited situations of minimal-risk research where a requirement for informed consent would make the research impracticable, the Common Rule permits an IRB to waive the requirement for informed consent. [25]

The applicability of the Common Rule is not limited to biomedical research. Instead, the rule is applicable to a wide range of social, behavioral, and educational research. The scope of the applicability of the Common Rule is the subject of debate. Critics have criticized officials for extending the applicability of the Common Rule far beyond the type biomedical and behavioral studies originally envisioned by its framers.[26,27]

In anticipation of revisions to the Common Rule, HHS published an ANPRM in July 2011. The Common Rule NPRM was issued on September 2,

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[24]General Administrative Requirements, 45 CFR 160 (2000), and Security and Privacy, 45 CFR 164 (2007). HIPAA was updated under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

[25]This is not generally the case with FDA regulations except in the case of emergency research involving in vitro diagnostic device studies using excess, anonymized human specimens. See Common Rule, 45 CFR 46 (2009) and FDA alignment of the Common Rule [Protection of Human Subjects, 21 CFR 50 (2011)].

[26]C. K. Gunsalus, Edward M. Bruner, Nicholas C. Burbules, et al., "Mission Creep in the IRB World," *Science* 312, no. 5779 (2006): 1441.

[27]National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Washington, DC: The National Academies Press, 2014).

2015, as the current report was going to press. As the committee firmly believed that it was important to consider human subjects research regulations in the current report, the July 2011 ANPRM is the focus of the committee's comments. The committee considers additional issues related to human subjects research in Part 2 of this report and comments on the NPRM's proposed revisions to the Common Rule.[28]

Regulations for protecting human subjects in biomedical and behavioral research were born following revelations of unethical and harmful research, such as the PHS-sponsored Tuskegee Study of Untreated Syphilis in the Negro Male.[29] More recent revelations of unethical federally sponsored research conducted during earlier eras, including the radiation experiments that took place during the Cold War and PHS-sponsored studies in the 1940s that deliberately exposed people in Guatemala to sexually transmitted infections without their consent, reinforce the need for oversight of human subjects research.[30,31]

Over the past half century, the research enterprise has undergone dramatic changes that raise questions about whether the Common Rule and other applicable human research regulations are the most appropriate regulatory framework. Much current research seeks to evaluate the safety and efficacy of new drugs or biological agents and devices designed to treat or prevent human disease or to compare the safety and efficacy of existing drugs and devices. Much of this research offers potential benefit to individuals who participate in the research. The result is often less a demand for protection by possible participants than a demand for access.[32] In addition, NIH and other agencies now emphasize the need for inclusion of groups (such as women, members of ethnic and racial minorities, and children) who were historically underrepresented in research and therefore did not benefit fully from the knowledge that research produced.[33,34] In addition, federally sponsored research increasingly extends to the social, behavioral, and educational sciences; health care services and systems; research involving electronic health rec-

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[28]The committee provides this anticipated analysis in Chapter 9 of Part 2 of the current volume.

[29]*Moral Science: Protecting Participants in Human Subjects Research* (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2012), http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf.

[30]Ibid.

[31]Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments: Final Report of the Advisory Committee on Human Radiation Experiments* (New York, NY: Oxford University Press, 1996), 620.

[32]A. Mastroianni and J. Kahn, "Swinging on the Pendulum: Shifting Views of Justice in Human Subjects Research," *Hastings Center Report* 31, no. 3 (2001): 21-28.

[33]Additional regulatory protections directed at children and pregnant women created further barriers to their participation and contributed to their underrepresentation in research.

[34]National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Washington, DC: The National Academies Press, 2014).

ords and "big data"; and research involving biological specimens. Much of this research does not involve physical risk to participants; rather, risks are limited to the more remote possibility of informational harm resulting from the inadvertent release of confidential information.

Nature of the Concern

The current regulatory framework governing human subjects research may not be appropriately calibrated to the risks associated with the type of research performed. In addition, research has become increasingly multicentered and collaborative in nature, with individual studies potentially involving tens or hundreds of sites, and there are questions as to whether the system of site-specific institutional review, with its roots in local review of single-site studies, has evolved in response to the trend towards multicenter research. Furthermore, HIPAA protections may be inappropriate for human subjects research, as HIPAA policies fail to align with those of the OHRP that enforces the Common Rule.[35,36,37,38] In addition, proposed changes to the Common Rule would require researchers to obtain written consent to use biospecimens, even those that have been de-identified, creating additional administrative burden without adding to the protections of human research subjects. Finally, there is lack of harmonization of human subjects research regulations, policies, and processes, even among the 18 federal agencies that follow the Common Rule.[39]

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[35]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[36]"Regulatory and Financial Reform of Federal Research Policy Recommendations to the NRC Committee on Research Universities," *Association of American Universities, Association of Public and Land-Grant Universities, Council on Governmental Relations*, January 21, 2011, accessed September 9, 2015, https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=11662.

[37]Federation of American Societies for Experimental Biology, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.

[38] Institute of Medicine, *Beyond the HIPAA Privacy Rule: Enhancing Priavcy, Improv*ing Health Through Research (Washington, DC: The National Academies Press, 2009).

[39]The 18 agencies that have signed on to the Common Rule are the Central Intelligence Agency, Consumer Product and Safety Commission, National Aeronautics and Space Administration, National Science Foundation, U.S. Agency for International Development, U.S. Department of Agriculture, U.S. Department of Commerce, U.S. Department of Defense, U.S. Department of Education, U.S. Department of Energy, U.S. Department of Health and Human Services, U.S. Department of Homeland Security, U.S. Department of Housing and Urban Development, U.S. Department of Justice - National Institute of Justice, U.S. Department of Transportation, U.S. Department of Veterans Affairs, U.S. Environmental Protection Agency, and the U.S. Social Security Admin-

Analysis

Federally sponsored research involving human subjects traverses a spectrum of risk, ranging from the innocuous (e.g., analysis of electronic health system data in which patients are identified only by a code or the administration of surveys that do not address sensitive topics) to the substantially risky (e.g., the use of invasive procedures to collect biological specimens for research or first-in-human administration of drugs with unknown risks). The review and approval procedures specified by the Common Rule are risk stratified. Research that falls within specified categories (e.g., select research involving educational tests, surveys or interviews or research that involves preexisting data or specimens so long as researchers do not retain identifiers) is exempt from Common Rule requirements. For such research, there is no regulatory burden. Researchers must, however, demonstrate exemption eligibility. Other minimal-risk research that falls within defined categories[40] may be approved under expedited procedures (i.e., by the IRB chair or by an experienced designated IRB member, rather than by the full board). However, research that does not qualify for exemption or expedited review, including much minimal-risk research, requires review and approval by a full IRB. Full-board review can be particularly burdensome, time consuming, and delay prone. For example, one study of federally funded cancer trials showed that initial review and approval of a single trial required an average of 14 hours of research staff time and 3.9 hours of IRB staff time, and that time from starting IRB paperwork to initial approval averaged 62.3 days.[41] Expedited review can shorten time lines to approval because it does not require review by a convened IRB at a meeting that may take place only once or twice a month. Fearing federal compliance actions, many institutions have increased procedural oversight, requiring detailed applications from investigators in order for the institution to determine exemption and full protocol submissions for minimal-risk research. This can result in self-imposed administrative burden that delays the approval process and increases the workload for both investigators and reviewers.

Regulatory changes that further calibrate appropriate oversight requirements to the risk of the research would considerably reduce regulatory burden on investigators conducting minimal-risk research, while preserving the re-

istration. Amongst these agencies, there is variation in the implementation of the Common Rule.

[40]"Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure," U.S. Department of Health & Human Services: Office for Human Research Protections (OHRP), accessed August 24, 2015, http://www.hhs.gov/ohrp/policy/expedited98.html.

[41]T. H. Wagner, C. Murray, J. Goldberg, J. M. Alder, and J. Adams, "Costs and Benefits of the National Cancer Institute Central Institutional Review Board," *Journal of Clinical Oncology* 28, no. 4 (2010): 662–666.

sources of IRBs to focus on protecting participants in higher-risk research.[42,43] At the one extreme, the lowest-risk categories of research should not require prospective IRB review and approval. Rather, as a National Research Council committee recommended in 2014, a requirement simply to register the study with the responsible IRB—ensuring transparency, a tracking mechanism, and the possibility of audit—will suffice to protect participants and ensure investigator accountability.[44] At the other extreme, research that involves greater than minimal risk should continue to require full-board review and approval, with modest reductions in ancillary requirements such as the minimum frequency of continuing review. Research that falls between these two extremes should continue to be approvable via expedited procedures, and should no longer be required to undergo periodic continuing review.

Although both OHRP and FDA permit an institution to delegate another institution's IRB as the IRB of record, or to use a central IRB model, research institutions frequently opt for local review. This insistence on local ethics review may stem from concerns about legal liability, from habit and tradition, or from lack of confidence in the quality of review at other institutions. Yet evidence suggests that redundant local review does not improve, and paradoxically may even compromise, the quality of research protocols and consent forms.[45, 46] As contemplated in the Common Rule ANPRM and as recommended by the Presidential Commission for the Study of Bioethical Issues, a regulatory mandate or presumption that a single IRB serve as the IRB of record for all domestic sites, with narrow exceptions for sites with community sovereignty concerns such as those within Native American reservations, would reduce redundancy and inconsistency while enhancing efficiency of review.[47,48,49]

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[42]"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," *Federal Register* 76, no. 143 (July 26, 2011): 44512, http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf.

[43]National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Washington, DC: The National Academies Press, 2014).

[44]Ibid.

[45]D. K. Check, K. P. Weinfurt, C. B. Dombeck, J. M. Kramer, K. E. Flynn, "Use of Central Institutional Review Boards for Multicenter Clinical Trials in the United States: A Review of the Literature," *Clinical Trials* 10, no. 4 (2013): 560–567.

[46]W. J. Burman, R. R. Reves, D. L. Cohn, and R. T. Schooley, "Breaking the Camel's Back: Multicenter Clinical Trials and Local Institutional Review Boards," *Annals of Internal Medicine* 134, no. 2 (2001): 152–157.

[47]*Moral Science: Protecting Participants in Human Subjects Research* (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2012), http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.

[48]"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," *Federal Register* 76, no. 143 (July 26, 2011): 44512, http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf.

There is a lack of harmonization among agencies that follow the Common Rule. The Department of Defense (DOD) and NIH differ in policies for research-related injuries, while the NIH and the FDA differ in their definitions of "human subject."[50] The Common Rule and FDA have different policies for the maintenance and storage of research documents. Unlike other agencies, the FDA does not allow for waivers or modification of the requirement for informed consent for minimal-risk research in instances[51] where requiring informed consent would make the research impracticable. The NIH now requires IRB review and informed consent for protocols that would share large-scale genomic research data, which would otherwise not be required under the Common Rule. Furthermore, although DOD has accepted the Common Rule, it has promulgated additional regulations and policies that depart from the Rule and are unique to research funded by DOD. Finally, FDA and NIH have different requirements for data-monitoring committees.[52,53]

Biospecimens are materials taken from the human body and can include tissue, blood, saliva, and urine, among others.[54] Currently, the Common Rule

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[49]*Moral Science: Protecting Participants in Human Subjects Research* (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2012), http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf.

[50]The basic HHS policy for the protection of human research subjects defines a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information." See Common Rule, 45 CFR 46.102(f) (2009). FDA defines a human subject as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control." See Protection of Human Subjects, 21 CFR 50.3(g) (2011).

[51]Such instances can have logistical causes, such as needing to obtain informed consent from thousands of participants for retrospective use of discarded specimens, or scientific causes, such as the informed consent requirement leading to selection biases in large-scale epidemiological studies based on data from clinical registries (see Jack Tu, Donald Willison, Frank Silver, Jiming Fang, et al., "Impracticability of Informed Consent in the Registry of the Canadian Stroke Network," *The New England Journal of Medicine* 350, (2004): 1414-1421.

[52]A data-monitoring committee is a committee of experts, typically including clinicians, statisticians, and often patient representatives, ethicists, and others, who review confidential interim data from a clinical trial and may recommend changes, including early termination of the trial, based on emerging evidence of benefit, harm, or other outcomes.

[53]Several prior reports have called for harmonization of human subjects research regulations and policies between statutes and among federal agencies. See, e.g., National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf and Federation of American Societies for Experimental Biology, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.

[54]"Patient Corner: What are Biospecimens and Biorepositories," National Cancer Institute: Biorepositories and Biospecimen Research Branch, accessed August 24, 2015, http://biospecimens.cancer.gov/patientcorner/.

allows for research to be performed using existing biospecimens without informed consent as long as the specimens are deidentified. In the 2011 ANPRM, HHS indicated that it is considering requiring written consent for research using biospecimens, even those that have been de-identified.[55] The HHS Secretary's Advisory Committee on Human Research Protections, in its 2011 comments on the Common Rule ANPRM, noted that the proposed revisions would add administrative burden without providing any additional protections for research participants.[56]

In 2014, the NSB Task Force on Administrative Burden published a report that detailed the administrative workload of investigators who receive federal funding for their research. The report presented the results of a survey of more than 3,000 investigators and a series of roundtable discussions with research faculty and administrators. Research involving human subjects and IRB requirements were among those that respondents identified as having the highest level of administrative workload. Respondents suggested that federal regulations and IRB requirements have become increasingly complex, yet are not calibrated to risks.[57] Several respondents suggested that increased scrutiny by IRBs has not resulted in an appreciable improvement in participant safety.[58] Finally, respondents conducting multisite research studies reported that submission to multiple IRBs was time consuming due to both a lack of standardization of forms and procedures and the requirement that the institutional protocols and informed consent documents conform across research sites, requiring multiple iterative reviews for minor changes in wording. Often this results in research projects being significantly delayed.[59]

The Federation of American Societies for Experimental Biology (FASEB) surveyed its members in response to the NSB's request for information and concluded that human subjects regulations and IRB policies are a major source of administrative burden for research institutions and investigators.[60] Respondents to the FASEB survey noted that regulations are not calibrated to the level of risk posed by a given research study and that multisite research protocols are associ-

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[55]"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," *Federal Register* 76, no. 143 (July 26, 2011): 44512, http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf.

[56]Secretary's Advisory Committee on Human Research Protections (SACHRP). Letter to Kathleen Sebelius (Secretary of Health and Human Services) October 13, 2011. http://www.hhs.gov/ohrp/sachrp/commsec/sachrpanprmcommentsfinal.pdf.

[57]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[58]Ibid.

[59]Ibid.

[60]Federation of American Societies for Experimental Biology, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.

ated with long delays due to a lack of standardization of IRB procedures at different sites. FASEB suggested that regulations affecting human subjects research be streamlined so that IRBs can focus on higher-risk studies, relative to research protocols that pose minimal risk to participants.[61,62] Like both the NSB and FASEB surveys, the 2012 Federal Demonstration Partnership (FDP) Faculty Workload Survey concluded that IRB requirements are among the most time consuming and burdensome investigator administrative responsibilities. Respondents suggested that the amount of work required to obtain IRB approval for minimal-risk research was unnecessary and that completing multiple IRB submissions for multisite research studies was time consuming and redundant.[63]

Regulations for the protection of human subjects in biomedical and behavioral research are essential to protect the rights and welfare of the participants, as well as to preserve the public's trust and confidence in the research enterprise. However, as currently written, interpreted, and enforced, the regulations impose considerable burden on investigators and institutions conducting research, without a foundation of convincing evidence of commensurate benefit in terms of the goals and values that they are intended to serve. Modest revisions to ensure that regulations are calibrated to the nature and risk of the particular project and are reflective of the changing nature of federally sponsored research—particularly its evolution towards multicenter studies—can substantially reduce burden without compromising robust protections for human subjects in research.

Findings

Federally sponsored research involving human subjects encompasses a wide range of risk to participants.

The review and approval procedures specified by the Common Rule are risk stratified only to a limited extent.

Improved calibration of regulations and oversight procedures to the level of risk posed to participants would both reduce administrative burden on investigators conducting minimal risk research and allow IRBs to focus on protecting participants in higher-risk research studies.

There is a high level of administrative burden associated with conducting multisite research studies. This burden is likely to continue to increase, given the increasing prevalence of studies involving multiple research centers within an increasingly collaborative scientific enterprise.

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[61] Ibid.

[62] Ibid.

[63] Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, Randy Brutkiewicz, *Federal Demonstration Partnership (FDP): 2012 Faculty Workload Survey Research Report* (2014), 19–20, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.

There is a lack of harmonization of human subjects research regulations, policies, and processes, even among the 18 federal agencies that follow the Common Rule.

Requiring consent for all research involving biospecimens, as contemplated by the ANPRM, would substantially increase administrative burdens on investigators, research staff, and institutions, and would markedly hinder the conduct of critical science.

RECOMMENDATIONS

5.2. The committee recommends that Congress direct federal agencies following the Common Rule to institute a risk-stratified system of human subjects protections that substantially reduces regulatory burden on minimal-risk research while reserving more intensive regulatory oversight for higher-risk research.[64]

- The committee recommends the following designations:[65]

1. Category One: Excused Research
   a. Most observational research that does not involve invasive procedures for the collection of research data satisfies criteria for minimal risk and should be placed in an "excused" category. Investigators should be required to register excused research with the responsible IRB using a brief form. One week after filing the form, investigators should be permitted to begin their research unless, during that week, the IRB has requested additional information or has notified the investigators that the research does not qualify for excused status.
   b. OHRP and other relevant agencies may define narrowly circumscribed categories of observational research that do not qualify for excused status and that require additional review for the protection of human subjects. Examples might include certain categories of research involving vulnerable populations such as prisoners, research involving sensitive information, or research involving collection of information that might place participants at legal risk.

[64]This is consistent with the 2014 NAS Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences and the proposed changes in the 2011 Common Rule ANPRM. The committee's recommendation differs from the 2014 proposal in advising that all minimal-risk research not meeting criteria for the "excused" category be eligible for expedited review. The committee nevertheless agrees with the proposal in the 2011 Common Rule ANPRM to eliminate the requirement for annual continuing review for studies qualifying for expedited review.

[65]These are consistent with the recommendations of the report of the 2014 NAS Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences and the ANPRM.

Any categorical determination that would elevate observational research to a higher level of review should be reviewed by the responsible regulatory agency no less than every 2 years.

c. Excused research should not require the filing of annual continuing reviews or amendments, unless a proposed amendment changes the risk level such that expedited or full-board review is required.

2. Category Two: Minimal-Risk Research Not Meeting Criteria for Excused Status
   a. All minimal-risk research not meeting criteria for excused status should be eligible for expedited rather than full-board review.
   b. Annual continuing review should not be required for minimal-risk research that qualifies for approval by expedited procedures.
3. Category Three: Research Involving Greater than Minimal Risk
   a. Research involving greater than minimal risk should continue to require full-board approval by the responsible IRB.
   b. Research involving greater than minimal risk should undergo continuing review and approval at least every 2 years. IRBs may choose to require continuing review for a particular project more frequently than every 2 years, as they deem appropriate in light of the risks or other characteristics of the research.
   c. Continuing reviews should no longer be required once study interventions that impose greater than minimal risk have ceased and the study enters the follow-up or data analysis phase.

5.3. The committee recommends that Congress direct federal agencies following the Common Rule to require, for multisite research studies, that a single IRB with the necessary staff and infrastructure serve as the IRB of record for all domestic sites.[66]

- The requirement for single-site review should not be applied to sites subject to Native American or Alaska Native tribal sovereignty. Such sites may choose, but should not be required, to participate in single IRB review mechanisms.
- Within a designated period of time, a standard set of policies and procedures should be developed for single-site review of multisite trials.

[66]The committee also endorses a proposal contemplated by the 2011 Common Rule ANPRM to mandate single ethics review, and a single IRB of record, for all domestic sites in a multisite trial. The committee's recommendation differs from the ANPRM's proposal in exempting Native American and Alaska Native sites from this requirement, given sovereignty concerns. The committee's proposal aligns with that in the 2011 report of the Presidential Commission for the Study of Bioethical Issues, (see *Moral Science: Protecting Participants in Human Subjects Research* (Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2012, http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf) but goes further in mandating rather than simply establishing a presumption of single-site review.

In the absence of standardized policies and procedures, administrative burden will be significantly increased as each study team must try to learn and comply with different processes and policies for each protocol with which they participate. Further, a nationally uniform, workflow-based informatics infrastructure should be developed to support a coordinated system of single-site review for multisite research.

5.4. The committee recommends that Congress direct agencies, within a designated period of time, to align and harmonize their regulations (and definitions) concerning the protection of human subjects.

- While 18 agencies have signed on to a part of the Common Rule, many have, over time, developed additional regulations that diverge from the standard.
- Furthermore, forms used for applying to, maintaining compliance with, and reporting to the cognizant agencies should be aligned and invariant, and electronically accessed, signed, and submitted.

5.5. In instances of minimal-risk research where requiring informed consent would make the research impracticable, the committee recommends that Congress amend the FDA's authority so as to allow the FDA to develop criteria for waiver or modification of the requirement of informed consent for minimal-risk research.

- The criteria for waiver or modification of informed consent should harmonize with those in the Common Rule.

5.6. The committee recommends that Congress instruct HHS to work with other agencies to ensure that research involving biospecimens is eligible for a waiver or modification of informed consent, so long as the proposed research meets the conditions for waiver or modification of informed consent as specified in the Common Rule.

- Informed consent should not be required for the use of biospecimens that have been previously collected and are no longer needed for clinical use. Further, secondary research using identifiable data and specimens should be deemed to be minimal risk following the procedures for excused research described in Recommendation 1 above.

ANIMAL RESEARCH

The relationship between the research community and research animals has received special attention because of the relationship between humans and animals, especially with respect to the important role animals have played in our

understanding of human health and disease. Animal-based research has contributed in many significant ways to our understanding of fundamental mechanisms of life, human and animal health and disease, and the development of new treatments and devices. An additional feature of the relationship is the interaction between the scientific community and the public, especially with those most concerned about the rights and treatment of animals.

Much of the general public continues to recognize the importance of animal-based research for the advancement of treatments and cures of animal and human disease. Over the years, improvements in animal care have paralleled the emergence of laboratory animal science and of animal welfare groups. Rising research budgets resulted in an increased use of animals in the discovery process. Laboratory animal medicine and an understanding of husbandry needs of animals have evolved as well. There also has been an increase in the efforts by animal rights groups wishing to stop all research involving animals. While some of these efforts have led to a more nuanced approach to the care and treatment of animals, other efforts have resulted in unproductive harassment or even violent actions against researchers and their families. Research institutions and researchers, along with federal agencies, share a desire to use animals in research in the most appropriate manner possible, providing the best care and treatment.

The oversight of the care and use of research animals is complex and is governed by multiple laws as well as by policies and conditions of specific funding agencies. The U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985) and the Animal Welfare Act (AWA; enacted in 1966) apply to all agencies. Depending on the proposed work, the regulatory and policy requirements of individual agencies may be applicable as well. The AWA, enforced by the U.S. Department of Agriculture (USDA), applies to certain species[67] regardless of funding agency. NIH-funded activities are governed by the Health Research Extension Act (HREA; enacted in 1985), and the PHS Policy applies to all vertebrate animals in PHS-funded activities. Individual agencies are authorized to oversee animal use through other regulations as well (see Table 5-1). Compliance with all laws is required as applicable. Several agencies have chosen to adopt the AWA and, in some cases, the HREA in addition to their own guiding legislation and policies. Many of the requirements to protect research animals are the same from agency to agency, and in some instances, one agency will simply adopt another agency's requirements. In some instances, agencies disseminate guidance documents without specifying them as suggested policies, leaving investigators and institutions to interpret them as regulatory documents.

[67]The AWA covers cats, dogs, hamsters, rabbits, nonhuman primates, guinea pigs, and any other warm-blooded animal as determined by the Secretary of Agriculture for research or pet keeping. Birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, as well as all cold-blooded animals, are excluded from AWA coverage.

TABLE 5-1 Federal Oversight of Research Involving Animals

Agency	NIH	FDA	DOD	CDC	NSF	EPA	NASA	NIST	USDA-NIFA	NOAA	USAID	VA	DHS
Principles													
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training	■	■	■	■	■	■	■	■	■	■	■	■	■
International Guiding Principles for Biomedical Research Involving Animals (Council for International Organizations of Medical Sciences and International Council for Laboratory Animal Science)	■				■		■						
Statutes													
Public Law 89-544; Animal Welfare Act; 7USC Sect 2131-2156; 9CFR,Ch1, Subch A, Pt 2	■	■	■	■	■	■	■	■	■	■	■	■	■
Public Law 99-158; Health Research Extension Act; 42USC 6A, Subch II, Pt A Section 283e and Pt H Section 289d	■	■		■									
Public Law 92-522; Marine Mammal Protection Act; 16 USC Ch 31										■			
Public Law 102-40; VA Authorization; 38USC Pt V, Ch73, SubchI,Sect 7303												■	

(Continued)

TABLE 5-1 Continued

Agency	NIH	FDA	DOD	CDC	NSF	EPA	NASA	NIST	USDA-NIFA	NOAA	USAID	VA	DHS
Public Law 107-188; Select Agents and Toxins; 42 CFR Part 73	■			■					■				■
Public Law 89-544?; Care and Use of Animals in the Conduct of NASA Activities; 42 USC Sect 2451; 14 CFR Part 1232.							■						
Agency Policy and Directives													
Public Health Service Policy on Humane Care and Use of Laboratory Animals	■	■	■	■	■		■	■					■
Guide for the Care and Use of Laboratory Animals (National Research Council)	■	■	■	■	■		■	■			■		■
Guidelines for the Euthanasia of Animals (American Veterinary Medical Association)	■	■	■	■	■		■	■					■
NSF Grants Policy					■								
NASA Policy Directive 8910.1							■						
NASA Procedural Requirements 8910.1							■						
DHS Management Directive 10200.1 (Care and Use of Animals in Research)													■
Technology Innovation Program. Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects								■					

USDA-NIFA Grants Policy													
Use of Animals in DoD Programs. Directive 3216.1													
VA Handbook Directive 1200.07													
Reference Manuals													
Biosafety in Microbiological and Biomedical Laboratories (US Center for Disease Control and Prevention)													
Occupational Helath and Safety in the Care and Use of Research Animals (National Research Council)													
Guide for the Care and Use of Agricultural Animals in Research and Teaching (Federation of Animal Science Societies)													
Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (National Institutes of Health)													
Guidelines for the Care and Use of Mammals in Neuroscience and Behavior Research (National Research Council)													

SOURCE: Courtesy of Joseph R. Haywood.

Oversight is further complicated by agencies having different missions (e.g., enforcement versus funding) and specific mechanism(s) of oversight (inspection versus assurance versus terms and conditions of grant awards). For example, the NIH uses the approval of an assurance by the Office of Laboratory Animal Welfare (OLAW) combined with a wide range of terms and conditions of the NIH Grants Policy, PHS Policy, the National Research Council's Guide for the Care and Use of Laboratory Animals, and other guidelines. Most agencies use conditions of funding as an oversight mechanism relying on the force of the AWA and the PHS assurance process to ensure that basic requirements are met by grantees. Specific requirements relevant to an agency's mission are often added to the baseline requirements. For example, the National Aeronautics and Space Administration includes space-related care and the National Oceanic and Atmospheric Administration includes marine mammals. Because there are so many different regulations and policies applied to animal research, there is redundancy, omission, confusion, and sometimes contradiction in the regulations of the present oversight system.

Nature of Concern

The research community takes its responsibility to protect the health and well-being of research animals seriously. As early as 1952, when dogs were the primary research animal model, the scientific community developed best practices in *Standards for the Care of Dogs Used in Medical Research*. Almost a decade later this document evolved into the *Guide for Laboratory Animal Facilities and Care*. In 1965, the second edition of the guide was released[68] and the voluntary accreditation body, the American Association for the Accreditation of Laboratory Animal Care (AAALAC; now Association for the Assessment and Accreditation of Laboratory Animal Care, International), was incorporated. These were important attempts by the scientific community to assure the public that serious efforts were being made to care for animals involved in research. However, also in 1965, a series of articles brought to public attention use of animals in university research. A *Sports Illustrated* article revealed the theft of pets that were sold for research, and an article in *Life* focused on pet theft and poor treatment of those animals. The public response was profound, and in a few short months the AWA was passed. Although much of the AWA was devoted to requirements related to general animal well-being and animal health, the focus was stolen pets, licensing animal dealers, registration of research facilities, research activities, and reporting requirements. The AWA changed the conduct of research using animals. The development of the regulations to implement the AWA took 23 years, during which time there were amendments to the AWA, and the passage of and amendments to the HREA.

[68] The guide is now in its the eighth edition published by the National Research Council.

The myriad rules, regulations, documents, assurances, grant conditions, Frequently Asked Questions, and conveyance of guidance over the last 30 years has contributed to considerable confusion in the scientific community. The complexity of the system creates problems such as contradictions in process and redundancy in reporting. For many researchers, it has been difficult to distinguish between regulations, grant requirements, and best practices. This has been further exaggerated by the AAALAC's accreditation process. In striving to have a risk-free animal research program, universities have sometimes conflated regulations and best practices. This has led to additional and unnecessary burden for investigators, leading some institutions to treat AAALAC best practices as regulation. It takes considerable expertise to sort through the regulations, rules, guidance, and best practices that have been established and have evolved over time. Consequently, institutions have tended to over-interpret the requirements so as to err conservatively and not be out of compliance or inconsistent with what could be construed as grant conditions. For various reasons, many institutions have tried to maintain a zero tolerance for risk of noncompliance in their programs. In many cases, the result has arguably been unnecessary burdens borne by institutions and investigators.

An example of contradiction in the present system is the protocol review process. Before any animal research can begin, the proposed work must be reviewed and approved by an institutional animal care and use committee (IACUC). This is a common feature of the laws and agency requirements described above. However, beyond the initial review of the protocol, the agencies sometimes differ or remain silent on the process. The USDA requires continuing review of the whole protocol, while the NIH requires only triennial review. Since protocols are frequently amended during the course of a research project, the annual and triennial reviews become redundant. In addition, many institutions have initiated post-approval monitoring programs. Unfortunately, less emphasis is placed on this continuing review of protocol amendments and post-approval monitoring than the initial protocol review process, yet the latter can be an effective means of both ensuring appropriate oversight and protecting the welfare of research animals.

Like protocol reviews, requirements for assurances and reporting vary significantly from agency to agency. All agencies require at least an annual report of progress of work. In addition to the annual report, the NIH requires an annual report from the Animal Care and Use Program regarding any changes in the program. In addition, the institution must report any noncompliance events as they occur, regardless of the level of significance or the impact on the health and/or safety of the research animals. NIH also requires an institutional assurance that is renewed every 4 years that describes specific aspects of the program, including IACUC functions, protocol review, occupational health, and congruency between the animal care procedures specified in grant proposals and those carried out in the laboratory setting. All of these activities suggest that NIH is striving for a zero-risk system. The NIH has set itself apart from other agencies in the redundancy of processes, the detailed guidance to institutions, and reporting requirements.

Analysis

In 2014, the NSB Task Force on Administrative Burden published a report that detailed the administrative workload of investigators who receive federal funding for their research. The Task Force surveyed more than 3,100 individuals through a request for information disseminated to universities and scientific and professional societies. The Task Force also held a series of roundtable discussions with more than 200 faculty and administrators. Research involving animal subjects and IACUC requirements were among those that respondents associated with the greatest administrative workload. Burden was linked primarily to escalating regulations, prescriptive guidance, institutional and accrediting body requirements exceeding federal requirements, and duplicative federal agency and institutional review of grants and protocols.[69]

Respondents noted that many of the requirements increased their administrative workload, such as USDA's requirement that proposals include literature searches for alternative experimental models that reduce, replace, and/or refine the procedures using animals, but did not seem to improve the care and treatment of animals. Many noted that the requirement for annual and triennial IACUC reviews of animal protocols was redundant, as protocols are continually amended. Specifically, while institutional requirements demand that protocols include the exact numbers of animals that will be used in a given study, it is impossible to predict the direction of research, leading to numerous and continual protocol amendments over the lifetime of a project.[70]

The FASEB, a professional society that represents the nation's largest coalition of biological and biomedical researchers, also concluded, after surveying its members in response to the NSB's request for information, that animal care and use regulations are a major source of administrative burden for investigators and institutions. FASEB suggested that an important first step to reduce this burden would be to distinguish the responsibilities for review of grants and protocols between IACUCs and the federal agencies.[71] This would help reduce duplication and align requirements more closely to their original intent. FASEB also suggested that complete reviews of animal care and use protocols be brought into alignment with the time frame of a typical grant.[72] FASEB's conclusions based on its survey of members are consistent with those of the 2012 FDP Fac-

[69]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[70]Ibid.

[71]Federation of American Societies for Experimental Biology, *Findings of the FASEB Survey on Administrative Burden* (2013), http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.

[72]Ibid.

ulty Workload Survey.[73] The FDP survey respondents ranked IACUC issues highly on their list of concerns. Among the FDP member respondents that performed animal research, IACUC-related issues received the greatest level of dissatisfaction among all areas of regulatory compliance. The faculty responses indicated that protocol reviews are excessive and that inconsistencies between federal agency requirements and institutional requirements contribute significantly to administrative burden, without necessarily improving the care and treatment of animals.[74]

Findings

The complexity of the multiple oversight systems associated with the care and use of animals is a significant source of regulatory burden. USDA and NIH have attempted to coordinate their rulemaking and oversight activities since the late 1990s; however, the differences in agency mission and approach to oversight have resulted in significant variations in requirements between these two agencies. While other agencies have largely used the requirements of the USDA and NIH, on occasion they issue agency-specific documents, further adding to the complexity of compliance. The resulting burdens are placed not only on investigators but also on institutions, which must develop detailed compliance procedures and processes for different funding agencies. The use of different systems (e.g., inspection versus assurance) requires additional processes to be in place. This is further complicated by multiple systems of verification of assurances for multiple agencies. There is growing concern that this wide range of requirements and processes negatively affects the ability of the institution to oversee animal research.

There are three document-intensive processes that require significant commitment by the institution and the investigator without any direct significant benefit for animals.

Federal and Institutional Assurances

Federal agencies usually provide oversight of the use of animals in research through conditions of the grant or contract or reliance on the U.S. Government Principles and the AWA (Table 5-1); however, the submission of documents to the agencies assuring and reporting the status of animal oversight and

[73]See Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, and Randy Brutkiewicz, *2012 Faculty Workload Survey: Research Report*, (Washington, DC: Federal Demonstration Partnership, 2014).

[74]Sandra Schneider, Kristen Ness, Sara Rockwell, Kelly Shaver, Randy Brutkiewicz, *Federal Demonstration Partnership (FDP): 2012 Faculty Workload Survey Research Report* (2014), 19-20, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.

animal health has generally been limited to PHS funding. Until very recently only the PHS (NIH, FDA, Centers for Disease Control and Prevention) has required institutions to provide an assurance by the institution that describes oversight function.[75] Typically, when an institution accepts an award, it is viewed by agencies as acceptance that the institution will abide by the terms and conditions of the award. For PHS, the institutional assurance is submitted every 4 years and describes detailed descriptions and processes for IACUC functions (including protocol review, semiannual review of the program and facilities, reporting concerns about animal use), institutional program evaluation and accreditation, recordkeeping, reporting, institutional policy, and institutional leadership. However, documentation is not limited to a single Assurance. An annual report indicating any changes in the program, documentation of the semiannual program and facility reviews, and IACUC membership is also submitted. If an institution is not AAALAC accredited, it is also required to submit its most recent semiannual review to OLAW with its Assurance. Finally, OLAW requires submission of reports of noncompliance (NOT-OD-05-034) within a reasonable amount of time of any such event. While these multiple reports are reviewed and responded to, they can take a significant amount of time.

There is redundancy in the protocol review process and submission of grants to NIH. No animal research can be initiated without approval of an IACUC for the work. However, PHS applications also require that applications have Vertebrate Animal Sections that include a significant amount of detail about the procedures and care of animals in the proposed study. This information is part of the peer review of the proposed work and is included in the grant score. The same information has been (or will be reviewed "just in time") by the local IACUC. Furthermore, according to NIH Grant Policy Statement, the institution is charged with verifying congruency between the proposed work in the application and the protocol reviewed by the IACUC. These processes result in unnecessary additional work by investigators on review panels and institutional staff to oversee the legal mandate to the local IACUC.

Protocol Review

Within an institution, any proposed research must be reviewed by the IACUC. The protocol review includes a description of the research, approaches to minimize animal numbers, justification for the use of animals, and information on alleviation of pain and distress, methods of euthanasia, and veterinary care, among other topics. All of this is prospective, since approval must be granted before work can begin. There also is a requirement for periodic or continuing review. Additionally, as a research plan evolves, approval for modifica-

[75] In 2015, NSF entered into a Memorandum of Understanding with OLAW requiring grantee institutions to have an approved PHS assurance. See *Office of Laboratory Animal Welfare - MOU Between NIH and NSF*, available at: http://grants.nih.gov/grants/olaw/references/mou_nsf.htm).

tions must be sought from and granted by an IACUC before work can be continued. The process has become extensive and burdensome with a focus on proposed work at the expense of monitoring ongoing research.

Reporting

The USDA, DOD, and NIH require annual reports about the care and use of animals. In addition, the NIH requires reports of noncompliance as they occur, regardless of the severity of the effect the noncompliance event had on the health and welfare of the research animal.

RECOMMENDATIONS

The committee recommends that:

5.7. Congress direct the White House Office of Science and Technology Policy to convene within one fiscal year representatives from federal agencies that fund animal research and representatives from the research community to assess and report back to Congress on the feasibility and utility of developing a unified federal approach for the development, promulgation, and management of policies and regulations pertaining to the care and use of research animals.

- This feasibility assessment should consider whether harmonization might be best achieved using a Federalwide Assurance mechanism.
- The Assurance mechanism should ensure that regulations and policy are evidence based and should distinguish the regulatory aspects of animal research oversight from the terms and conditions of grants, so as to ensure that consistent oversight is applied to all animals.
- The Assurance mechanism should empower IACUCs to streamline the protocol review process and change the emphasis of institutional efforts to the ongoing protection of research animals through targeted and effective training and post-approval monitoring of animal use activities.

5.8. Reporting, assurances, and verifications to agencies should be reduced and streamlined. Agencies should adjust their requirements for reporting such that animal-related noncompliance reports are tiered to the level of significance or impact on animals and included in an annual report rather than submitted on an individual event basis. Annual reports to individual agencies about animal care programs should be replaced by a single annual report under the proposed Federalwide Assurance mechanism. Processes that are redundant to the IACUC approval process, such as the Vertebrate

Animal section of PHS grant applications and the DOD central administrative protocol review, should be eliminated.

5.9. Research institutions should assess their own regulatory processes to determine where their compliance activities can be streamlined to ensure effective use of indirect research recovery costs, while still meeting the requirements of federal regulations.

- Processes that should be reviewed include the following:

1. Full IACUC review of all animal use protocols.
2. Multiple individuals involved in designated member review of animal use protocols.
3. Performing annual and triennial reviews of protocols instead of using a continuing review process and "restarting the clock" after each review.
4. Applying USDA and PHS standards to all processes and protocol reviews where they do not apply (e.g., literature searches on rodent protocols not covered by the USDA).
5. Accepting suggestions made by accrediting bodies and other non-federal entities as if these suggested best practices had the force of agency regulations or policy.
6. Performing unnecessary training on topics that do not directly benefit research animals (e.g., training on procedures irrelevant to their day-to-day activities or regulatory background that does not pertain to active protocols).

6

Regulations and Policies Related to the Financial Management of Research Grants

The focus of this chapter is regulatory requirements related to the financial management of a research grant. The specific areas of consideration are the audit climate, reporting on compensation for personnel expenses for research grants, and problematic elements of the Uniform Guidance.[1]

THE AUDIT CLIMATE

Introduction

Research institutions are subject to frequent federal audits. Institutions receiving more than $750,000 in federal grants are required to undergo a yearly audit known as a Single Audit, formerly known as an OMB A-133 Audit.[2] The Single Audit is designed to ensure that recipient institutions of federal grants comply with federal program requirements for how federal dollars can be spent. The Single Audit Act was intended to reduce burden on grant recipients that were previously subject to multiple ongoing audits, and it established standards for achieving consistency and uniformity among federal agencies for the audit of states, local governments, and nonprofit organizations (e.g., research institutions) expending federal grant awards.

In addition to the annual Single Audit, research institutions are subject to agency-specific audits undertaken by federal grant-making agencies' inspectors general, which are established in departments and agencies of the federal government as formalized by the Inspector General Act of 1978.[3] The Act required the creation of independent and objective units within agencies to:

[1]Text in this chapter has been revised from the prepublication version to incorporate minor editorial corrections, including clarification of the relationship between offices of inspectors general and their agencies and the difference between audits and investigations.

[2]Audits of States, Local Governments, and Non-Profit Organizations (Circular No. A-133) (Washington, DC: Office of Management and Budget Compliance), https://www.whitehouse.gov/sites/default/files/omb/assets/a133/a133_revised_2007.pdf.

[3]*Inspector General Act of 1978*, Pub. L. No. 95-452, 5 U.S.C. App. (1978) [As Amended Through Pub. L. No. 113-126, Enacted July 07, 2014]. While 12 inspectors

1. "Conduct and supervise audits and investigations relating to the programs and operations of" [these departments and agencies]…;
2. Provide leadership and coordination and recommend policies for activities designed (A) to promote economy, efficiency, and effectiveness in the administration of, and (B) to prevent and detect waste, fraud and abuse in, such programs and operations; and to
3. Provide a means for keeping the head of the establishment and the Congress fully and currently informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for and progress of corrective action."[4]

The Inspector General Reform Act of 2008[5] amended the 1978 Act in a number of ways. Reforms included the establishment of the Council of Inspectors General on Integrity and Efficiency (CIGIE), an independent entity within the executive branch comprising inspectors general and other federal agencies' administrators. CIGIE was created "to address integrity, economy, and effectiveness issues that transcend individual Government agencies; and increase the professionalism and effectiveness of personnel by developing policies, standards, and approaches to aid in the establishment of a well-trained and highly skilled workforce in the offices of the Inspectors General."[6] As required in the 2008 Reform Act, each inspector general provides semiannual reports to Congress summarizing the inspector general's activities during the previous 6 months.

Nature of Concern

Concerns have been raised about a lack of understanding amongst federal agencies, inspectors general, and research institutions regarding what constitutes compliance with financial policies and procedures. There are concerns about the

general offices were initially established under the 1978 Act, there are currently 57 different and autonomous offices of inspectors general. Inspectors general of the largest departments and agencies are appointed by the President of the United States and confirmed by the U.S. Senate (e.g., the inspector general of the Department of Health and Human Services, the parent agency of the National Institutes of Health). Inspectors general for some federal agencies with smaller budgets and smaller staffs are appointed by the head of the designated federal entity. In the case of the National Science Foundation (NSF), the inspector general is appointed by the National Science Board (NSB).See *Inspectors General: Reporting on Independence, Effectiveness, and Expertise* (GA0-11-770) (Washington, D.C.: U.S. Government Accountability Office, 2011), http://www.gao.gov/products/GAO-11-770.

[4]*Inspector General Act of 1978*, Pub. L. No. 95-452, 5 U.S.C. App. (1978) [As Amended Through Pub. L. No. 113-126, Enacted July 07, 2014].

[5]*Inspector General Reform Act of 2008*, Pub. L. No. 110-409 (2008).

[6]See "CIGIE Governing Documents," *Council of the Inspectors General on Integrity and Efficiency,* accessed September 9, 2015, https://www.ignet.gov/content/cigie-governing-documents.

extent to which inspectors general, agencies, and research institutions partner in the proactive promotion of economy, efficiency, and effectiveness in the administration of federal grants. Not uncommonly, audits of research institutions lead to initial findings (inspectors general–alleged misuses of substantial federal funds, meriting further investigation). Such findings may be announced and publicized before the completion of an in-depth investigation, causing institutional concern that such preliminary findings may cause unwarranted reputational harm to the investigated institution. Not uncommonly, final audit findings that end in discussion and negotiation between designated agency staff and institutional staff resolve the audit with penalties that are significantly smaller than what was reported in initial findings. Institutions regret that, in contrast to preliminary findings, final resolutions receive little or no attention.

Audited institutions are also concerned about a lack of transparency regarding the specific criteria used by auditors to determine which institutions are likely candidates for an agency audit, what types of institutional policies and procedures raise the highest levels of concern among inspectors general, and what measures institutions can adopt to ensure findings of financial compliance and bring about a reduction of the likelihood of being chosen to undergo often multiyear, time-consuming agency audits.

Analysis

Examples of audits and investigations illustrate the benefits and costs of such activities. Numerous audits end in final audit resolutions requiring only modest sums to be paid to the government following inspectors general audits (see Box 6-1). Some investigations have resulted in findings that reveal significant misuse of funds by research institutions that have received federal research funding, and the result has been that those institutions paid a penalty for the misuse of federal funds and remitted sums that had been misspent. In addition, those institutions have taken steps to strengthen their internal management oversight policies and procedures.

Estimates of research institutions' costs associated with responding to agency audits range from $300,000 to $1 million per campus plus a significant commitment of faculty researcher time.[7] In some instances, inspectors general and the agency leadership are not in agreement on the audit outcomes and findings. In the case of the National Science Foundation (NSF) audit of the University of California, Santa Barbara as described in Box 6-1, for example, in spite

[7]University of California Officials, Personal communication to Committee Member Charles Louis, former Vice Chancellor for Research, University of California, Riverside, June 30, 2015.

BOX 6-1 Audit Activity and Investigations

An Example of Audit Activity

The National Science Foundation (NSF) has begun to publish on its website the final outcomes of its audit resolution agreements. Recent NSF Office of inspector general (OIG) audits of six major research universities receiving a total of almost $2 billion in annual federal research funding[a] reported initial audit findings (that is, disallowed expenditures, a significant portion of which was associated with the use of NSF's 2-month senior investigator salary[b]) totaling more than $12.8 million. The final resolutions of these audits, however, resulted in the audit findings being reduced to approximately 4.8 percent of the initial disallowance ($610,121).[c]

The largest of the NSF OIG audit findings for the six institutions was for the University of California, Santa Barbara (UCSB). The initial audit identified $6,325,483 in disallowed costs, a major disallowance being senior investigator salary charges[d] Following audit resolution, this finding was reduced to $43,551, as NSF and NSF's OIG concurred that most of the charges were allowable. Yet these very same types of senior investigator salary charges were disallowed in audits of other universities subsequent to the UCSB audit, even though the agency had made clear in the UCSB audit that these NSF senior investigator salary charges were an allowable cost (see University of California, Los Angeles, and University of California, Berkeley, audit findings).[e]

In contrast to the NSF OIG, the Department of Health and Human Services (HHS) OIG, which is responsible for oversight of NIH awardee institutions, conducts proportionately fewer financial compliance audits of universities.

An Example of an Investigation

In 2008, HHS, Department of Energy, Department of Defense, NSF, National Aeronautics and Space Administration OIGs, the Federal Bureau of Investigation, and several other federal agencies jointly performed an investigation of Yale University. Following the issuance of multiple OIG subpoenas, Yale cooperated with federal authorities in an investigation of research grant expenditures over a period from January 2000 to December 2006. The investigation revealed that Yale researchers had undertaken improper cost transfers to "spend down" grant funds and had overstated effort reports that resulted in salary overcharges. In a civil False Claims Act settlement announced in late 2008, Yale agreed to pay $7.6 million to the government, half of which represented actual damages for false claims, and half of which were penalties. One important and beneficial outcome of the investigation was that Yale strengthened its research compliance administration and infrastructure.[f]

[a] "Survey of Federal Funds for Research and Development," National Science Foundation, accessed August 24, 2015, http://nsf.gov/statistics/srvyfedfunds/#tabs-3.

[b] As a general rule, NSF limits salary compensation for senior project personnel on grant awards to no more than 2 months of their regular salary in any one year. This limit includes salary received from all NSF-funded grants. As such, proposal budgets submitted are not typically permitted to request, and NSF-approved budgets do not

(Continued)

BOX 6-1 Continued

typically include, funding for an individual investigator or co-principal investigator which exceeds 2 months of their regular year salary. See "Chapter II - Proposal Preparation Instructions," National Science Foundation, accessed August 24, 2015, http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/gpg_2.jsp.

[c] University of Wisconsin; University of California, Los Angeles; Virginia Tech; University of California, Santa Barbara; New York University; and San Andreas Fault Observatory at Stanford. See "Management Responses to External Audits and Internal Reviews," National Science Foundation, accessed August 24, 2015, http://www.nsf.gov/bfa/responses.jsp.

[d] National Science Foundation, Division of Institution and Award Support. Letter to Henry T. Yang (Chancellor, University of California, Santa Barbara) June 13, 2004, http://www.nsf.gov/bfa/dias/caar/docs/auditreports/auditrep121005_ucsb.pdf.

[e] "Management Responses to External Audits and Internal Reviews," National Science Foundation, accessed August 24, 2015, http://www.nsf.gov/bfa/responses.jsp.

[f] "Yale University to Pay $7.6 Million to Resolve False Claims Act and Common Law Allegations," U.S. Department of Justice press release, December 23, 2008, accessed August 24, 2015, https://oig.nasa.gov/press/pr2009-B.pdf.

of acceptance by the NSF agency leadership that most of the audit findings represented allowable costs, the NSF Office of Inspector General (OIG) stated in its semiannual report to Congress that "OIG disagrees with NSF's decision to allow $6 million of costs questioned in the audit."[8]

The question is not whether audits should occur, but rather under what conditions the audits should take place. When there are well-founded concerns about the misuse of funds, then audits are appropriate mechanisms for detecting waste, fraud, and abuse. On the other hand, if audits are conducted without prior evidence of waste, fraud, and abuse, in many cases, after years of an audit investigation and subsequent negotiations, the costs of the investigative process can be much greater than the amount the audited university must repay.

Findings

The relationship between inspectors general and universities can be most productive when it is based on a shared commitment to advancing the nation's interests through a dynamic and productive research enterprise. Inspectors general are important monitors of the expenditure of government funds. However, a renewed spirit of collaboration among inspectors general, agencies, and universities can identify strategies to enhance mutual understanding of the rules and

[8] *Semiannual Report to Congress*, (Washington, DC: National Science Foundation, Office of Inspector General, 2014), 16, http://www.nsf.gov/pubs/2015/oig15001/oig15001.pdf.

regulations regarding the expenditures of grant funds and preclude the misuse of such funds.

Inspectors general are expected to guide institutions in the prevention of questionable practices and thus empower research institutions to operate in compliance with federal rules and regulations on the use of federal funds. When agencies, inspectors general, and research institutions have shared understandings and interpretations of the rules and regulations governing financial expenditures, there are fewer disagreements about the expenditure of federal funds. Without a shared understanding, an environment is created with competing assertions and findings.

There are questions regarding the basis on which agency inspectors general decide to conduct audits of research institutions. This process was characterized by one inspector general as being based on a risk analysis "that comprises a soup"[9] from which auditors are able to identify the institutions that have the highest risk of misuse of federal funds.

The internal analytics tools used by the NSF and the Department of Health and Human Services (HHS) inspectors general offices to identify outlier data among institutions and to detail the precise nature and scope of questionable financial management patterns and practices are deemed by the inspectors general to be confidential and unavailable to research institutions.[10] Were agencies, inspectors general, and research institutions to agree on the need to reexamine the risk-based methodologies used in identifying likely audit candidates, that knowledge could increase institutional awareness of potentially inappropriate expenditures and better reflect the original intent of the 1978 Inspectors General Act (i.e., provide leadership and coordination, recommend policies to promote economy, efficiency, and effectiveness in the administration of research institutions' programs and operations). A more open and collaborative approach would support the principle that institutions and inspectors general are partners working to ensure compliance with federal financial regulations, monitor university actions and decisions regarding the uses of federal funds, promote cost efficiencies, and reduce waste, fraud, and abuse.

In an effort to promote transparency and to disseminate the results of the resolution process, NSF recently began posting comparisons of initial findings and the final outcomes of audit resolutions on its website.[11] These final audit outcomes are published in the NSF OIG semiannual reports to Congress in the audit resolu-

[9]Allison Lerner, Inspector General of the National Science Foundation, Presentation to the Committee, April 17, 2015.

[10]Allison Lerner, Inspector General of the National Science Foundation, Presentation to the Committee, April 17, 2015; Julie Taitsman, Chief Medical Officer, U.S. Department of Health and Human Services' Office of Inspector General, Presentation to the Committee, July 21, 2015.

[11]"Management Responses to External Audits and Internal Reviews," National Science Foundation, accessed August 24, 2015, http://www.nsf.gov/bfa/responses.jsp.

tion section. The HHS OIG publishes the results of the final audit resolution,[12] rather than reporting initial findings, which may differ from final audit findings.

RECOMMENDATION

6.1. The committee recommends that Congress require inspectors general to:

- **Resolve issues regarding their interpretation of agency policies and priorities with the agency before conducting formal audits of research institutions; this should not apply in those situations in which the audit itself is directed toward inconsistent agency policy interpretations.**
- **Include in their semiannual reports, publish on their websites, and highlight in their presentations to Congress examples of effective, innovative, and cost-saving initiatives undertaken by research institutions and federal research agencies that both advance and protect the research enterprise.**
- **Provide to Congress and make publicly available information generated each year on the total costs (agency and institutional) of inspectors general audits of research institutions, the total amounts of initial findings, the total amounts paid by institutions after audit resolution, and any significant management, technology, personnel, and accountability steps taken by research institutions as the result of a completed audit.**
- **Reexamine the risk-based methodology in identifying institutions as candidates for Offices of inspectors general audits to take into account the existing compliance environment and oversight on campuses, recognizing that many research institutions have clean single audits, are well managed, and have had long-standing relationships with the federal government.**
- **Encourage all federal inspectors general to report only final audit resolution findings on their websites and in their semiannual reports to Congress.**

REPORTING OF COMPENSATION FOR PERSONNEL EXPENSES

As a condition of receiving federal research grants, the Office of Management and Budget (OMB) requires awardee institutions to ensure that "charges to Federal awards for salaries and wages must be based on records that accu-

[12]Julie Taitsman, Chief Medical Officer, U.S. Department of Health and Human Services' Office of Inspector General, Presentation to the Committee, July 21, 2015.

rately reflect the work performed."[13] The traditional system for accomplishing this has been "effort reporting," whereby faculty who serve as principal investigators for federal grants are responsible for certifying the percentage effort that they and their employees expended on grant-supported activities (see Box 6-2). The Uniform Guidance eliminates this requirement and permits institutions to adopt their own system of personnel management and reporting as long as internal controls provide reasonable assurance that the charges are accurate, allowable, and properly allocated.[14]

Nature of Concern

As noted by the Federal Demonstration Partnership (FDP), "Effort reporting is based on effort that is difficult to measure, provides limited internal control value, is expensive, lacks timeliness, does not focus specifically on supporting direct charges, and is confusing to faculty when all forms of remuneration are considered."[15] For many institutions, effort reporting also requires the development or purchase, and the continuing maintenance, of expensive specialized software systems.[16]

BOX 6-2 The Effort Reporting Process

In general, each quarter, an institution's sponsored funds accounting unit reviews all current research awards for all faculty and staff, and identifies the percentage of effort every individual has devoted to each of his or her federal awards. An effort report is prepared for each individual listing the percentage effort expended on each grant, as well as the percentage of effort devoted to all other activities compensated for by the institution. The accounting office must ensure that all activities add up to no more than 100 percent of each individual's total effort. The effort reports are sent to the departments of each faculty investigator, wherein the departmental accountant, who manages the awards of a particular investigator, reviews the effort report, making adjustments (such as institutional cost-sharing arrangements that are part of a grant award agreement) and modifying the effort report accordingly. This information is then provided to the principal investigator, who is required to acknowledge by signature that the information in the effort report, to the best of his or her knowledge, is accurate.

[13]See Compensation – Personal Services, 2 CFR § 200.430 (2014).

[14]"Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590, (http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf.

[15]Federal Demonstration Partnership, Quoted in Tobin L. Smith, Josh Trapani, Anthony Decrappeo, and David Kennedy "Reforming Regulation of Research Universities," *Issues in Science and Technology* XXVII, no. 4 (2011).

[16]Tobin L. Smith, Josh Trapani, Anthony Decrappeo, and David Kennedy "Reforming Regulation of Research Universities," *Issues in Science and Technology* XXVII, no. 4 (2011).

Analysis

In a 2011 American Association of Universities (AAU)/Association of Public and Land-grant Universities (APLU)/Council on Government Relations (COGR) request for information from universities, virtually every institution that responded identified effort reporting as an area that has significant cost and productivity implications. One public university in the Midwest stated that nine separate full-time employees spend approximately one quarter of their time each year monitoring certifications, at a total estimated cost per year of $117,000.[17] Another public university, in the West, estimated that its total administrative cost of monitoring certifications for the effort reporting system exceeded $560,000, including $320,000 in the central administrative accounting office and an additional $241,000 for faculty and staff time across various academic departments.[18] A "private university in the Midwest estimated that on its campus there are over 6,000 effort reports completed three times per year, resulting in more than 18,000 effort reports processed per year overall. Estimating that 60–90 minutes were spent on each effort report—including issuing instructions, completion by faculty and staff, administrative review, tracking, and storing—yields a conservative estimate of 20,000 hours per year spent on this process."[19] A public university in the Midwest reported that the estimated cost to purchase necessary effort reporting software from an external vendor was in excess of $500,000, exclusive of implementation and training costs. A public university in the West estimated the cost of its system at $435,000 annually. Several universities reported that overall they spent between $500,000 and $1 million annually on effort reporting.[20]

> In its 2014 report,[21] the National Science Board (NSB) stated: Effort reporting
>
> "is incongruent with the administrative structure of universities and the actual manner in which faculty perform research, which is difficult to track given their simultaneous work on multiple projects and the degree to which activities are interwoven (e.g., mentoring graduate students and post-docs, participating in professional meetings and conferences, working in the laboratory, and studying papers describing related research)."

[17]"Regulatory and Financial Reform of Federal Research Policy Recommendations to the NRC Committee on Research Universities," *Association of American Universities, Association of Public and Land-Grant Universities, Council on Governmental Relations*, January 21, 2011, accessed September 9, 2015, https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=11662.

[18]Ibid.

[19]Ibid.

[20]Ibid.

[21]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

Through FDP, a number of institutions have piloted Payroll Certification (see Box 6-3), a more streamlined and efficient compensation management and reporting system than effort reporting.[22] The Payroll Certification pilots were implemented in 2011 at four universities: University of California, Riverside; University of California, Irvine; George Mason University; and Michigan Technological University.[23] At the pilot sites, investigators were asked to confirm the accuracy of salary expenditures based on the work performed on their awards during their grant's previous budget year. Initial key outcomes of the FDP Payroll Certification pilot were the following:

- The paperless process of payroll certification consolidated information in a more meaningful format.
- There was a significant increase in the review of monthly expenditures by investigators, resulting in greater accountability that funds are spent as intended.
- There was a higher level of compliance with accounting procedures by investigators than with the existing effort reporting system.[24]

The audit report from the NSF Office of Inspector General (OIG) of George Mason University's Payroll Certification pilot was recently published and appeared to identify no major issues or concerns regarding the university's methodology.[25] The HHS OIG provided the results of its audit of the pilot payroll certification program at the University of California, Irvine in a report dated December 2014.[26] Also, shortly after the release of Part 1 of the committee's report, the NSF OIG provided the results of its audit of the pilot payroll certification program at Michigan Technological University.[27] Neither of these audits

[22]"Payroll Certifications: A Proposed Alternative to Effort Reporting," The Federal Demonstration Partnership, January 3, 2011, accessed August 24, 2015, http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_055994.pdf.

[23]Federal Demonstration Partnership Project Payroll Certification Pilot, (2011), http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_055994.pdf.

[24]Ibid.

[25]*Labor Effort Reporting under the Federal Demonstration Project's Pilot Payroll Certification Program at George Mason University* (OIG 15-1-017) (Arlington, VA: National Science Foundation, Washington, DC: Office of Inspector General, July 31, 2015), https://www.nsf.gov/oig/_pdf/15-1-017-GMU.pdf.

[26] *The University of California at Irvine's Pilot Payroll Certification System Could Not Be Assessed* (Bethesda, MD: U.S. Department of Health and Human Services, Washington, DC: Office of Inspector General, December 2014), http://oig.hhs.gov/oas/reports/region4/41301027.pdf.

[27] *Labor Effort Reporting under the Federal Demonstration Partnership Pilot Payroll Certification at Michigan Technological University* (OIG 15-1-23) (Arlington, VA: National Science Foundation, Washington, DC: Office of Inspector General, September 30,

BOX 6-3 The Payroll Certification Process

With Payroll Certification, grant awardees are asked, on an annual basis, to confirm the reasonableness of salary expenditures based on the work performed by each individual supported on an award during the grant's budget year period. An annual Payroll Certification is required, and investigators are "strongly encouraged" (but not required) to review their monthly grant budget statements that include both salary expenditures and all other expenditures on each award.

The monthly review complements the annual certification process for the investigators, as both are directly derived from the institution's financial and personnel systems (thus ensuring no overcharging of salaries). An annual certification schedule is created for the award's project period for all salary and wage expenses charged to an award. These expenses are reviewed by the investigator to confirm that: (1) salary and wage expenses charged to an award are appropriate and reasonable in relationship to the work performed; (2) salaries associated with proposal preparation activities are not charged to a sponsored project; and (3) senior project personnel receiving salary payments from NSF funding adhere to the 2-month salary restriction placed on all NSF awards or, in the case of NIH, that salaries adhere to the NIH salary cap.

found deficiencies in the institutions' payroll certification methodologies. Many universities that anticipate adopting a system such as payroll certification are awaiting the results of all four audits before doing so.[28]

Findings

The Uniform Guidance provides a government-wide framework for grants management. In the latest guidance, OMB moved away from a detailed prescription on how personnel expenses should be documented—meaning that the traditional effort reporting system is no longer required. Instead, OMB requires that "charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed and be supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated."[29] Furthermore, it states that "cognizant agencies for indirect costs are encouraged to approve alternative proposals based on outcomes and milestones for program performance where these are clearly documented. Where approved by the Federal cognizant agency for indirect costs, these plans are acceptable as an alternative to the requirements of paragraph (i)(1) of this section."[30]

2015), https://www.nsf.gov/oig/_pdf/15-1-023-MTU.pdf.

[28] The text of this paragraph has been revised to incorporate information on the results of the audits of the University of California, Irvine and Michigan Technological University payroll certification pilot programs.

[29] See Compensation – Personal Services, 2 CFR § 200.430 (2014).

[30] "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for

As noted above, the NSB has concluded that "effort reporting is incongruent with the administrative structure of universities and the processes by which faculty actually perform their research."[31] The Uniform Guidance now permits greater flexibility in how personnel expenses on grants can be documented by institutions. One such method is Payroll Certification, which has been piloted by the FDP and has demonstrated a compelling case for efficiency, accuracy, and cost reduction.

One institution piloting an alternative approach—Payroll Certification—experienced a significant reduction in burden over a 3-year period, changing from processing more than 14,000 paper-based effort reports to 2,100 online payroll certifications.[32]

Research institutions can take advantage of the flexibility provided by Uniform Guidance by adopting more effective and efficient management and certification systems as long as they have robust internal institutional controls "supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated."[33]

RECOMMENDATION

6.2. The committee recommends that Congress, in concert with the White House Office of Management and Budget, affirm that research institutions may take advantage of the flexibility provided by the Uniform Guidance with regard to the documentation of personnel expenses.

THE UNIFORM GUIDANCE

The Uniform Guidance significantly reforms federal grant-making procedures in an effort to focus resources on improving performance and outcomes and reducing administrative burdens on grant applicants while concurrently reducing the risk of waste, fraud, and abuse.[34] Three significant items in the Uniform Guidance require further modification: Procurement Standards, Financial Reporting, and Cost Accounting.

Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf.

[31]National Science Foundation, *Reducing Investigators' Administrative Workload for Federally Funded Research* (NSB-14-18) (Arlington, VA, 2014), http://nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[32]Bobbi McCracken, "Payroll Certification Pilot: FDP Update" (presentation, FDP Meeting, Washington, DC, January 5-7, 2014), http://sites.nationalacademies.org/PGA/fdp/PGA_086497.

[33]See Compensation – Personal Services, 2 CFR § 200.430 (2014).

[34]"Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," *Federal Register* 78, no. 248 (December 26, 2013): 78590, http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf.

PROCUREMENT STANDARDS

Introduction

The new Uniform Guidance requires universities, beginning in 2017, to document multiple bids for purchasing transactions exceeding $3,000 in value.[35]

Nature of Concern

Most universities have purchasing thresholds ranging between $5,000 and $10,000, above which competition and price comparisons ("external bids") are required to be documented. Adjusting to the Uniform Guidance standard of $3,000 for all purchases supported by federal grants will require extensive changes in institutions' procurement systems, increases in procurement staff to handle the associated increased number of required bids, and increased time to process relatively low-risk and low-cost procurement transactions. This lower threshold may result in compliance costs far exceeding any corresponding reduction in waste, fraud, and abuse.

Analysis

The Uniform Guidance requires documented multiple bids for university purchasing transactions exceeding $3,000. This lower threshold means that institutions will have to issue bids for a larger proportion of their expenditures and add additional administrative burden for faculty and purchasing offices. For example, Stanford's current procurement guidelines require bids for transactions exceeding $25,000 in value. An adjustment to the lower threshold of $3,000 will require Stanford to document competitive bids for six times more transactions than it currently does (see Table 6-1). Additionally, changing the threshold may delay investigators from getting essential materials they need to advance their research.[36]

COGR states that the $3,000 threshold was selected without an objective analysis of what is appropriate for grants, without any input from the grant-recipient community, and without consideration of the impact on administrative burden.[37]

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[35]Office of Management and Budget. "Universal Identifier and System of Award Management; Corrections." *Federal Register* 80, No. 175 (September 10, 2015): 54407, http://www.gpo.gov/fdsys/pkg/FR-2015-09-10/pdf/FR-2015-09-10.pdf.

[36]Randy Livingston, Vice President for Business Affairs and CFO, Stanford University, Presentation to the Committee, May 28, 2015.

[37]Council on Government Relations, Letter to David Mader (Controller, Office of Management and Budget) February 13, 2015, http://www.purdue.edu/business/sps/pdf/COGR_Response_OMB-2015-0001.pdf.

TABLE 6-1 Stanford University Purchasing Transactions for FY 2014

	Transactions		Purchasing Value		Avg.	3% of Avg.	10% of Avg.
Transaction Size	#	%	$000	%	Transaction	Transaction	Transaction
$0 - $3,000	466,552	95.50%	$ 142,942	12.30%	$ 306	$ 9	$ 31
$3,000 - $10,000	13,679	2.80%	$ 68,873	5.90%	$ 5,035	$ 151	$ 503
$10,000 - $25,000	4,885	1.00%	$ 70,010	6.10%	$ 14,331	$ 430	$ 1,433
> $25,000	3,420	0.70%	$ 818,175	75.70%	$ 239,250	$ 7,177	$ 23,925
Total	488,536	100.00%	$ 1,100,000	100.00%			

SOURCE: Courtesy of Randy Livingston, Vice President for Business Affairs and Chief Financial Officer, Stanford University, May 2015.

Findings

The added administrative burden required by the new $3,000 threshold will be significant, as institutions will have to require competitive bids for purchases of this amount or greater. These delays may negatively impact the ability of investigators to obtain research materials in a timely manner and may delay the completion of research. In general, research institutions have thresholds typically ranging from $5,000 to $10,000 for procurement. Lowering the threshold to $3,000 will require institutions to account for a significantly greater number of transactions.

In the case of public universities, many institutions have linked their thresholds to be in compliance with state requirements that adhere to thresholds in excess of $3,000.

RECOMMENDATION

6.3. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance as follows:

- **Amend Section 200.329 to read: Procurement by micro-purchases. Procurement by micro-purchase is the acquisition of supplies or services on a purchase order from a single vendor, the aggregate dollar amount of which does not exceed $10,000 (or $2,000 in the case of acquisitions for construction subject to the Davis-Bacon Act).[38] OMB shall periodically revisit and adjust the $10,000 threshold to account for escalating costs of supplies and services.**

[38]The Uniform Guidance currently reads, "Procurement by micro-purchases. Procurement by micro-purchase is the acquisition of supplies or services, the aggregate dollar amount of which does not exceed the micro-purchase threshold (§ 200.67 Micro-purchase)."

- **Amend the list of criteria for the permissible purchase of supplies and services through noncompetitive bids in Section 200.320 to include: The procurement is necessary for research, scientific, or other programmatic reasons, such as instances where the purchase is for a specialized service or of a necessary quality that is available only from a single vendor or if only one vendor can deliver in the required time frame."[39]**

FINANCIAL REPORTING

Introduction

The Uniform Guidance requires submission of financial reports 90 days following the end of an award period.[40] The 90-day requirement is inconsistent with requirements at NIH and NSF.

Nature of Concern

It was anticipated that the Uniform Guidance would provide uniform financial reporting requirements. Without consistency among agency policies and practices, compliance with financial reporting requirements leads to additional administrative burden for universities (see Box 6-4).

Analysis

While the Uniform Guidance has set 90 days following the end of an award as the deadline for the submission of financial reports, two major federal research agencies, NIH and NSF, allow 120 days for reporting following the end of an award. This additional month recognizes the trend of increased multi-institutional collaborations on research proposals and the resulting increase in the complexity of financial reporting.

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[39] 2 CFR 2 § 200.320(f) (2014) currently reads:

"Procurement by noncompetitive proposals. Procurement by noncompetitive proposals is procurement through solicitation of a proposal from only one source and may be used only when one or more of the following circumstances apply:

(1) The item is available only from a single source;

(2) The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation;

(3) The Federal awarding agency or pass-through entity expressly authorizes noncompetitive proposals in response to a written request from the non-Federal entity; or

(4) After solicitation of a number of sources, competition is determined inadequate."

[40] See Closeout, 2 CFR § 200.343 (2014).

BOX 6-4 Differences in Timing of Final Financial Reporting

Uniform Guidance: "The non-Federal entity must submit, *no later than 90 calendar days after the end date of the period of performance*, all financial, performance, and other reports as required by the terms and conditions of the Federal award. The Federal awarding agency or pass-through entity may approve extensions when requested by the non-Federal entity." [emphasis added][a]

National Institutes of Health: "All reports required for closeout must be submitted *no later than 120 days after the project end date*." [emphasis added][b]

National Science Foundation: "Grantees must submit final financial disbursements *no later than 120 days after the grant end date*." [emphasis added][c]

[a] See Closeout, 2 CFR § 200.338 (2014).
[b] See National Institutes of Health, "Frequently Asked Questions: Grants Closeout," accessed September 10, 2015, http://grants.nih.gov/grants/closeout/faq_grants_closeout.htm#4011.
[c] See Article 16, "National Science Foundation (NSF) Grant General Conditions (GC-1) Effective December 26, 2014."

The standard use of a 120-day time period more appropriately reflects the amount of time necessary for project closeout and eliminates the burden of responding to different agency requirements.

Findings

A 120-day time period for the preparation and submission of all reports for grants from all federal funding sources for the closeout process (technical, financial, patents) would allow universities sufficient time to prepare these reports.

The NSF and NIH policy of 120 days for the submission of financial reports is more appropriate than the new Uniform Guidance requirement of 90 days. A consistent requirement of 120 days across all agencies would acknowledge the increasing trend toward inter-institutional collaboration on research grants and reduce the burden of compliance with multiple report deadlines.

RECOMMENDATION

6.4. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance to establish a mandatory 120-day timetable for the submission of all financial reports for all federal research funding agencies.

COST ACCOUNTING STANDARDS

Introduction

OMB requires a university with more than $25 million of federal grants in a given fiscal year to disclose its cost accounting standards in a Cost Accounting Disclosure Statement (DS-2).[41] This statement identifies the cost accounting practices that a university follows, and describes the methodology for distinguishing direct costs from indirect costs. The federal government expects universities to abide by cost accounting standards to ensure that double charging on federally sponsored agreements does not take place. The cost accounting disclosure statement must be submitted to each university's cognizant[42] federal agency for review and approval during indirect cost negotiations.

Nature of Concern

Research universities already publish their accounting policies and practices. As such, the cost accounting disclosure statement is not a useful compliance document. It is simply a restatement of accounting policies and practices that are already documented in the official published policies of an institution.[43]

Analysis

Whenever there is a change in an institution's accounting practices, institutions are required to revise their disclosure statement and resubmit the document to the appropriate cognizant federal agency for review and approval. This is a time-consuming process for both grantees and cognizant agencies. Furthermore, there is little evidence that the approved document is actually used by agencies or by inspectors general as an auditing tool. Auditors generally do not request cost accounting disclosure statements when conducting annual audits, and all information contained in such statements is generally available on university websites.

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[41] See General Requirements, 48 CFR § 9903.202-1 (2010).

[42] "To simplify relations between federal grantees and awarding agencies, OMB established the cognizant agency concept, under which a single agency represents all others in dealing with grantees in common areas. In this case, the cognizant agency reviews and approves grantees' indirect cost rates. Approved rates must be accepted by other agencies, unless specific program regulations restrict the recovery of indirect costs." See"Grants Management, Grants Circular Attachments," Office of Management and Budget, accessed August 24, 2015, https://www.whitehouse.gov/omb/grants_attach/.

[43] David Kennedy and the COGR Costing Policies Committee, *COGR Letter to OMB on Uniform Administrative Requirements, Cost Principles, and Audit Requirements* (Washington, DC: Council on Government Relations An Association of Research Universities, 2015), http://www.cogr.edu/viewDoc.cfm?DocID=152118.

Findings

The reinstatement of the cost accounting disclosure statement in the Uniform Guidance as a required disclosure document fails to recognize that the document is a restatement of publicly available information about a university's accounting policies and practices. Moreover, the regularly updated DS2 is already submitted by a university every 1 to 5 years at the same time as its updated F&A proposal is submitted to the cognizant federal agency.

Only colleges and universities are subject to the cost accounting disclosure statement requirement. Other federal grant recipients, including state, local, tribal governments, and nonprofits are excluded from this requirement.

RECOMMENDATION

6.5. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance so that research universities are not required to submit a revised Cost Accounting Disclosure Statement (DS-2) each time they change their accounting practices, as long as those practices are in compliance with the Uniform Guidance and are posted promptly on the universities' websites. Rather, the initial disclosure statement and revisions to it should be submitted to the research institution's cognizant agency in coordination with the institution's Facilities and Administrative proposal.

7

A New Regulatory Framework for the Nation's Investment in Academic Research

Having completed, in the preceding three chapters, its analyses of several policies and regulations, the committee offers its overarching findings, principles to guide the partnership, and recommends a new regulatory framework to govern the government-academic research partnership.

An immensely productive research enterprise emerged following World War II from the decision of the federal government to support basic research by flowing funds through academic research institutions, thereby creating what has often been termed the federal-academic research partnership. This partnership has been built on the belief that each of the partners would fulfill its roles and obligations with honesty, integrity, and credibility, and with the public good always in mind. The compact has produced a national research enterprise that engages in a constant process of discovery, creating new knowledge and advancing our understanding of human health and disease, our world, and our universe, while simultaneously training the next generation of researchers.

Research fuels the economy by generating new products, processes, and services; creating jobs; enabling new means of communication and commerce; and founding entirely new industries, such as biotechnology and information technology. Research contributes to national security through the development of weapons and defense systems and by strengthening the security of our national communication, transportation, financial, and public health and safety systems. Research has improved the quality of life and the overall health and well-being of the population. Research in the social and behavioral sciences has provided novel insights into human behaviors and into the social, political, and economic problems facing the nation. Scholarship in the humanities has enriched our understanding of our own culture and the cultures of others. Importantly, the remarkable growth and success of this enterprise has created a mutual interdependence between the federal government and the academic research community.

Despite the achievement of these extraordinary benefits, the partnership has come under stress from increasingly numerous and complex federal regulations and reporting requirements. While began as a means of exercising responsible oversight, regulations and reporting requirements have grown such that they now

unduly encumber and strain the very research enterprise they were intended to facilitate. The accumulation and complexity of regulations have required ever-greater commitments of time and resources from investigators. Indeed, they have generated a new category of university administrators: research compliance officers. Regulations, reporting requirements, and congressional mandates often overlap, resulting in duplication of effort, multiple reporting of the same information in different formats, and multiple submissions of information on different schedules. Conflicting guidance on compliance requirements has created uncertainty and confusion, often leading universities to implement overly prescriptive procedures in an effort to avoid penalties and thereby adding additional burden.[1] The bottom line for the nation's research enterprise is that we may be increasingly funding researchers to perform administrative tasks at the expense of research and teaching. It is time for a reaffirmation of the partnership and the development of a sensible regulatory framework adapted to the current needs of research enterprise.

OVERARCHING FINDINGS

As noted throughout this report, the research performed at research institutions by individual investigators and research teams, selected on the basis of scientific merit and capability, fuels economic growth, strengthens national security, enhances the overall health, education, and well-being of U.S. citizens, and often, of all humanity, and greatly contributes to U.S. leadership in science, technology, and social and behavioral sciences. Thus, federal investment in such research serves the interests of the nation. With the importance of this investment to the well-being of the nation as its backdrop, the committee noted nine overarching findings that characterize the current climate for federal support of research at academic research institutions:

1. Effective regulation is essential to the overall health of the research enterprise, protecting both national investment and the various parties in the partnership (research participants, investigators, universities, and agencies).
2. Continuing expansion of the federal regulatory system and its ever-growing requirements are diminishing the effectiveness of the nation's research investment by directing investigators' time away from research and training toward overlapping and incongruent administrative matters that do not take into consideration the environment under which research is conducted at academic institutions today. Our understanding of the cumulative effect of regulations is, however, constrained by a lack of empirical data.[2]

[1]Universities may also impose additional requirements in order to comply with state and local regulations or because of institutional approach.

[2]Particularly quantitative data.

3. Most federal regulations, policies, and guidance, in and of themselves, are efforts to address important issues of accountability and performance associated with scientific integrity, the stewardship of federal funds, and the well-being of the people and animals involved in research. But these well-intended efforts often result in unintended consequences that needlessly encumber the nation's investment in research.
4. Many regulations fail to recognize the significant diversity of academic research institutions (e.g., in geographic location, public or private, size, legal structure, missions, financial and physical resources, and research capability). This diversity translates into widely varying capabilities to respond to increasing and overlapping research regulations.
5. When regulations are inconsistent, duplicative, or unclear, universities may place additional requirements on research investigators, thereby diminishing the effectiveness of the national investment in research.
6. Academic research institutions often receive research funding from multiple federal agencies, but approaches to similar shared goals and requirements (formats of grant proposals and biosketches, animal care, financial conflicts of interest, etc.) are not harmonized across these agencies. Consequently, investigators and administrative staff spend unnecessary time, energy, and resources complying with different sets of rules, regulations, and policies that address common core issues and concerns.
7. Some academic research institutions have failed to respond appropriately to investigators' transgressions or failed to use effectively the range of tools available to create an environment that strongly discourages, at both the institutional and individual level, behaviors in conflict with the standards and norms of the scientific community.
8. Academic research institutions may be audited by any agency's Inspector General office, many of which have very different approaches that in some cases are incongruent with stated policies of their agency.
9. The relationship between federal research funding agencies and academic research institutions has for the past seven decades been considered a partnership. Yet, there exists no formal entity, mechanism, or process by which senior stakeholders from both partners, dedicated to fostering, sustaining, and strengthening our nation's unique research partnership, can consider the effectiveness of existing research policies and review proposed new policies needed to sustain a maximally dynamic, efficient, and effective research enterprise. Further, no entity exists that can collect the data necessary to provide a true measure of the effectiveness and unintended consequence of existing research regulations.

As the committee learned, stresses in the federal-academic partnership diminish returns on the nation's investment in academic research. The current structure of the regulatory regime needs to be recalibrated in order to best serve the nation's interests.

A NEW REGULATORY FRAMEWORK FOR THE NATION'S INVESTMENT IN ACADEMIC RESEARCH

With these findings and in accord with its explicit charge, the committee sought to develop a new federal framework that, in conjunction with academic research institutions, allows for the conceptualization, development, harmonization, and reconsideration of research policy and regulation across federal agencies. The committee agrees on the importance of the following provision in the *Statement of Task*:

> "Develop a framework and supporting principles for the Federal regulation of research universities in the 21st century, taking into account (a) the purposes, costs, benefits, and reporting requirements of regulation, (b) the processes used to promulgate regulations and reporting requirements, (c) the roles of Congress, Offices of Inspectors General and Federal agencies, including the Office of Science and Technology Policy and Office of Management and Budget, and (d) the missions of research universities."

Throughout its study, the committee heard that the current volume of regulation steals from the nation's investment in research and has become self-defeating. Inefficient and over-scaled regulation diverts, at the very least, researchers' attention from research and must, as a consequence, reduce not just output, but also creativity and innovation. The effect of regulatory overburden is inevitably a less ambitious national research agenda.

Over the course of the committee's deliberations, it became evident that to achieve a more efficient and effective research enterprise—one that maximizes the social benefits resulting from deployment of its intellectual capital and public and private investment of funds—it is essential to establish a much more focused, integrated, and forward-looking framework for managing the research partnership. The committee recognizes, as have others, "the importance of ensuring that policies have strong empirical foundations, both through careful analysis in advance and through retrospective review of what works and what does not."[3] In this report, the committee aims to articulate a framework that can meet the complexity and scale of 21st-century issues and that can adapt to the

[3]Cass Sunstein, *Simpler: The Future of Government* (New York, NY: Simon & Schuster, 2013), p. 41.

challenges that will arise inevitably from the results of research and from social change during decades ahead.

Background and Analysis

A distinguishing feature of the U.S. research enterprise is that a large, central part, including most fundamental and much applied research, operates as a partnership among federal agencies and academic research institutions and is built on the mutual investment of public and private funds. Historically, the largest share has derived from federal and state appropriations, although more recently, the second largest share of funds has come from the research universities themselves (see Figure 2-2). The public investment flows through mission-based research agencies that provide programmatic leadership and oversee processes to identify the very best research talent and meritorious ideas. Research institutions provide, in addition to intellectual capital, state-of-the-art facilities and infrastructure necessary for the safe and efficacious conduct of cutting-edge research performed by outstanding faculty, students, and trainees. Moreover, these institutions anchor local, regional, and national scientific and technological ecosystems that have profound and positive economic effects and that foster the development of hundreds of thousands, if not millions, of jobs. This research partnership, involving the mutual investment of talent and resources, has for the past seven decades produced the world's most successful national research enterprise, an enterprise that has been and continues to be widely emulated around the world.

Historically, this system was based primarily on investigator-initiated project proposals, which, if deemed meritorious by anonymous peer review, were funded by grants to the successful investigators' institutions to be used for research by the applicants. Under this system, the research institutions became legally responsible for overseeing the safe conduct of the research, as well as the legal and appropriate expenditure of the awarded funds. Initially, it was tacitly, if not explicitly, agreed that while expenditures of federal funds would comply with applicable regulations, the institutions would continue to be responsible for overseeing their faculty members' conduct of research and training. During the "founding era" in the 1950s and early 1960s, an assurance system was implemented, by which institutional officials would certify for each research proposal that their institutions were in compliance with applicable federal regulations, largely related to expenditures of research funds, but also covering such topics as radiation and chemical safety. In the 1960s and 1970s, concerns for the rights and safety of human research participants and for the humane care of research animals led to regulations addressing these activities. During those years, each research funding agency promulgated its own individual requirements and formats regarding progress reports, financial reports, and invention reports. The basic system of research administration was project-centered and was reflected in a host of reports over the lifetime of each funding award.

The research partnership has grown immensely and is today far more complex. What began as a few hundred applications, awards, and reports, now numbers over 100,000 proposals annually with associated awards and reports. What was once an investment of millions of dollars in the 1950s now involves over $65 billion of public, private, and institutional resources. What could once be managed largely on a grant-by-grant basis through individualized, transaction-based applications and reports, can no longer be so managed. Although it was once sufficient for an institution to provide a few assurances regarding its conformity with applicable federal rules, now there is a need for a sophisticated infrastructure of compliance systems and safeguards to ensure the protection of human subjects, the humane care and use of animals, the appropriate use of taxpayer funds, the management of the potential for financial conflicts of interest, the safe storage and handling of potentially hazardous materials, and the appropriate recognition and management of biosafety and national security concerns. Today, government and academic research institutions expend substantial resources on the implementation of these requirements, on information systems for tracking transactions to effectively manage and report on these matters, and on training for faculty and staff to fulfill these requirements. All of this requires significant additional staff, as well as sophisticated facilities and information systems. Most research today must be conducted in institutional environments that have increasingly expensive and complicated physical facilities, as well as a complex infrastructure of procedural and physical safeguards.

The point here is that, for very good reasons, regulatory activities within the research partnership have grown dramatically in scale and sophistication. Activities that once required relatively minor costs and time commitments, and that could be managed fairly simply, now require large commitments of time, staff, and money; consequently, they entail large opportunity costs—so large that intelligent management of the cumulative regulatory load is important to the overall effectiveness of the nation's investment in research.

An optimal regulatory framework must focus on the competence, efficiency, and harmonization of the entire system and the interdependence of the component parts, that is, agencies, institutions, faculty investigators, administrators, and electronic infrastructure. The entire system must work effectively to advance new knowledge and to move enabling ideas and innovations rapidly into practice.

Every transaction—proposal, progress report, financial transaction, and audit—must either contribute to positive outcomes and innovation or run the risk of detracting from and undermining the system. Friction and inefficiency in these transactions consumes time and funds that would otherwise be devoted to research, so that the entire system becomes less effective in producing outcomes and improving the well-being of the American public. Considered individually, many of these transactions are well intentioned and appear appropriate, but when considered holistically, they create unnecessary, conflicting, and duplicative efforts.

The maturation and continued success of the American research enterprise, founded on the basis of a federal-academic partnership, calls for a new framework, one that operates to ensure that the entire system, while ensuring integrity and safety, is focused on the identification of scientific talent and expertise, promising new ideas, innovative resources, and the optimal investment of public funds. The goal of the new framework should be the development of a holistic rather than piecemeal approach to the regulatory system so as to harmonize regulatory requirements across research funding agencies and to create a more effective and efficient partnership between agencies and research institutions. Another goal of the new framework is the routine exchange of information regarding safeguards, financial transactions, reports of inventions, and other matters in federal-wide standard systems such as e-commerce solutions to facilitate standard investigator- and project-specific exchanges of applications, biosketches, and progress reports.

A successful framework must ensure that investigators can conduct research in an environment that aims to ensure safety, efficiency, and integrity while facilitating scientific progress and the optimal use of researchers' time. Each party in the enterprise must have a clear role in the effective operation of the system of requirements. Investigators should be provided with the administrative and project assistance to successfully navigate institutional and agency systems, thereby facilitating the appropriate use of their time on the conduct of research and training and the exchange of essential information.

The concept involves three parts:

1. A forum – the proposed Research Policy Board (RPB).
2. A responsible federal officer – the proposed White House Office of Science and Technology Policy (OSTP) Associate Director, Academic Research Enterprise.
3. A set of underlying principles to guide the partnership.

Each of these components is described below.

Research Policy Board

The need for an analytical, anticipatory, and coordinating forum on regulatory matters seems clearly evident to the committee; however, its constitution, financing, and most effective connection to federal processes are far from obvious. The partnership involves quite diverse agencies and institutions and bridges the public-private boundary. As the committee contemplated organizational possibilities, it found useful analogues in what the federal government has already done in four different arenas.[4] In each of those cases, tailored entities were cre-

[4]Established models for coordination of complex federal partnerships include (a) the Advisory Committee on Intergovernmental Relations, which, by congressional authoriza-

ated to facilitate partnerships involving multifaceted external institutional partners or constituencies.

The committee considered the National Science Board (NSB) as a home for the entity, but found that while the board "serves as advisors to both the President and Congress on policy matters related to science and engineering," its responsibility to and alignment with the National Science Foundation limits its ability to provide the comprehensive approach to government-wide regulation that is needed to foster a sensible regulatory system. In addition, the NSB has other responsibilities and does not have the strong relationship to the Office of Information and Regulatory Affairs (OIRA) that the committee believes to be necessary.

The committee judges that the most relevant model for a research policy board is that used by the Securities and Exchange Commission (SEC) for the operation of the Financial Accounting Standards Board (FASB), which has functioned successfully for over four decades. FASB's authority is derived entirely from the SEC. Membership is defined through formal processes approved and overseen by the SEC. However, FASB operates on private-sector funding raised by assessments on gross income of all public companies. It is a government-enabled, private-sector entity having a staff capable of coordinating the flow of business and supporting project teams assembled from time to time to address extant policy matters.

This model should be adapted to establish an RPB. The RPB can best function as a government-enabled, government-linked, private-sector entity, supported by assessments on academic research institutions to provide it the ability to support needed expert teams and future-oriented work.[5] The assessments should be mandatory and based on total volume of federally funded research. Given the scope and importance of the RPB's mission, the institutions should perceive the assessment mechanism as a cost-effective, practical provision to optimize the efficient functioning of the research partnership under federal regulatory oversight. The RPB will provide research institutions a formal mechanism by which they can participate in the development of new regulations, the harmonization of existing regulations, review of the effectiveness and efficiency of the existing regulatory burden, and proposals for modification of existing regulations to minimize their

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tion, addressed the interfaces and linkages among federal, state, and local government; (b) the Small Business Regulatory Enforcement Fairness Act (SBREFA), which calls for the creation, under law, of individual, issue-oriented, representative panels to assess the impact on small business of new regulatory proposals and requires agencies to address the concerns raised by these panel members; (c) the Base Realignment and Closure Commission (BRAC), charged to develop recommendations for packages of closings and realignments of military bases for action by Congress on an up-or-down basis, and (d) Financial Accounting Standards Board (FASB) and Public Company Accounting Oversight Board (PCAOB), established by the Securities and Exchange Commission for policy making and regulation relevant to public accounting and auditing in the United States.

[5]The committee recognizes that Federal Advisory Committee Act considerations will need to be resolved by Congress.

burden while maintaining and enhancing their effectiveness. Additionally, the RPB offers the opportunity to collect data and empirically test regulations.

The RPB should connect formally to government through both the proposed Associate Director, Academic Research Enterprise, in OSTP and the Administrator of OIRA. (Relationships involving the RPB are laid out schematically in Figure 7-1.) These two officials should, in turn, have the obligation to report annually and jointly to Congress on regulatory issues affecting the research partnership and suggested steps to create a more effective regulatory environment.

The proposed new entity, the RPB, bridges the governmental organizations (shown in blue) and the private institutions and associations involved in the partnership (shown in green). Details of the bridging relationship are described in the report. The arrows show only those reporting and communication channels relevant to the operation of the RPB. There is no effort here to show operational channels within the government or the academic communities, which would not be altered in the proposed structure.

The RPB should manifest the following characteristics and roles:

1. Its mission should be to improve and maintain a regulatory environment that is conducive to optimal performance of the research partnership by providing necessary data-driven information about regulatory benefits and burdens to the government, as gathered from the nation's research institutions.

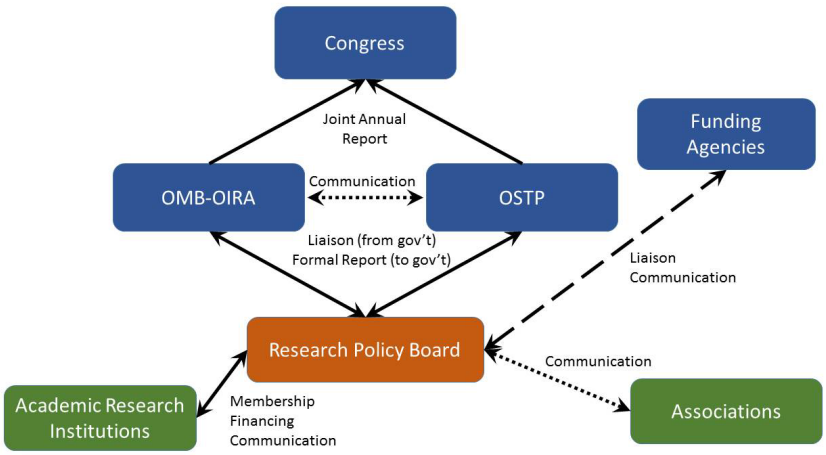

FIGURE 7-1 Schematic representation of relationships in a new regulatory framework. SOURCE: Courtesy of Larry R. Faulkner.

2. It should be composed of 9 to 12 members from academic research institutions and 6 to 8 liaisons from federal agencies involved in the partnership, with members and liaisons being designated through formal processes of nomination and selection. Participants on both sides should be high-level leaders capable of addressing the broad range of policy issues relevant to the partnership.
3. It should become the primary policy forum relating to the regulation of federal research programs in academic research institutions, with its members and liaisons serving as principal contacts for communication, both within their respective communities and across the boundary between the federal government and the research institutions.
4. It should have general ability and responsibility to make recommendations concerning the conception, development, and harmonization of policies having similar purposes across research funding agencies. Toward fulfillment of this general purpose, the RPB should have these particular responsibilities:
   a. To provide thorough and informed analysis in the regulatory and policy-making processes.
   b. To identify negative or adverse consequences of existing policies and to make actionable recommendations regarding their possible improvement.
   c. To facilitate efforts within the government to coordinate research policy mechanisms, for example, via regulation, agency policy, agency application, and report formats, or audit standards and criteria.
   d. To create a forum for discussion of patterns in audit findings, compliance gaps, need for policy clarification or harmonization, and best practices.
   e. To conduct ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes to ensure that the administrative burden of research policy is minimized to the greatest extent possible consistent with maintaining responsible oversight of federally funded research.
5. The RPB should be future oriented. It should be cognizant of trends affecting the overall regulatory load, and it should anticipate future regulatory challenges, especially those emerging from new science, such as synthetic biology, gene editing, and autonomous technology. It should organize expert project teams, as needed, to develop timely analysis on matters under consideration.
6. The RPB should become a more systematic, integrated, and effective operational forum than any or all of the professional associations that have historically spoken for academic institutions on research-related matters. The committee recognizes and appreciates the excellent work often done by these organizations, but also believes that a more inte-

> grated entity formally connected to the federal policy-making process is necessary to address the scale and complexity of current and future regulatory needs. Indeed, an effective RPB would become a means for leveraging continued work by these professional organizations.

Associate Director, Academic Research Enterprise, OSTP

While the RPB, as conceived, would fulfill the need for an active forum bridging the public-sector and private-sector partners, there remains a need for a federal officer with a focus on the healthy functioning of the government-academic research partnership.

The mission for the proposed OSTP Associate Director, Academic Research Enterprise, should be:

> To coordinate the federal research policy and regulatory process and to routinely integrate and organize input in a broadly representative fashion among federal research agencies, the RPB, and other representatives of institutions of higher education and their representative associations.

This officer would routinely coordinate with senior agency staff including those in the Office of Management and Budget (OMB); research funding agencies; NSB, Chief Financial Officers Council; Council of Inspectors General on Integrity and Efficiency; President's Council of Advisors on Science and Technology; National Science and Technology Council (NSTC), and other agencies as appropriate.

The Associate Director should address his or her mission through the following specific roles:

1. To serve as the principal federal official responsible for coordination of federal agency policy and regulation relating to federally funded research in academic institutions, including policies in other areas, such as national security or immigration, that affect either academic research institutions or the conduct of research.
2. To serve as an ex officio member of the NSTC and its primary committees, as appropriate.
3. In partnership with OMB, to assist with coordination of the conception, development, and harmonization of regulations, policies, and proposal application formats having similar purposes across federal research agencies.
4. To foster inclusion of representative input from the RPB and the university community on a routine basis in the regulatory and policy-making process, with the expectation that these comments will be given particular weight as agencies develop regulation and policy.

5. To address with the RPB and the academic research community any unintended consequences of existing policy and to initiate appropriate corrective action.
6. To ensure that input from the RPB and the research community is considered in the development of all policy mechanisms affecting research, for example, regulation, agency policy, agency application and report formats, and audit standards and their criteria.
7. To serve as a coordinator among federal research agencies to discuss concerns identified by the RPB regarding audit findings, compliance gaps, or undue regulatory burdens. In addition, this individual will identify the need for policy clarification, harmonization, and clarification of audit standards, as appropriate.
8. In partnership with the Administrator of OIRA, to report annually to Congress the results of ongoing assessment and evaluation of regulatory burden, including the development of metrics, periodic measurement, identification of process improvements, and policy changes that ensure that the administrative burden of research policy and regulation is minimized to the greatest extent possible while being mindful of the need to prevent fraud, waste, and abuse. Reports to Congress will include the results of such assessments from the RPB.

While, at times, the OSTP Associate Director for Science has taken on some of these responsibilities, it is often ad hoc and inconsistent, as the Associate Director for Science is required to address other pressing issues facing an administration. The position called for in this report would engender a consistent, long-term commitment to the overall health of the partnership. While OSTP often benefits from agency staff rotations, the position should be permanent. Federal research agencies could, however, provide the necessary funding for this OSTP Associate Director position.

Principles to Guide the Regulatory Framework

Finally, the committee offers the following principles to consistently guide the recalibration and future development of federal research regulations:

1. Regulations should reflect the shared commitment of academic research institutions and federal agencies to the effective and efficient conduct of research and the maintenance of research integrity.
2. Regulations should be harmonized across all federal research funding agencies. To the extent that agency-specific missions require agencies to depart from a uniform approach, agency-based deviations should be reviewed and approved by OIRA in consultation with the Associate Director, Academic Research Enterprise, OSTP.
3. Regulations should be written with the input of the RPB.

4. Regulations and their enforcement should take into account the risk of malfeasance and the overall cost of compliance. Before proposing any new regulation, an agency should determine whether the problem that the regulation is intended to address is systemic. Actions need to be targeted where transgressions occur. Minor issues should not become cause for disproportionate regulatory response. Egregious transgressions that are found to be isolated events should not trigger disproportionate responses.
5. Regulations should be framed with the recognition that risk levels will never be reduced to zero.
6. Regulations should be reviewed periodically to determine their effectiveness. If a regulation is deemed to be ineffective or excessively burdensome, it should be repealed or reformed.
7. Wherever practical and appropriate, new regulations should be piloted at a small number of institutions to determine whether they efficiently accomplish the intent of regulation, and funds should be provided to pilot institutions for related personnel expenses.
8. Academic research institutions must take timely and appropriate action against members of their communities who violate the values of trust and integrity to which community standards and federal funding of research, as well as academic responsibilities, require strict adherence.

RECOMMENDATIONS

The committee recommends the creation of a new mechanism, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research regulations of similar purposes across agencies.

7.1. Specifically, the committee recommends that *Congress* take the following actions:

1. Establish a new entity, a Research Policy Board. The RPB would be a self-funded, government-linked entity serving as the primary policy forum for discussions relating to the regulation of federally funded research programs in academic research institutions.
2. Establish a new Associate Director, Academic Research Enterprise, in the White House OSTP, having responsibilities to (a) serve as one of two principal federal contact points for the RPB; (b) oversee and facilitate the general health of the government-academic research partnership; (c) work in partnership with OMB-OIRA to manage the overall regulatory burden; and (d) jointly, with the Administrator of OIRA, issue an annual report to Congress on regulatory issues and actions affecting the research partnership.

7.2. Specifically, the committee recommends that *participants in the government-academic research partnership* adopt the above set of operational principles as a part of the new regulatory framework for federally funded academic research.

Part 2

8

Introduction

As indicated in Part 1 of the committee's report, Congress requested that the committee expedite its work and deliver a report at the end of September 2015. In meeting this request, the committee divided its work[1] into two parts. Part 1 addressed a number of regulations governing research along the continuum from proposal submission to the final accounting and reporting of research results and upon which Congress might take immediate action. In addition, the committee offered a new regulatory framework for federally funded research.

In this, Part 2, the committee concludes its analysis of topics that adversely affect the nation's ability to optimize its investment in academic research. This analysis includes a discussion of the implications of a recent Notice of Proposed Rulemaking (NPRM) that seeks to revise the Common Rule governing human subjects research. Because the proposed rule raises serious concerns and questions and has elicited powerful reactions from the research community, the public, and relevant federal agencies, the committee has focused particular attention on the NPRM and associated issues (see Chapter 9).

As it did with the first report, the committee gathered data, analyzed written materials, and invited presentations from experts and stakeholders to discuss additional issues of concern to the academic research community. A meeting was held at Rice University, in Houston, Texas, in late October 2015 to gather additional information on topics including human subjects research, technology transfer, select agents, and export controls. Further, the committee sought input on how best to operationalize the Research Policy Board recommended in Part 1. An additional data-gathering meeting was held in Washington, D.C. in January 2016. In addition, members of the committee briefed Senator Lamar Alexander, congressional staff, agency personnel, and other stakeholder groups on the findings and recommendations of Part 1 of its report (see Appendix I). These briefings were the source of useful and valuable input to the committee.

The additional input provided further evidence in support of the committee's recommendations that the regulatory framework governing feder-

[1]See pp. 22-23 for the charge to the committee.

ally funded academic research should be critically reexamined and recalibrated and that a new mechanism be created to foster more effective cooperation between the federal government and research institutions in the conception, development, implementation, and harmonization of research policies.

In Part 2, the committee concludes its analysis and offers additional recommendations designed to optimize the nation's investment in academic research. Chapter 9 addresses the Common Rule NPRM and the regulatory framework for human subjects research. The reporting of inventions derived from academic research is covered in Chapter 10. Research involving select agents and toxins is discussed in Chapter 11, and export controls are discussed in Chapter 12. In Chapter 13, the committee illustrates how future regulations might be developed as part of its proposed regulatory framework and elaborates on the roles that the proposed Research Policy Board, the White House Office of Science and Technology Policy, and the Office of Management and Budget might play.

9

Ethical, Legal, and Regulatory Framework for Human Subjects Research

The National Research Act of 1974[1] created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[2] The act charged the commission with identifying the "basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects" and with developing associated guidelines for the ethical conduct of research.[3] The resulting Belmont Report, issued in 1978, drew a sharp distinction between research, defined as "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge," and practice, or "interventions…designed solely to enhance the well-being of an individual patient or client."[4] In addition, and most important, the report articulated three basic principles that provide the ethical foundation for the conduct of research involving human subjects (see Box 9-1).

Respect for persons involves two ethical considerations: (1) individuals are and should be treated as autonomous agents and (2) individuals with diminished autonomy, due to youth, illness, mental disability, or restricted liberty (e.g., prisoners) should receive additional protections. The principle of respect for persons means recognizing the authority of an individual's preferences and choices about his or her life. In the context of research, the principle of respect for persons is expressed primarily in the use of informed consent, which requires

[1]See National Research Service Award Act of 1974. Pub. L. No. 93-348 (2014).

[2]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was succeeded by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. An independent entity established by Congress under Public Law 95-622 in 1978, the latter commission operated from January 1980 to March 1983.

[3]See Commission Duties, Pub. L. No. 93-348 § 202.1a (1974).

[4]National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, MD: 1978), available at: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

that, as a general rule, individuals be afforded the opportunity to choose whether or not to be involved in research. It is incumbent upon investigators to disclose information about a study in language that is comprehensible to potential subjects so that they can provide meaningful and voluntary informed consent. These disclosures typically include the purpose of the research, the research procedures, risks, anticipated benefits (if any) to the subject, the opportunity to ask questions and receive satisfactory responses, and a statement that participation is voluntary and that the subject has the right to withdraw from the study at any time, for any reason.

Beneficence involves two considerations: (1) the maximization of possible benefits for society and subjects; and (2) the minimization of possible harm to subjects. The principle of beneficence presents obligations that are woven throughout the research enterprise. Investigators, institutions, and sponsors must always endeavor to design and conduct research studies so that these obligations are met. Defining the optimum balance between the obligation to maximize benefit and minimize harm is often challenging. Notably, although the principle of beneficence refers to maximizing benefits for society, the Belmont Report does not expand upon this requirement.

Justice is articulated in the Belmont Report as "fairness in distribution" of research benefits and burdens.[5] Questions of justice and equal treatment in the research context are critical in the selection of subjects. The application of justice means that investigators must not offer potentially beneficial research only to some groups, nor select only some accessible, vulnerable, or disadvantaged groups for research that involves high risk or little prospect of direct benefit.

BOX 9-1 Ethical Principles and Applications Outlined in the 1978 Belmont Report

Ethical Principle	Application in the Research Setting
Respect for Persons	Informed consent – information – comprehension – voluntariness Additional protections for persons with diminished autonomy
Beneficence	Maximizing benefits for research participants and society Minimizing harm to research participants
Justice	Ensuring fair distribution of the benefits and burdens of research

[5]Ibid.

Nature of Concern

The core principles of respect for persons, beneficence, and justice remain central to the protection of human research subjects. However, in the nearly four decades since publication of the Belmont Report, the biomedical and sociobehavioral research enterprises have grown enormously and witnessed profound changes in knowledge, technologies, methodologies, and capabilities, as well as in the potential implications of research findings for individual subjects and society. These continuing changes in research contexts and capabilities, in turn, raise questions as to the proper application and balancing[6] of the Belmont principles.

There is, for example, disagreement regarding how best to balance the Belmont principles in the context of clinical trials that compare the effectiveness of widely used interventions for given disorders to determine whether one approach may in fact have a better outcome than the other.[7] Questions about application of these principles also arise in research involving deidentified human biospecimens or genomic data, community-based participatory research, clinical trials conducted in emergency settings, study designs that incorporate randomization at the unit (cluster) rather than the individual level, and observational research involving large-scale databases.[8] Furthermore, while the Belmont Report did not explicitly articulate an obligation to participate in research, some believe that as all are potential beneficiaries of biomedical and sociobehavioral research, all have a responsibility, when opportunities arise and risks are minimal, to participate in research, as broad participation contributes to a greater understanding of human health, disease, and the effectiveness of proposed therapies across a broader spectrum of society, thus providing benefits to the entire population. Thus, research involving human subjects poses profound and unanswered questions about our status as both potential participants in and beneficiaries of the knowledge gained from biomedical and behavioral studies and about our rights and responsibilities as individuals versus our obligations as members of society.

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[6]T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics,* 7th ed. (New York: Oxford University Press, 2013): 459.

[7]See, e.g., R. Platt, N. E. Kass, and D. McGraw, "Ethics, Regulations, and Comparative Effectiveness," *JAMA*, vol. 311, no. 15 (2014): 1497–1498.

[8]See, e.g., E. W. Clayton et al., "Confronting Real Time Ethical, Legal, and Social Issues in eMERGE Consortium," *Genetics in Medicine* 10 (2010): 616–620; E. Bromley et al., "From Subject to Participant: Ethics and the Evolving Role of Community in Health Research." *American Journal of Public Health*, vol. 105, no. 5 (2015): 900–908.; M. Mitka, "Aiding Emergency Research Aim of Report on Exceptions to Informed Consent," *JAMA*, vol. 298, no. 22 (2007): 2608–2609; C. Weijer et al., "The Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials," *PLOS Medicine*, vol. 9, no. 11 (2012): 1–9; and M. A. Rothstein, et al., "Ethical Issues in Big Data Health Research," *Journal of Law, Medicine, and Ethics*, vol. 43, no. 2 (2015): 425–429.

Moreover, the scope of regulations for the protection of human subjects in research, as guided by the Belmont principles, is the focus of considerable discussion.[9] In medical settings, the boundaries and distinctions between research involving human subjects and activities designed to assure and improve the quality of care (i.e., in clinical practice) can, at times, be difficult to judge with confidence. Furthermore, the optimal application of regulations, developed primarily in the context of biomedical research, to the entire spectrum of sociobehavioral research has been contested for decades[10] and remains unresolved.

Given these formidable questions about the application and scope of the Belmont principles, it is necessary to broadly reconsider the legal and regulatory frameworks governing human subjects research, including the optimal locus of regulatory authority within the executive branch. Should oversight reside within each executive branch agency that funds human research, as is currently the case, or within a single independent federal agency that oversees and regulates all federally funded human research?

Analysis

Currently, there are tremendous opportunities to improve human health, behavior, and well-being, as exemplified by recent federal initiatives to advance our understanding of the pathobiology, diagnosis, and treatment of cancer,[11] treat Alzheimer's disease,[12] and advance precision medicine.[13] However, pro-

[9]See, e.g., Institute of Medicine, *Responsible Research: A Systems Approach to Protecting Research Participants* (Washington, DC: The National Academies Press, 2002) and Institute of Medicine, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs* (Washington, DC: The National Academies Press, 2001).

[10]See, e.g., National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Washington, DC: The National Academies Press, 2014) and C. K. Gunsalus et al., "Mission Creep in the IRB World." *Science*, vol. 312, no. 5779 (2006): 1441.

[11]In February 2016, the Obama Administration launched the "National Cancer Moonshot with a $1 billion initiative to provide the funding necessary for researchers to accelerate the development of new cancer detection and treatments." See White House Office of the Press Secretary, "FACT SHEET: Investing in the National Cancer Moonshot," February 1, 2016, https://www.whitehouse.gov/the-press-office/2016/02/01/fact-sheet-investing-national-cancer-moonshot.

[12]"The National Alzheimer's Project Act (Public Law 111-375), passed unanimously by Congress in December 2010 and signed into law by President Barack Obama in January 2011, required the creation of a national strategic plan to address the rapidly escalating Alzheimer's disease crisis and the coordination of Alzheimer's disease efforts across the federal government." See Alzheimer's Association, "The National Alzheimer's Project Act (NAPA)," http://napa.alz.org/national-alzheimers-project-act-background.

[13]In January 2015, the Obama Administration launched a $215 million "Precision Medicine Initiative" to "pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge,

gress and success hinge upon an expansion of research involving human subjects. At the same time, there are persistent and varied questions about the sufficiency of the current regulatory framework. The rapidly changing circumstances surrounding research involving human subjects have led many to ask how the protections of human subjects articulated by the Belmont principles can best be maintained given new research capabilities, the accumulation and accessibility of large amounts of personal information, including health data, and the size and reach of the research enterprise. Addressing these challenges, which the framers of the Belmont Report and Common Rule could not have envisioned, will require judicious and creative thinking about how to balance our societal obligation to protect human subjects in research with the goal of maximizing the benefits to human well-being of society's investments in biomedical and socio-behavioral research.

A prior Institute of Medicine report called for the formation of an independent committee to reassess the adequacy of the federal regulatory system for overseeing human research.[14] The authors of that report noted that the "the language of the Common Rule deserves a careful and comprehensive reassessment for clarity and relevancy" and recommended that Congress "authorize and appropriate funding for a standing independent, multidisciplinary, nonpartisan expert Committee on Human Research Participant Protections whose membership would include the perspective of the research participant."[15] That committee was not created.

In 2011, the Department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking as part of an effort to update the Common Rule governing human subjects research. HHS subsequently issued a Notice of Proposed Rule Making (NPRM)[16] in September 2015.[17] Both notices elicited many comment letters describing the deficiencies of the proposals and the risks they pose to the conduct of important research.[18]

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and therapies to select which treatments will work best for which patients." See White House Office of the Press Secretary, "FACT SHEET: President Obama's Precision Medicine Initiative," January 30, 2016, https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

[14]See, e.g., Institute of Medicine, *Responsible Research: A Systems Approach to Protecting Research Participants*, (Washington, DC: The National Academies Press, 2002).

[15]Ibid, pp. 198-199.

[16]Federal Policy for the Protection of Human Subjects," Federal Register 80, no. 173 (September 8, 2015): 53933, https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

[17]The NPRM was issued at the time of the release of Part 1 of the committee's report thus precluding the committee's ability to comment fully at that time.

[18]See, e.g., letters from the Association of American Medical Colleges, available at: https://www.aamc.org/download/451896/data/aamcsubmitscommentstohhsonthecommonrulenprm.pdf; the Council on Governmental Relations, available at: http://cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000257/NPRMCommonRuleCOGRResponse12-8-15%20(2).pdf; the Association of American Universities and the Association of Public and Land-grant Universities, https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=16885;

Several provisions of the proposed regulations have been identified as problematic. These include: (1) proposed changes relating to the definition and handling of biospecimens; (2) how determinations are made regarding whether certain types of research may be excluded from administrative or institutional review board consideration; (3) inconsistencies amongst the proposed changes; and (4) an absence of specifics for key deliverables.

Both the significant number of comments and the concerns expressed in response to the proposed rule highlight a need to address numerous issues that have emerged since publication of the Belmont Report. Indeed, the regulations governing human subject research merit regular examination and updating. As will be demonstrated below, the current regulatory atmosphere indicates that our nation would benefit from a standing independent national advisory commission tasked with regularly examining and updating regulations governing all federally funded human subjects research and charged with addressing difficult and precedent-setting cases as well as matters of general policy.

During a presentation at a recent meeting of the Secretary's Advisory Committee on Human Research Protections,[19] Lauren Hartsmith of the HHS Office of Human Research Protections (OHRP)[20] provided an analysis of the public comments on the September 2015 NPRM. She noted that:

> "There was concern about the overall complexity and the length of the NPRM. Concern about the lack of availability of some of the key deliverables in the NPRM. Specifically, those were the exemption determination tool, the broad consent template, and the Secretary's list of privacy safeguards."[21]

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and Public Responsibility in Medicine and Research, available at: http://www.primr.org/WorkArea/DownloadAsset.aspx?id=10166.

[19]The Secretary's Advisory Committee on Human Research Protections (SACHRP) "provides expert advice and recommendations to the Secretary of HHS on issues pertaining to the protection of human subjects in research." See http://www.hhs.gov/ohrp/sachrp-committee/. The committee is charged with advising "the Secretary on how to improve the quality of the system of human research protection programs, including the responsibilities of investigators, institutional review boards (IRBs), administrators, and institutional officials, and the role of the Office for Human Research Protections and other offices within the Department of Health and Human Services." See SACHRP Charter, available at: http://www.hhs.gov/ohrp/sachrp-committee/charter/index.html.

[20]The Office for Human Research Protections "provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services." See "About OHRP," available at: http://www.hhs.gov/ohrp/about-ohrp/index.html.

[21]L. Hartsmith. HHS Office of Human Research Protections (OHRP). *NPRM Update: Summary of Public Comments.* Presentation to the Secretary's Advisory Committee on Human Research Protections (SACHRP), May 18, 2016.

Video of the SACHRP meeting and Hartsmith's presentationare available at: https://videocast.nih.gov/summary.asp?Live=19186&bhcp=1.

With regard to the "exemption determination tool," the NPRM proposes that federal departments and agencies develop a voluntary research exemption determination tool. Based on information input by a researcher, the web-based tool would determine whether research is exempt from the human subjects regulations.[22]

Regarding the broad consent template, the NPRM proposes the development of a template for acquiring consent from an individual for the storage or maintenance of biospecimens for use in future research.[23] Templates are expected to contain all required consent elements (such as a description of the research material covered, the option to consent, and the ability to withdraw consent). The NPRM indicates that at least two broad consent templates will be developed: (1) for information and biospecimens originally collected in the research context; and (2) for information and biospecimens originally collected in a non-research context. The templates will be issued for public comment at a later date.

A third key deliverable, the Secretary's "list of privacy safeguards," is also unavailable. This list is to be developed following public comment on the types of safeguards that would be appropriate.[24] These safeguards would be designed to protect the privacy of human participants in research by protecting the confidentiality of personal information. Other laws or regulations that currently mandate the protection of human research participants would need to be examined as a part of the development of the envisioned safeguards.

The omission of specifics on key tools and guidelines like the exemption determination tool, consent templates, and list of privacy safeguards is problematic; because the items are undefined at present, it is impossible to comment on their merit or utility prior to the issuance of the final rule. Furthermore, it is not possible to provide an accurate estimation of regulatory impact without a clear understanding of what compliance will involve.

Uncertainty may also lead to an increased regulatory burden as institutions, in an effort to comply with vague or fragmentary regulations, implement speculative procedures which may ultimately be unwarranted. Institutions may also elect to reject, delay, or halt research in areas of regulatory vagueness.

In her presentation to SACHRP, Hartsmith also noted that there is "concern about some of the proposals being internally inconsistent and concern about

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[22]See "Federal Policy for the Protection of Human Subjects," Federal Register 80, no. 173 (September 8, 2015): 54009. The NPRM states that, "Under the proposed rule, unless otherwise required by law, exemption determinations may be made by (1) an individual who is knowledgeable about the exemption categories and who has access to sufficient information to make an informed and reasonable determination, or (2) the investigator who accurately inputs information into the federally created web-based decision tool."

[23]Ibid, p. 53969.

[24]The NPRM states that "For the purposes of informing the development of…privacy safeguards, comment is sought on what types of safeguards would be appropriate. There are additional statutes or acts that mandate the protection of privacy and confidentiality of identifiable private information that may be reasonable to include." Ibid, p. 53979.

proposals giving investigators too much leeway to determine if their research falls under the rule." The latter concern "was specifically around the proposed concept of exclusions in the NPRM."[25]

With regard to exclusions, the NPRM identifies eleven types of research that fall outside the scope of the proposed regulations. Some of this research is also "exempt" under current Common Rule regulations. As envisioned by the NPRM, excluded research is not subject to administrative or IRB review. Instead, investigators have the responsibility to make determinations as to whether the research should be subject to external review. Examples of excluded research include: "collection and analysis of data, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes;" "quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services;" and "public health surveillance activities, including the collection and testing of biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority and limited to those necessary to allow the public health authority to identify, monitor, assess, or investigate potential public health signals or the onset of a disease outbreak."[26]

In assessing the proposed exclusions, one researcher observed that some exclusions "will likely be widely welcomed, such as…[an] explicit exclusion of journalism, oral history, biography, and historical scholarship activities." However, there is "worry that the exclusion of certain activities…could lead to a weakening of subject protections." "The proposed rule does not…offer insight into how determinations about whether the disclosure of information would reasonably place subjects at risk will be made."[27] Further, the NPRM does not sufficiently describe how the proposed exclusions will be implemented to ensure adequate protection of human research participants.

Finally, Hartsmith presented the following comment as illustrative of the regulated community and public's comments on the NPRM. She prefaced the comment by stating, "This is…a sample quotation from one of the commenters. It is a good summary of the concerns that were expressed about the overall document.":

> The urgency to approve a final revised Common Rule prior to the end of the 2016 is deeply concerning and has resulted in a premature, rushed

[25]L. Hartsmith. HHS Office of Human Research Protections (OHRP). *NPRM Update: Summary of Public Comments.* Presentation to the Secretary's Advisory Committee on Human Research Protections (SACHRP), May 18, 2016.

[26]See "Federal Policy for the Protection of Human Subjects," Federal Register 80, no. 173 (September 8, 2015): 53948-53949.

[27]E. A. Hurley, "Unpacking the NPRM: A New Category of Exclusions," *Ampersand*, October 13, 2015, available at: http://blog.primr.org/unpacking-the-nprm-a-new-category-of-exclusions/.

> document that is replete with deficiencies, contradictions, areas of conflict or overlap with other federal requirements, undefined processes, categories or lists and yet to be developed forms and templates. The lack of availability of these items at this late stage in the rule making process makes commentary particularly challenging.[28]

During the SACHRP meeting, there was significant discussion about the process of moving from an NPRM to a final rule. An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it. Rather, the agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.[29] At the meeting, OHRP Director Jerry Menikoff reiterated that a final rule "should be a logical outgrowth of what was originally presented or something that was appropriately discussed as part of the comments in the public comment process."[30]

The comments and issues highlighted in Hartsmith's presentation to SACHRP align with the results of an analysis of public comments by the Council on Governmental Relations and the Association of Public and Land-grant Universities (see Box 9-2). They also align with the assessment of members of the leadership of the nonprofit Public Responsibility in Medicine and Research (PRIM&R) in a letter to the *New England Journal of Medicine*:

> The NPRM is a troublingly incomplete product: internally inconsistent, dependent on untested assumptions, and too inchoate to be ready for promulgation with just some minor editing. The document, which had largely been crafted behind closed doors, invited public response to 88 unresolved policy questions in addition to comments on the proposed rules themselves. It introduces new regulatory mandates when less rigid solutions would offer sensible alternatives and permit adjustment in light of experience.[31]

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[28]L. Hartsmith. HHS Office of Human Research Protections (OHRP). *NPRM Update: Summary of Public Comments.* Presentation to the Secretary's Advisory Committee on Human Research Protections (SACHRP), May 18, 2016.

The source for this statement is a comment letter from Emma A. Meagher, Senior Associate Dean, Clinical Research and Associate Vice Provost, Human Research and Dawn Bonnell, Vice Provost for Research, University of Pennsylvania. The letter is available at: https://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-0579.

[29]See Office of the Federal Register, "A Guide to the Rulemaking Process," available at: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

[30]J. Menikoff, HHS Office of Human Research Protections at May 18-19, 2016 SACHRP Meeting.

Video of the SACHRP meeting is available at: https://videocast.nih.gov/summary.asp?Live=19186&bhcp=1.

[31]D. H. Strauss, E. A. Hurley, and A. M. Capron, "Reform of Clinical Research Regulations," *New England Journal of Medicine*, no. 374 (2016): 1693-1694.

BOX 9-2 Council on Governmental Relations (COGR)/Association of Public and Land-grant Universities (APLU) Analysis of Comments on the HHS Notice of Proposed Rulemaking (NPRM) on the Federal Policy for the Protection of Human Subjects

2,186 public comments were submitted in response to the NPRM on the Federal Policy for the Protection of Human Subjects.[a]

In all, of the nearly 2,190 comments received,

- Approximately 204 were received from universities/medical centers/Institutional Review Boards
- Approximately 401 were received from researchers
- Approximately 1,151 were received from patients/members of the general public
- Approximately 177 were received from industry/professional associations/advocacy groups[b]

COGR and APLU reviewed responses to "a number of major proposals in the NPRM, including the proposal to expand the definition of 'human subject' to include non-identified biospecimens, to mandate broad consent for secondary research use of biospecimens, and to restrict Institutional Review Board (IRB) waiver of consent for secondary research use of biospecimens."[c] The associations also reviewed comments on "proposals to mandate use of a single IRB for multisite studies; extend the Common Rule to all clinical trials regardless of funding source at institutions that receive federal funding for human subjects research; proposed standard security safeguards; and the proposal to post clinical trial consent forms to a federal website."[d] In addition, "general assessments of the status of the NPRM were considered."[e]

The review found "significant opposition to most major proposals" and a number of responses that "suggested that the NPRM is overly complex, poorly written, and not supported by data."[f]

The associations note that, in its comment letter, the Presidential Commission for the Study of Bioethical Issues "suggested that the primary proposal to expand the definition of 'human subject' to include all non-identified biospecimens is inconsistent with the ethical rationale described in the NPRM and will stall certain kinds of research using deidentified biospecimens that pose no risk to human subjects and are unlikely to impact participants' autonomy interests."[f] Further, the HHS Secretary's Advisory Committee for Human Research Protections (SACHRP) "concluded that, 'To the extent that the NPRM's core proposal is meant to ensure that subjects provide meaningful consent to future research with biospecimens and to prevent biospecimen re-identification, the NPRM would do nothing of the sort.'"[g]

A "majority of responses, approximately 1,520, addressed one or more of the proposed changes…involving non-identified biospecimens. Of these responses, 94 – 100% of patients and members of the research community, including researchers, universities, medical centers and industry, opposed the changes."[h]

(Continued)

BOX 9-2 Continued

"Among members of the general public, 55% opposed and 45% supported one or more of the major proposed changes related to biospecimens. Support was largely provided in response to a December 30, 2015, *New York Times* opinion piece by Rebecca Skloot, author of the book *The Immortal Life of Henrietta Lacks*, which provided a link to the proposed regulations and encouraged readers to respond."[i]

Nine of the top 10 research institutions ranked by level of NIH support submitted comments on the NPRM. All were opposed to three major provisions (the expansion of the definition of human subject to include deidentified, excess or residual biospecimens; the expansion of scenarios where broad consent is required; and the mandated use of a single IRB for multisite studies). Of the top 30 ranked institutions, 83% submitted comments, and of those, 96% opposed the major biospecimen and broad consent provisions. In this group, two institutions did not comment on single review boards and only one institution expressed partial support for two of the three provisions. 74% of the top 40 ranked research institutions responded and 96% opposed the biospecimens and broad consent provisions.[j]

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[a] Council on Governmental Relations and Association of Public and Land-grant Universities. "Analysis of Public Comments on the Common Rule NPRM," (Preliminary Findings), May 2016, p. 1. Available at: http://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000346/Analysis%20of%20Common%20Rule%20Comments.pdf.

[b] Council on Governmental Relations and Association of Public and Land-grant Universities. "Table 1- Number of Responses to the Common Rule NPRM by Respondent Category." Available at http://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000339/Table%201_Responses%20by%20Category.pdf).

[c] Council on Governmental Relations and Association of Public and Land-grant Universities. "Analysis of Public Comments on the Common Rule NPRM," (Preliminary Findings), p. 1.

[d] Ibid.

[e] Ibid.

[f] Ibid, p. 2.

[g] Ibid.

[h] Ibid.

[i] Ibid, p. 3.

[j] Skloot's book tells the story of Henrietta Lacks, an African American woman whose excised cancer cells were used to create the first ever continuously reproducing human cell line. When her cells were excised at Johns Hopkins University in the 1950s, as was customary at the time, neither Lacks nor her family was asked for permission to harvest the cells. The cell line, known as the "HeLa" cell line after Ms. Lacks, was commercialized and has become the most commonly used cell line by researchers around the world. Skloot examines the relationship between Johns Hopkins University and its researchers, Lacks, and the Lacks family and argues that Lacks' family should receive compensation for the use of the cell line.

On issues related to tissue and property rights, see B. J. Evans, "Congress' New Infrastructural Model of Medical Privacy," *Notre Dame Law Review*, vol. 84, no. 2 (2009): 585–654. Evans writes, "Under federal law and the law of many states, individuals do not have property rights in their own health data and stored biospecimens." See also R. Hakimian and D. Korn, "Ownership and Use of Tissue Specimens for Research," *JAMA*, vol. 292, no. 20 (2004): 2500–2505; and R. A. Charo,

(Continued)

BOX 9-2 Continued

"Body of Research – Ownership and Use of Human Tissue," *New England Journal of Medicine*, vol. 355 (2006): 1517–1519. Charo notes that "research regulations are built on a theory of autonomy that is independent of any property right in one's tissue" and that "after the tissue has been properly excised, its use without the patient's consent may be permitted under federal research regulations, if the patient's identify is unknown or adequately obscured."

[j] See Council on Governmental Relations and Association of Public and Land-grant Universities, "Research Universities and Institutions; Medical Centers and Schools of Medicine; Academic Institutional Review Boards and University and Medical Center Staff – Preliminary Findings from a Review of Responses to the Common Rule NPRM," May 2016. Available at: http://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000344/Universities%20and%20Medical%20Centers.pdf. NIH ExPORTER (available at: http://exporter.nih.gov/Default.aspx) was used to relate research institution responses to NIH funding levels. The top 40 institutions receive 76 percent of NIH funding.

It is instructive to examine a key item in the NPRM that raised particular concern, as such a consideration illustrates the problems of moving the NPRM to a final rule.

The NPRM proposes an expansion of the definition of human subject to include deidentified, excess, or residual biospecimens. This expansion would require that individuals provide written "broad" consent for the use of such biospecimens in research—a significant departure from current practice. This would permit patients undergoing tissue excisions to grant permission for future unspecified uses of their de-identified biospecimens. It is important to understand that biospecimens, properly preserved, can last for generations. Such specimens have proved helpful in addressing unanticipated medical issues using technologies that did not exist at the time of excision or collection. The inability to envision future opportunities for research that could advance knowledge raises questions about the meaning and ethical sufficiency of "broad consent." If, for example, waivers were unavailable for the clinical use of biospecimens for which no research use was intended at the time of excision or collection, critical post facto correlations, for example, between the Zika virus and microcephaly, may go unrecognized.

Redefining research with de-identified biospecimens as human subjects research would impose significant burdens and limitations on research institutions and the ability of research institutions to obtain specimens from health institutions that do not have the infrastructure or resources to comply with the proposed revisions to the Common Rule. As a result, research samples may not be as broadly representative of the population as they have been and research findings may no longer be so generalizable. Such limitations will likely imperil the conduct of

long-established and remarkably fruitful areas of research.[32] Research on excess or residual biospecimens has contributed enormously to the growth of medical knowledge for nearly a century and a half, improving human health with little evidence of harm to individuals whose biospecimens were used in this way.[33] That some find the implications of broad consent for future research troubling[34] is another compelling example of the need for thoughtful deliberation about how best to protect individual human research subjects while continuing to advance medical knowledge that will benefit many—including, potentially, subjects themselves and their loved ones. Further, there is little evidence that individuals understand exactly what they are being asked to consent to. Nor can patients or their caregivers credibly envision what the future might hold.

In addition, as envisioned by the NPRM, broad consent would expand informed consent practices to nonresearch settings where the individual's priority is exclusively clinical care, and it would involve institutional personnel unfamiliar with research or with the principles guiding human subjects research.[35] Thus, whether the elements of informed consent laid out in the Belmont Report (information, comprehension, and voluntariness) can be achieved by broad consent as envisioned by the NPRM is debatable.[36]

As the example of biospecimens demonstrates, a new assessment is needed to determine whether current measures adequately protect human subjects in contemporary biomedical research without unjustifiably impeding the conduct of well-designed research that contributes to human well-being. Put differently,

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[32]See, e.g., the joint statement issued on May 6, 2016, the Association of American Universities, the Association of Public and Land-grant Universities, and the Council on Governmental Relations. In the statement, the organizations state that, "There is broad consensus that the proposed regulations regarding biospecimens, as written, would be damaging to science, medicine, and human health and would not improve participant safety and autonomy." See http://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/0000000000347/050916prCommonRuleFinal.pdf.

[33]Under current regulations, requests for discarded specimens are reviewed when specimens are: (1) identifiable or (2) de-identified but collected specifically for a particular research project. If specimens do not have identifiers, they are exempt from institutional review board (IRB) review. In instances where IRB review is required, investigators must affirm to the IRB that identifiers will not be retained and provide information about the procedures that will be used to ensure that the specimens will be de-identified. Under the proposed regulations, a waiver of consent would be difficult to obtain, and the ability of an IRB to follow the current practice of review of discarded specimens for use in research would essentially be eliminated.

[34]See, e.g., D. H. Strauss, E. A. Hurley, and A. M. Capron. "Reform of Clinical Research Regulations." New England Journal of Medicine, no. 374 (2016): 1693–1694.

[35]See, e.g., N. E. Kass et al., "The Research-treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight," Hasting Center Report, vol. 43, no. S1 (2013): S4–S15.

[36]See, e.g., Jocelyn Kaiser, "Researchers Decry Consent Proposal," *Science*, vol. 352, no. 6288 (2016): 878–879.

where should the balance points be set among autonomy, beneficence, and justice? The current system may, for example, be better served by explicit sanctions against investigators and institutions seeking to re-identify biospecimen sources by any method, including linkage of genomic sequence data to identifiers, rather than by redefining all research with de-identified biospecimens as human subjects research subject to a revised Common Rule.

Implementation of the proposed rule necessitates maintaining a link between the consent document and the biospecimen. This proposal per se raises substantial risks of re-identification and loss of privacy. Further, the associated financial[37] and societal costs will be significant. Many clinical care facilities, such as those serving underserved or rural populations, for example, may not be able to bear these costs, thereby undermining the principles of justice and beneficence by skewing research toward studies and populations that can be accommodated only at large medical centers. As PRIM&R noted in its comment letter in response to the NPRM:

> The stated goal of the NPRM is to reduce unnecessary administrative burden associated with regulation, [but] the requirements related to the use of biospecimens in research will likely create new barriers to research participation without advancing subject autonomy. New systems and mechanisms for obtaining and tracking broad consent across all patients entering a facility will need to be developed and implemented. This process will require significant resources on the part of institutions that collect biospecimens; it will be entirely out of reach for small healthcare institutions and community and school-based clinics, and may very well be beyond the capability of some larger and better-resourced institutions. As some facilities decide that they cannot manage the costs (in terms of time, staff, infrastructure, and other resources) of obtaining and tracking broad consent (is the consent still valid? does it impose any limits or requirements regarding the use of an individual's specimens? etc.), specimens collected for clinical purposes at such facilities will no longer be available for future research. As a result, the populations within the communities those institutions serve may be excluded from such research. This is problematic from the perspectives both of justice and of good science.[38]

[37] As calculated by HHS, over the 2016–2025 period, present-value benefits of all proposed changes will be $2.6 billion with annualized benefits of $308 million (as estimated using a 3 percent discount rate). Present-value costs are estimated at $13.3 billion with annualized costs of $1.6 billion (as estimated using a 3 percent discount rate). See "Federal Policy for the Protection of Human Subjects," *Federal Register* 80, no. 173 (September 8, 2015): 53933, https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf. Weill Cornell Medicine, however, estimates that "it could cost [the institution] as much as $4 million annually to comply with the expanded regulations." See L. H. Glimcher, "How Not to End Cancer in Our Lifetimes," *Wall Street Journal*, April 4, 2016.

[38] See http://www.primr.org/WorkArea/DownloadAsset.aspx?id=10166.

Research regulations should facilitate innovative ways for institutions to communicate with patients in meaningful and effective ways about participation in activities aimed at improving health care delivery. Such activities, when carried out systematically, are often referred to as quality improvement (QI) research.[39] Lack of clarity in the NPRM regarding which quality improvement activities constitute research, and when written consent is required for institutions to conduct such research, may discourage valuable and low-risk efforts to improve patient care.

The NPRM is marred by omissions, the absence of essential elements, and a lack of clarity. In addition, important questions about the overall impact and long-term costs of the proposed regulatory changes are unresolved. In light of these deficiencies, it would be impractical to use the current NPRM as the basis for achieving a meaningful, consistent, and harmonious revision of the regulations governing human subjects research that is optimally responsive to developments that have occurred since the publication of the Belmont Report.

Findings

The core principles of respect for persons, beneficence, and justice as articulated in the 1978 Belmont Report are central to the protection of human subjects in research studies.

In the nearly four decades since the publication of the report, however, the biomedical and sociobehavioral research enterprises have grown enormously. This growth, accompanied by the development of a remarkable number of new research capabilities and contexts, raises questions as to the optimum application and balancing of the Belmont principles, as well as whether these principles are, in and of themselves, still sufficient pillars upon which to build human research protection programs and regulations. In addition, the overarching legal and regulatory frameworks and institutional arrangements governing human research subjects require reconsideration and clarification.

Addressing contemporary challenges associated with human subjects research, including new research capabilities and contexts; the profusion, sharing, and accessibility of personal data; and increasing privacy concerns, will require creative and forward-looking legal, regulatory, and institutional frameworks. The important work of addressing these challenges is critical both for enhancing protections for individuals participating in research and for optimizing the federal investment in human research to advance knowledge and improve individual and societal well-being.

The Notice of Proposed Rulemaking on the Federal Policy for the Protection of Human Subjects would impose additional burdens that could be detrimental to areas of important research. The committee believes that the NPRM does not ade-

[39]See, e.g., D. H. Strauss, E. A. Hurley, and A. M. Capron, "Reform of Clinical Research Regulations," *New England Journal of Medicine*, no. 374 (2016): 1693–1694.

quately or effectively address the breadth, depth, and import of unanswered questions; rather, its inadequacies signal a pressing need for a comprehensive review of the nation's ethical, legal, regulatory, and institutional frameworks for protecting human research subjects.[40] At this time, there is no entity that can carry out this review. SACHRP and OHRP perform valuable roles,[41] but neither could conduct the type of review that is required. SACHRP, through OHRP, advises the Secretary of HHS, and neither OHRP nor SACHRP engages other departments and agencies. The current complexity of the issues related to human subjects research requires thorough, independent, cross-agency consideration and expert input from a wide range of disciplines and stakeholder groups.

RECOMMENDATIONS

9.1. The committee recommends that Congress authorize, and the President appoint, an independent, free-standing national commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. This commission was authorized by Congress under Public Law 95-622 in 1978, appointed by the President in 1979, and existed outside the structure of federal departments and agencies. The commission had a direct line-item appropriation from Congress, appointed its own staff, and set its own agenda.

Congress should charge the proposed commission with examining and updating as necessary the ethical, legal, and institutional frameworks governing human subjects research. The commission should make recommendations to the President, Congress, and relevant federal agencies regarding how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts, including but not limited to:

- Research involving anonymous and de-identified human biospecimens;
- Research involving large datasets, for example, research with human genomic, transcriptomic, proteomic, or metabolomic data or associated DNA, RNA, and protein analyses and relevant integrated approaches;
- Research in which the interests of discrete and insular communities are at stake;
- Clinical studies conducted in emergency settings;
- Research involving adults with diminished decision-making capacities;

[40]The committee notes that the National Research Council report cited earlier recommended the formation of an independent committee or commission to address comparable issues.

[41]See footnotes 19 and 20 in this chapter.

- Clinical trials where the unit of intervention is a cluster or group;
- Clinical studies comparing the effectiveness of different accepted interventions for a given disorder to determine whether one approach may be preferable to the other;
- Observational research involving large-scale databases;
- The appropriate boundaries of regulation of minimal-risk sociobehavioral research; and
- Research aimed at clinical innovation and quality assurance and improvement.

The commission should have two broad charges:

a. Recommend to the President and Congress ethically sound regulatory approaches for unresolved questions in human subjects research, including:

- The scope of human research activities that should be covered by federal regulations for human subjects research (including the determination of the types of low-risk research activities, such as some types of sociobehavioral research, that should fall outside the scope of the regulations);
- How regulation should address the increasingly blurred boundaries between research and medical care and the means by which new regulations should distinguish between the two;
- How to incorporate investigator responsibilities into human subjects research regulations; and
- How to balance individual rights, such as the right to privacy, with collective obligations to advance public health and well-being.

b. Recommend to the President and Congress revisions in the legal and institutional structures for regulating research with human subjects that address such questions as:

- Where in the executive branch should the regulatory authority for human subjects research lie? Should it rest within each agency that conducts or funds such research, as is currently the case, or should there be a single, independent agency that regulates all federally funded human subjects research? Which model best serves the interests of efficiency, harmonization, and the mitigation of conflicts of interests?
- Should the United States have a standing advisory committee on human subjects protections? If so, what types of cases or questions should it address, how should it be structured, whom should it advise, and where should it fit within the agency structure?

9.2. To ensure that the proposed national commission can address the full range of unanswered questions regarding the protection of human subjects in federally funded research, the committee recommends that the executive branch withdraw the Notice of Proposed Rulemaking on the Federal Policy for the Protection of Human Subjects. The committee further recommends that the regulatory structure protecting human research subjects not be revised until the national commission has issued its report and the research community, patient groups, the public, and others have had an opportunity to consider and respond to the commission's recommendations.

10

Reporting of Intellectual Property and Technology Transfer

As noted in Part 1 of this report, the National Research Council (NRC) observed in 2010 that:

> Discovery, learning, and societal engagement are mutually supportive core missions of the research university. Transfer of knowledge to those in society who can make use of it for the general good contributes to each of these missions. These transfers occur through publications, training and education of students, employment of graduates, conferences, consultations, and collaboration as well as by obtaining rights to inventions and discoveries that qualify for patent protection (intellectual property) and licensing them to private enterprises. All of these means of knowledge sharing have contributed to a long history of mutually beneficial relations among U.S. public and private universities, the private sector, and society at large.[1]

The management of intellectual property derived from federally funded research is largely governed by the legal framework promulgated by the Bayh-Dole Act of 1980 (Pub. L. 96-517, Patent and Trademark Act Amendments of 1980). The act fostered greater uniformity regarding the manner in which agencies treat the inventions arising from sponsored research. In most instances, research institutions are permitted to take title to inventions derived from basic research supported with federal funding, and the act encourages universities to become much more active in seeking to commercialize their faculties' inventions.[2] However, the primary goal of academic technology transfer is the dis-

[1]National Research Council. *Managing University Intellectual Property in the Public Interest* (Washington, DC: The National Academies Press, 2010), p. 1.

[2]Recently, as the result of litigation regarding university versus university employee ownership of inventions (see, e.g., *Stanford University v. Roche Molecular Systems, Inc.*), universities have modified employment documents to indicate that university employees

semination and development of scientific inventions for the public good. The costs associated with the development and maintenance of institutional capabilities for the transfer of intellectual property are borne by universities; only in rare instances are these costs recovered from patenting and licensing income.

As the result of increased university patent and licensing activity credited to the passage of the Bayh-Dole Act, questions were raised regarding which principles should govern this type of activity in a university setting. In 2006, representatives of a dozen major research universities met to draft a set of points for consideration by universities when making decisions about technology licensing. The resulting document, entitled "Nine Points to Consider in Licensing University Technology,"[3] was subsequently endorsed by more than 100 other research universities and organizations, including a number of non-U.S. universities, the Association of American Medical Colleges and the Association of University Technology Managers. The document set expectations that:

- "Universities should reserve the right to practice licensed inventions and…allow other non-profit and governmental organizations to do so";
- "Exclusive licenses should be structured in a manner that encourages technology development and use";
- "Universities should anticipate and help to manage technology transfer related conflicts of interest"; and
- Universities should "be mindful of the implications of working with patent aggregators" and "consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world."

The 2010 NRC report *Managing University Intellectual Property in the Public Interest* later examined the role and significance of the Bayh-Dole Act on technology transfer:

> One purpose of the Act was to provide consistency within federal agencies with respect to inventions developed with federally funded research. The broader purpose of the Act was to ensure that publicly funded inventions should, whenever possible, enhance the public welfare through commercialization of technology to contribute to public

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hereby assign to the university the rights to inventions and patents conceived or developed using university resources or facilities.

[3]California Institute of Technology et al., "In the Public Interest: Nine Points to Consider in Licensing University Technology," March 6, 2007. Available at: http://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf.

> health, government missions, job creation, international competitiveness, economic growth, and other public goods.[4]

The 2011 Leahy-Smith America Invents Act, the first major change in U.S. patent law in more than 60 years, also has significant implications for the management of university intellectual property. The act created a "first-inventor-to-file" system that harmonizes the U.S. patent system with that of trading partners across the globe; improved patent quality by strengthening the quality management and standards processes of the U.S. Patent and Trademark Office; and by creating more efficient alternatives to the courts for challenging patents, allows challengers an opportunity to eliminate weak patents and strengthen patents that survive a patent challenge;[5] and provided mechanisms to reduce both the backlog of patent applications and patent litigation.

Nature of Concern

While the Department of Commerce issued the regulations implementing provisions of the Bayh-Dole Act, federal research funding agencies are responsible for overseeing university management of intellectual property in accordance with the act. The act requires institutions to provide data to agency sponsors of research on inventions that result from the funded research. This reporting is accomplished through the Interagency Edison (iEdison)[6] invention reporting system. iEdison was developed by the National Institutes of Health (NIH) and allows government grantees and contractors to report via the web all federally funded subject inventions, patents, and utilization data to the agency that funded the research.

The iEdison reporting system is cumbersome to use, is not used by all agencies funding research, and the frequency and quantity of reported information is extensive.

Analysis

The iEdison system is inadequately staffed and maintained, making it difficult for universities to comply with agency requirements. Federal agencies do not uniformly use iEdison for invention reporting,[7] and those that use the system

[4]National Research Council. *Managing University Intellectual Property in the Public Interest* (Washington, DC: The National Academies Press, 2010), p.16.

[5]Association of American Universities, Association of American Medical Colleges, American Council on Education, and Association of Public and Land-grant Universities to Association Constituencies, June 4, 2011, available at: http://www.acenet.edu/news-room/Documents/Memo-on-Patent-Reform-Reminder-to-Support-the-America-Invents-Act.pdf.

[6]See https://era.nih.gov/iedison/iedison.cfm.

[7]NASA, for instance, does not utilize the system.

may require the submission of additional information beyond what is required by the Bayh-Dole Act.

Furthermore, there is a lack of clarity regarding the frequency and quantity of data required by iEdison reporting about inventions when compared with the actual reporting requirements of the Bayh-Dole Act.[8] Data entry is not a one-time event, as additional data have to be provided over the lifetime of the patent.[9] The requirement to report annually (for up to 20 years, the life of the patent) on the large percentage of inventions that are never successfully licensed by universities (less than half of U.S. patents issued by U.S. higher education institutions are successfully licensed, and of that, less than half generate income)[10] is particularly burdensome.

Uploading documents in iEdison can be very complicated. Frequent error messages prevent successful entry of data regarding inventions. Few improvements have been made to iEdison since the system was implemented nearly 20 years ago. Staffing is inadequate to implement needed changes to system infrastructure. Those who spoke to the committee identified inadequate funding as a primary reason for the failings of the iEdison system.

Findings

The Bayh-Dole Act is successful federal legislation. The concepts enshrined in the act, wherein universities are empowered to self-govern their actions, are a model for other regulations for the oversight and management of federally funded research. As the authors of the 2010 NRC report observed, "The Bayh-Dole Act removed the inconsistencies with regard to performer rights and was followed by a surge in patenting and licensing activity as well as in universities' capacities to undertake this activity."[11]

Upgrades to the iEdison invention reporting system and uniform data reporting requirements would help expedite the entry of data by university technology transfer offices and reduce the administrative workload for university inventors and technology transfer offices. While the National Institute of Stand-

[8]See, e.g., Council on Governmental Relations, "Meeting Report, October 27 and 28, 2011," (November 18, 2011), available at http://www.cogr.edu/COGR/files/ccLibrary Files/Filename/000000000246/151875.pdf and Association of University Technology Managers, "Advanced Bayh-Dole Compliance Discussion'" (2016 Annual Meeting), available at http://www.autm.net/2016-annual-meeting/schedule/filter/track-d/d4-advanced-bayh-dole-compliance-discussion/.

[9]National Institutes of Health. "iEdison Reporting Timeline." See https://era.nih.gov/iedison/invention_timeline.cfm.

[10]See Association of University Technology Managers, "AUTM U.S. Licensing Activity Survey: FY2014," available at http://www.autm.net/resources-surveys/research-reports-databases/licensing-surveys/fy-2014-licensing-survey/.

[11]National Research Council. *Managing University Intellectual Property in the Public Interest* (Washington, DC: The National Academies Press, 2010), p. 3.

ards and Technology has, by statute, federal responsibility for examining, reporting on, and recommending changes to the Bayh-Dole Act and related technology transfer policies,[12] the maintenance of iEdison is funded solely by NIH.

A requirement that all research funding agencies use the same patent reporting system and adhere to the same Bayh-Dole Act patent reporting requirements would reduce the administrative burden for both inventors and university technology transfer offices.

RECOMMENDATIONS

The committee recommends that:

10.1. Congress should transfer responsibility for the operation of the invention report system (currently iEdison) to the Department of Commerce and allocate appropriate resources to the department for upgrading the invention reporting system so as to create a user-friendly interface for the input of data on inventions.

10.2 The Department of Commerce, in consultation with the proposed Research Policy Board, should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act.

10.3 Congress should authorize the Department of Commerce to require that the invention data reporting obligations imposed on recipients of federal funding by all agencies are aligned with agreed-upon reporting requirements.

[12]The Director, National Institute of Standards and Technology, has authority over "functions relating to the promulgation of regulations pertaining to the ownership of inventions made with federal funding, the licensing of inventions owned by the Federal Government, and the ownership of inventions made by Federal employees under Section 6(a) of the Bayh-Dole Act (35 U.S.C. 206-209) and E.O. 10096, as amended by E.O. 10930." See http://www.osec.doc.gov/opog/dmp/doos/doo30_2a.html.

11

Research with Select Agents and Toxins/Dual-Use Research of Concern

Infectious agents and toxins considered by the Department of Health and Human Services (HHS) or the Department of Agriculture (USDA) as having the potential to pose a severe threat to human, animal, or plant health are regulated as select agents.

The Centers for Disease Control and Prevention (CDC) and USDA maintain the Select Agents and Toxins List (SATL) (see Appendix H) and restrict the possession of the listed agents. Research on select agents is heavily regulated, and those who are not authorized to possess, use, or transfer select agents but do so are subject to criminal and civil penalties.

The SATL originated in regulations introduced in the mid-1990s. Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 directed the secretary of HHS (and ultimately the CDC) "to promulgate regulations to establish and maintain a list of biological agents that have the potential to pose a severe threat to public health and safety. This list subsequently became known as the Select Agents and Toxins List."[55] Currently, there are 65 agents and toxins on the Select Agents and Toxins List: 34 are HHS BSATs (biological select agents and toxins), 10 are overlap BSATs,[56] 14 are USDA BSATs, and 7 are USDA Plant Protection and Quarantine BSATs.[57] It is important to recognize that the SATL is an instrument of biosecurity, not biosafety. *Biosecurity* is "a set of institutional and personal security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of biological materials that could

[55]See S. A. Morse, "Pathogen Security – Help or Hindrance?" *Frontiers in Bioengineering and Biotechnology*, vol. 2, no. 83, (2015): 2.

[56]The CDC and APHIS (Department of Agriculture Animal and Plant Health Inspection Service) share responsibility for these agents because they potentially threaten both humans and animals.

[57]The USDA's "Plant Protection and Quarantine (PPQ) program safeguards U.S. agriculture and natural resources against the entry, establishment, and spread of economically and environmentally significant pests, and facilitates the safe trade of agricultural products." See https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth.

be used with intent to harm people, livestock, agriculture, or the environment," [58] while *biosafety* is defined as "the containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release." [59] Although biosecurity and biosafety are related in the sense that securing these agents also provides a measure of safety, the concepts are separate and distinct.

HHS rulemaking requires those shipping and receiving BSATs to register with the CDC and requires that "safety procedures for agent transfer be established and enforced; that those handling these agents be properly trained; and that there are proper laboratory facilities to contain and dispose of the agents."[60]

Following 9/11 and the mailing of anthrax spores in 2001, the select agent regulations were greatly expanded. The 2001 USA Patriot Act[61] altered the criteria for who could handle or possess BSATs. Section 175 of U.S.C. 18 states that "whoever knowingly possesses any biological agent, toxin, or delivery system of a type or quantity that, under the circumstances, is not reasonably justified by prophylactic, protective, bona fide research, or other peaceful purpose, shall be fined under this title, imprisoned not more than 10 years, or both."[62] Under this statute, the terms *biological agent* and *toxin* did not include those in their naturally occurring environment so long as the agent or toxin had not been cultivated, collected, or otherwise extracted from its natural source.[63] The regulation of BSATs was also affected by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which directed the HHS secretary to, among other things, establish and maintain the Select Agents and Toxins List and provide safeguards and security requirements for possessing, using, and transferring the materials on the list. Select agent regulations further require that the theft, loss, or release of a BSAT be reported to the Federal Select Agent Program. In addition, select agent regulations institute background checks and personnel reliability programs to reduce insider threat.[64]

Over the past 15 years, the SATL has been modified several times. Agents have been added to and deleted from the list, and additional regulations have been implemented.

Unlike research on select agents and toxins, policies governing dual-use research of concern—"life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products,

[58] See Morse, p. 1.
[59] Ibid.
[60] Ibid., p. 2. These regulations were incorporated into Interstate Shipment of Etiologic Agents 1, 42 CFR 72 (2007).
[61] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001. Pub. L. No. 107-56 (2001).
[62] Prohibitions with Respect to Biological Weapons, 18 USC § 175b (2002).
[63] Morse, p. 3.
[64] Ibid.

or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security" [65]—have not been enacted into law, but institutions follow government guidelines. Questions related to research of dual-use concern are handled at most universities by Institutional Biosafety Committees and by the editors of scientific journals.[66] Research of dual-use concern may subsequently become the subject of tight regulatory control; however, as current regulations focus on select agents, the committee has elected to focus its attention on select agent regulations.

Nature of Concern

Select agent regulations have created a burdensome regulatory framework for individuals working with a very specific list of microbial agents and toxins. There is controversy over the agents listed, the fact that some items on the list are present in the environment (e.g., *Bacillus anthracis*), and concern that select agent regulations hinder research on agents that pose the most serious threats to human health.

Select agent regulations may not provide appropriate protection against biological threats. On the contrary, such regulations may impede the very research that could help protect against such threats. The limitations imposed by select agent regulations may negatively impact the number of collaborations, the size of research projects, and scientific research on microbial pathogens generally.[67]

Analysis

The items currently on the Select Agents and Toxins List differ significantly in degree of pathogenicity and in their capacity for use as agents of bioterrorism. The risk posed to public, animal, and plant health and safety varies depending on the agent. However, the strict controls in place for all agents impede researchers' abilities to conduct legitimate research on less pathogenic organisms.[68]

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[65]See National Institutes of Health Office of Science Policy, "Biosecurity," http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern.

[66]For a discussion of how publication of research of dual-use concern is handled at American Society of Microbiology (ASM) journals, see A. Casadevall et al., "Dual-use Research of Concern (DURC) Review at American Society for Microbiology Journals," *mBio*, vol. 6, no. 4 (2015): 1–3.

[67]N. Wurtz, M. P. Brobush, and D. Raoult. "Negative Impact of Laws Regarding Biosecurity and Bioterrorism on Real Diseases." *Clinical Microbiology and Infection*, vol. 20, no. 6 (2014): 507–515.

[68]National Science Advisory Board for Biosecurity. "Enhancing Personnel Reliability among Individuals with Access to Select Agents: Report of the National Science Adviso-

As a result of select agent regulations, the cost of research involving select agents and toxins has increased significantly. Dias and others conducted the most comprehensive study of the effects of these regulations on research and concluded that "the most striking effect was a loss of efficiency, with an approximate 2- to 5-fold increase in the cost of doing select agent research as measured by the number of research papers published per millions of U.S. research dollars awarded."[69]

Select agent regulations have led to the destruction of microbial collections and a dearth of new isolates of highly pathogenic organisms. Casadevall and Imperiale have documented that numerous microbial collections were destroyed as a consequence of their owners' concerns about compliance with the new select agent regulations.[70] As a result, many irreplaceable samples were lost in the destruction of these collections.

New clinical isolates of microbes on the Select Agents and Toxins List are routinely destroyed by clinical microbiology laboratories that lack the resources to transfer such materials in compliance with select agent regulations. This has affected the growth of microbial collections and resulted in a dearth of recent isolates.[71] Both of these conditions are significant given that microbes evolve over time in both virulence and antigenicity.

Although regulations that affect the acquisition and handling of specimens in a clinical setting are arguably outside the scope of federal research regulations, the collection of new specimens is an essential component of research into the biology of these agents. Hence, regulations that obstruct the availability of clinical specimens have an indirect effect on research productivity. Such obstructions are especially problematic for public health emergencies.

There are concerns that the regulations governing select agent research have become so costly and administratively burdensome that researchers and students are abandoning research on select agents.[72] There is evidence that re-

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ry Board for Biosecurity," (May 2009), p. vi, available at: http://osp.od.nih.gov/sites/default/files/resources/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.

[69]M. B. Dias et al., "Effects of the USA PATRIOT Act and the 2002 Bioterrorism Preparedness Act on Select Agent Research in the United States," *Proceedings of the National Academy of Sciences,* vol. 107, no. 21 (2010): 9556–9561.

[70]A. Casadevall and M. J. Imperiale. "Destruction of Microbial Collections in Response to Select Agent and Toxin List Regulations." *Biosecurity and Bioterrorism*, vol. 8, no. 2 (2010): 151–154.

[71]Ibid.

[72]In addition, dedicated funding for this type of work (biodefense) has been flat and thus declining in real value. See, e.g., T. K. Sell and M. Watson, "Federal Agency Biodefense Funding, FY2013–FY2014," *Biosecurity and Bioterrorism*, vol. 11, no. 3 (2013): 196–216. In addition, it is notable that NIH funding for Regional Centers for Excellence for research on biodefense and emerging infectious diseases ended in the spring of 2014. See National Institute of Allergy and Infectious Diseases, "Regional Centers of Excel-

search involving pathogens on the Select Agents and Toxins List has slowed relative to those not on the list. While it is difficult to compare agents on the list to agents outside the list, an analysis of *PubMed* papers for two *B. anthracis* strains, one a select agent and the other not, showed significantly more publications for the strain that does not appear on the list.[73]

There are large institutional costs associated with the maintenance of facilities where select agent research is conducted. Select agent research must be carefully controlled by the research institution. Such research must be conducted in designated spaces, increased security measures must be implemented, records must be scrupulously maintained, and facilities are subject to numerous inspections by the CDC and others.[74]

Following several biosafety incidents at U.S. government laboratories in 2014 and recognizing the burdens placed on those engaged in select agent research, the White House issued a memorandum outlining a series of short- and long-term actions to enhance both laboratory biosafety and laboratory biosecurity practices.[75] The National Science and Technology Council established a Fast Track Action Committee (FTAC) on the select agent regulations under the Subcommittee on Biological Defense Research and Development of its Committee on Homeland and National Security. In October 2015, the FTAC issued a report, *Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement*, which offers suggestions for improving the regulatory process and addressing perceived gaps in the select agent regulations in the future.[76] Regarding inventory requirements, the FTAC recommended "retaining requirements to maintain inventories of samples containing biological select agents and toxins, while ensuring that BSAT institutions are not requested to characterize biological agents quantitatively."[77] The FTAC also recommended the "development of

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lence in Biodefense and Emerging Infectious Diseases," available at: http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx.

[73]A. Casadevall and D. A. Relman. "Microbial Threat Lists: Obstacles in the Quest for Biosecurity?" *Nature Reviews Microbiology*, vol. 8, no. 2 (2010): 149–154.

[74]E.g., the USDA and the Department of Transportation.

[75]National Science and Technology Council. "Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement" (October 2015): p. iii, available at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/ftac-sar_report_20151029.pdf.

[76]Ibid.

[77]Ibid. The report further states that the FTAC "believes that institutions possessing BSAT are obligated to know and document what is stored in their laboratories and where those agents and toxins are located. It is therefore appropriate to require institutions to maintain inventories of their select agent stocks and be able to show not only that all their samples are documented, but that all entries in an inventory database correspond to physical samples. Maintaining and validating select agents are essential elements of responsible conduct, even if they cannot be used to rule in or rule out a theft or diversion.

Correlation of database and physical stocks is…an indicator of quality management, and entities should practice accountability. The SAR do not require quantitative inventory controls for select biological agents, only for select toxins. The FTAC therefore recom-

an approach to improve the consistency of the inspection process across inspectors, inspecting agencies, and inspected sites" and that "members of the regulated community establish a mechanism for sharing best practices."[78]

On January 19, 2016, HHS and USDA published notices of proposed rulemaking regarding select agents and toxins regulations.[79] In the notices, HHS and USDA consider whether to amend the select agents list by removing six biological agents.[80] HHS is also considering whether to amend the select agents list by removing *Brucella melitensis.*[81] In addition, the agencies are proposing several amendments to the select agent regulations, including "the addition of provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety, and clarification of regulatory language concerning security, training, incident response, and records."[82] According to the agen-

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mends that accountability in the SAR be maintained at the level of identifiable physical items, such as vials or plates, and not extended to quantitative measurements of size, volume, mass, or concentration of biological agents (other than needed to describe them quantitatively). Currently, record keeping and inventory validation do not require accounting for and verifying biological agent concentrations or volumes. The FSAP [Federal Select Agent Program] should ensure that inventory validation through quantitative sample characterization (such as by thawing a frozen sample to measure its volume) is not occurring during inspections, except with toxins as appropriate. Quantitative sample characterization could otherwise needlessly degrade or destroy samples." See p. 12.

[78]Ibid.

[79]For the proposed HHS rule, see "Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements," Federal Register 81, no. 11 (January 19, 2016): 2805, https://www.federalregister.gov/articles/2016/01/19/2016-00758/possession-use-and-transfer-of-select-agents-and-toxins-biennial-review-of-the-list-of-select-agents. For the proposed USDA rule, see "Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations," *Federal Register* 81, no. 11 (January 19, 2016): 2762, https://www.federalregister.gov/articles/2016/01/19/2016-00681/agricultural-bioterrorism-protection-act-of-2002-biennial-review-and-republication-of-the-select. The new rulemaking is in accordance with the Agricultural Bioterrorism Protection Act of 2002, which "requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary." See https://www.federalregister.gov/articles/2016/01/19/2016-00681/agricultural-bioterrorism-protection-act-of-2002-biennial-review-and-republication-of-the-select.

[80]*Coxiella burnetii*; *Rickettsia prowazekii*; *Bacillus anthracis* Pasteur strain; *Brucella abortus* and *B. suis*; *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*); *Phoma glycinicola* (formerly *Pyrenochaeta glycines*); and *Sclerophthora rayssiae*.

[81]This would mean that *B. melitensis* would be identified as a "USDA-only" select agent.

[82]See https://www.federalregister.gov/articles/2016/01/19/2016-00681/agricultural-bioterrorism-protection-act-of-2002-biennial-review-and-republication-of-the-select. The new requirements are summarized by the agencies as follows:

cies, the proposed changes "would increase the usability of the select agent regulations as well as provide for enhanced program oversight."[83] A reduction in the number of agents subject to select agent regulations will be seen as a welcome development by investigators working with infectious agents and toxins. Furthermore, the proposed removal of agents that have been on the Select Agents and Toxins List for more than 15 years suggests that additional agents might be candidates for removal.

- For a select agent to be considered "non-viable," and therefore excluded from the requirements of the regulations, an entity will be required to use a validated inactivation method. As part of the inactivation procedure, an entity will be required to develop a site-specific kill curve to identify conditions of inactivation for each select agent or regulated nucleic acid. In addition, a validated sterility testing protocol to ensure that the inactivation method has rendered a select agent non-viable, or regulated nucleic acid non-infectious, will be required.
- A requirement for a reference laboratory, which would conduct testing to confirm the identification of a select agent or toxin, to inform the specimen provider of a confirmation so the specimen provider will be aware they are in possession of a select agent or toxin and are subject to the select agent regulations.
- A requirement that the biosafety and incident response plans be submitted for initial select agent registration, renewal of registration, or when requested by [the] Federal Select Agent Program (FSAP).
- New specific requirements in the biosafety section would include: a written risk assessment for each registered select agent or toxin; written safety procedures to protect entity personnel, the public, and the environment from exposure to the select agent or toxin; written decontamination procedures; and written waste management procedures.
- A requirement that a laboratory-specific biosafety manual must be accessible to individuals entering a laboratory registered for select agents or toxins.
- Amend existing requirements for the security plan so that the security plan's description of how the entity authorizes the means of entry into areas where select agents or toxins are stored or used would include description of centralized access control management systems (e.g., keycards) and/or key management (mechanical keys).
- Require that required drills or exercises be documented to include how the drill or exercise tested and evaluated a plan, any problems identified and corrective actions that were taken, and the names of the individuals who participated in a drill or exercise.
- The rulemaking would codify existing policy that all individuals who have received FSAP approval to have access to select agents and toxins will be required to have training that addresses the particular needs of the individual and the risks posed by the select agent or toxin, regardless of whether they routinely access select agents or toxins.

[83]Ibid. The comment period on the SATL NPRM closed March 21, 2016. The committee urges that revised select agent regulations be issued as soon as possible. However, any new regulations should be viewed as only an initial step in the reform of SATL regulations and should not preclude action on the other recommendations in this chapter.

Findings

Select agent regulations incorporated an approach to inventory control adopted in the management of radioactive materials. This approach focused on a tight control of physical material. Hence, within select agent regulations, there is a tremendous focus on the tracking of individual vials. Select agents, however, are often living, self-replicating microbes that can be removed from a vial without obviously affecting the volume of material in a vial. Thus, there is an inherent dissonance when accounting for biological materials by conventional (i.e., physical and chemical) inventory practices. Because they are microscopic, minute amounts of materials can be removed from stocks unnoticed and then propagated. Accounting for vials will not prevent the removal of material for nefarious purposes, and inventory control systems that require researchers to account for every individual vial will not ultimately offer protection against the removal of materials. In addition, as life sciences data is increasingly digitized and amalgamated into ever larger datasets, the framework for preventing the misuse of such data may need to be reconsidered.

Select agent regulations were intended to prevent non-cleared individuals from obtaining dangerous materials and make it harder to obtain such materials from research laboratories. Those working with select agents must be cleared to do so.[84] The clearance process is lengthy[85] and may adversely affect the number of researchers conducting such research and may limit student participation in select agent research.

There is a lack of consensus as to whether all agents on the Select Agents and Toxins List are so dangerous as to warrant their place on the list. In addition, there is a lack of transparency in how agents are added to the select agents list. For example, the criteria used to include or exclude agents from the list have never been made public, and certain decisions about the content of the list are viewed as arbitrary by some in the research community.[86]

One measure that would immediately aid select agent research would be to exclude from the list a number of strains with a lower virulence. Current regulations group all microbial strains by species without accounting for the virulence of specific strains. An increase in the availability of low-virulence strains could allow investigators to carry out critical work outside the select agent regulations. This has already been done in limited instances. For example, the Sterne strain of *Bacillus anthracis* is not considered a select agent.

[84]Individuals seeking access to work with BSATs undergo health screenings and federal background investigations.

[85]The federal background screening alone may take anywhere from 3 to 24 months. See Shurtleff et al., "The Impact of Regulations, Safety Considerations and Physical Limitations on Research Progress at Maximum Biocontainment," *Viruses*, vol. 4, no. 12 (2012): 3936.

[86]See, e.g., A. Casadevall and D. A. Relman. "Microbial Threat Lists: Obstacles in the Quest for Biosecurity?" *Nature Reviews Microbiology*, vol. 8, no. 2 (2010): 149–154.

The classification system used by the select agents list is species based. However, there are problematic aspects of microbial species differentiation. The boundaries between microbial species can be indistinct. There is, for example, a *Bacillus cereus* strain that carries anthrax toxins and causes the same disease as *B. anthracis*. The *B. cereus* strain is not on the select agents list. *B. anthracis* is.

Institutions engaged in research on select agents and toxins may be subject to multiple inspections by multiple agencies. The time, effort, and cost of reconciling inconsistent inspection results and complying with different standards and interpretations of select agent regulations are a source of significant burden. Furthermore, violations identified during the course of an inspection receive equal treatment, regardless of the level of severity. Harmonizing of select agent regulations across agencies and entrusting a single agency with the responsibility for all select agents would increase efficiency and reduce administrative burden. The management of select agents presents unique challenges, and investing control within multiple agencies creates unnecessary tensions.

RECOMMENDATIONS

11.1. The committee recommends that the President assign the responsibility for regulating all microbes and toxins on the Select Agents and Toxins List to a single agency.[87]

11.2. The committee recommends that the Federal Select Agent Program develop and promulgate a reasonable inventory management system for biological select agents and toxins that takes account of the living, self-replicating nature of biological agents.

11.3. The committee recommends that the regulations[88] governing select agents and toxins be amended to:

- **Allow researchers to more readily access relevant select agents in times of public health emergencies;**
- **Increase the number of lower-virulence strains of select biological agents available to researchers;**
- **Make more transparent the process by which materials are added to and removed from the Select Agents and Toxins List.**

[87]The proposed Research Policy Board could take a leadership role in discussions about which agency should have responsibility for the regulation of the microbes and toxins on the Select Agents and Toxins List.

[88]See Possession, Use and Transfer of Select Agents and Toxins, 7 CFR 331 (2005); Possession, Use and Transfer of Select Agents and Toxins, 9 CFR 121 (2005); and Select Agents and Toxins, 42 CFR 73 (2005).

12

Export Controls

The strength of American science requires a research environment conducive to creativity, an environment in which the free exchange of ideas is a vital component.

—President Ronald Reagan, National Security Decision Directive 189, 1985

Since the Cold War, the U.S. government has placed controls on the physical export of certain manufactured items, software, biological agents, and technical information (technology) that could be of military use to an adversary. Many of the controlled items or technologies are considered "dual use," having both military and nonmilitary utility (e.g., a high-speed computer). The government also restricts the sharing of controlled technology with non-U.S. persons[1] within the United States, as such sharing is "deemed" to be an export (or in some cases, a "defense service"). The primary controls fall under either the jurisdiction of the Department of State, which administers the International Traffic in Arms Regulations (ITAR), or the Department of Commerce, which administers the Export Administration Regulations (EAR). [2] Each agency maintains extensive lists of controlled items and the countries to which specific controls may apply (the U.S. Munitions List [USML] or Commerce Control List [CCL], respectively). And each has procedures for obtaining licenses to permit a specific export. The United States also belongs to several multilateral international arrangements that coordinate control lists among U.S. allies.

[1]A non-U.S. person is any individual who is not a U.S. citizen; or who is not a U.S. permanent resident alien ("green card" holder); or who is not a protected individual (e.g., refugees, or have political asylum). If the individual is not a U.S. person, when applying the "deemed export" rules the EAR looks at the person's most recent citizenship or permanent residence, whereas the ITAR looks at the person's country of origin (i.e., country of birth) and all current citizenships. See Export Administration Regulations, 15 CFR §772 (2012); International Traffic in Arms Regulations, 22 CFR §120.15 (2011); and University of Pittsburgh Office of Research, "U.S. Person vs. Foreign Person," available at: http://www.research.pitt.edu/exco-us-person-vs-foreign-person.

[2]Other agencies, such as the Department of Energy and the Office of Foreign Asset Control at the Treasury Department also affect universities, but will not be addressed in this report.

While export controls primarily affect commercial transactions, they apply to all U.S. persons and institutions, including research universities. Even during the height of the Cold War, it was recognized that the application of export controls to university research could cause significant harm to U.S. progress in science and engineering by impeding the free flow of ideas and information. In other words, export controls on research activities would result in net harm to national security. Following a landmark study, *Scientific Communication and National Security*,[3] President Ronald Reagan issued, in 1985, National Security Decision Directive 189 (NSDD-189), which established the principle that "to the maximum extent possible, the products of fundamental research remain unrestricted."[4] NSDD-189 further states that, in specific cases where controls are necessary for national security, the means of control should be classification. The directive remains in effect[5] and has been explicitly reaffirmed on several occasions, notably shortly after the attacks of 9/11 by National Security Advisor Condoleezza Rice. More recently, the directive has been reaffirmed by Secretary of Defense Ashton Carter (then serving as undersecretary of defense).[6] Both ITAR and EAR contain provisions that recognize the so-called Fundamental Research Exclusion, for basic or applied research that is or will be openly published (e.g., is not proprietary).

Export regulations also provide specific exclusions for technology disclosed in the context of university courses. These exclusions are of paramount importance to research universities. But their application has never been straightforward and may conflict with the spirit of President Reagan's NSDD-189, that "no restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in applicable U.S. statues." The fundamental research exclusion is generally applied to the "results" of fundamental research, but not to the conduct of research (or the tools used to conduct it).

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[3]Institute of Medicine, National Academy of Sciences, and National Academy of Engineering, *Scientific Communication and National Security* (Washington, DC: The National Academies Press, 1982).

[4]National Security Decision Directive 189 (NSDD-189): National Policy on the Transfer of Scientific, Technical and Engineering Information (September 21, 1985).

[5]For further discussion of NSDD-189 and export controls, see National Research Council, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities* (Washington, DC: The National Academies Press, 2007): 27–28.

[6]See, e.g., Condoleezza Rice, Assistant to the President for National Security Affairs, to Harold Brown, Co-Chairman, Center for Strategic & International Studies (November 1, 2001), available at: https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=1580; John J. Young, Jr., Undersecretary of Defense (June 26, 2008) Memorandum for Secretaries of the Military Departments, available at https://www.fas.org/sgp/othergov/dod/atl062608.pdf; and Ashton B. Carter, Undersecretary of Defense (May 24, 2010) Memorandum for Secretaries of the Military Departments, available at: https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=10846.

Beyond university concerns, there is a broad consensus in government and industry that the current export control regime is broken. The National Research Council report *Beyond "Fortress America": National Security Controls on Science and Technology in a Globalized World*, for instance, concluded that "export controls and visa regulations that were crafted to meet conditions the United States faced over five decades ago now quietly undermine our national security and our national economic well-being."[7] An earlier report to the secretary of commerce reached similar conclusions regarding the deemed export provision and the EAR.[8] Over the years, numerous federal officials, including former Secretary of Defense Robert Gates and several members of Congress, have argued for major changes, as have leaders of industry and industrial associations.[9]

In response, the White House launched the Export Control Reform Initiative in 2009 as an interagency process to clarify, simplify, and better coordinate the control regimes. The initiative includes moving as many items as appropriate from the more stringently regulated USML to the CCL and using clearer descriptions of controlled items. This very commendable effort has indeed provided some significant improvements, although the impact on areas of interest to research universities has been modest.

Recently proposed rules to harmonize the Fundamental Research Exclusions in ITAR and EAR could be a notable improvement for research universities—or a detriment—depending on the text of the final rule. For example, as of this writing, the proposed modifications to ITAR regarding prepublication review would completely undermine the Fundamental Research Exclusion. The export control reform initiative is limited to regulatory and administrative changes that are consistent with current statutes. Furthermore, the interagency process for new rule making is laborious and time consuming, often involving nearly a dozen agencies, any one of which can veto a proposed simplification.

Nature of Concern

While universities recognize their obligations to adhere to export control regulations, they are concerned that the current regime is unnecessarily burdensome and even counterproductive to national security objectives. Export controls have impeded university research in areas such as integrated circuits, material sciences, advanced optics, encryption, earth observation, infectious disease, and

[7]National Research Council, *Beyond "Fortress America": National Security Controls on Science and Technology in a Globalized World* (Washington, DC: The National Academies Press, 2009), p. 1.

[8]U.S. Department of Commerce, *The Deemed Export Rule in the Era of Globalization*, 2007.

[9]See, e.g., M. B. Wallerstein, "Losing Controls, How U.S. Export Restrictions Jeopardize National Security and Harm Competitiveness," *Foreign Affairs*, vol. 88, no. 6 (2009): 10ff.

space research.[10] Deemed export regulations have been particularly difficult for universities, which strive to provide fully open campuses and typically have large numbers of international students and visitors. The negative effects have become even more pronounced over the past several decades, as both research and education become more and more globally interconnected, university campuses are increasingly international, communication via the Internet is instant and worldwide, and the United States is no longer a leader across the spectrum of research areas.

The current U.S. government interpretation of the Fundamental Research Exclusion does not encompass either the tools and instrumentation used to conduct the research or the components used to construct an advanced research apparatus. A major research university may have 100,000 or more pieces of instrumentation, and acquires many thousands of new items every year, some of which may be subject to control. At present, each university often must make its own assessment of whether a given instrument, component, software package (e.g., an integrated circuit design tool kit, a fast oscilloscope, an infrared sensor, or certain carbon nanotubes), or its accompanying technology (e.g., detailed specifications, operations, and repair manuals) is controlled by the USML or CCL. Depending on the control, the university has to choose between preventing some or all international graduate students or postdoctoral scholars from using the item in a campus laboratory, applying for a government license to allow the item's use in campus research, or settling for an inferior alternative item. All of these affect the pace and/or quality of the research. Sending any controlled instruments or fabricated equipment to international collaborators often requires an export license (even if the equipment originated overseas and is merely being returned). Most universities employ trained export control officers and/or specialist attorneys to discharge these duties and often must consult outside counsel for expert opinions. Universities must conduct continual outreach and training for faculty and research staff, some of whom may nevertheless remain unaware of possible restrictions on research conduct. In addition, contracting officers must be careful to structure the terms of all sponsored research agreements to meet the specific requirements of the Fundamental Research Exclusion.

More important than the administrative burden is the chilling atmosphere that surrounds research areas with significant controls, such as space research. At best, research may be hindered by lengthy licensing procedures or attempts to work around controlled areas. In other cases, researchers, and sometimes their university administrations, have chosen to forgo research projects altogether rather than cope with the complexities and delays associated with licensing. While

[10]See, e.g., National Research Council, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities* (Washington, DC: The National Academies Press, 2007); and National Research Council, *Beyond "Fortress America": National Security Controls on Science and Technology in a Globalized World* (Washington, DC: The National Academies Press, 2009).

difficult to document, any such abandoned research would seem to be contrary to national interests. Potentially fruitful interactions between research universities and industry or national laboratories are often particularly problematic because the latter are not covered by the Fundamental Research Exclusion.

Findings

Numerous studies have reached the conclusion that our export control regime is broken and requires a complete overhaul.[11] The Export Control Reform Initiative has been a valiant attempt to address some of the current shortcomings via regulatory changes, such as harmonization and clarification of control lists that do not fundamentally change the control regime specified by statute.

The Department of Commerce's Bureau of Industry and Security is to be commended for persisting with the reform effort despite numerous challenges. Through the good intentions of, and hard work by, government agencies, important progress has been made. In general, however, these efforts have thus far produced limited improvement and have been especially unsuccessful in addressing long-standing concerns about the effects of export controls, such as the deemed export provisions, on university research.

Since export controls primarily affect commercial or military activities, university concerns often receive secondary consideration. Additional means—beyond public comment or advisory bodies (such as a technical advisory committee to the Department of Commerce)—will need to be utilized if university concerns are to receive appropriate attention during a renewed initiative to reform export controls."

RECOMMENDATIONS

12.1. The committee recommends that Congress and the Administration support a robust continuation and renewal of the Export Control Reform Initiative. Even under current statutes, the initiative has the potential to make further, marked improvements (e.g., to the regulations, oversight process, and ease of compliance) that would bring significant benefits to national security, to commerce, and to the economy, as well as to federally funded university research. The lessons learned in the initiative over the past 5 years could help participants in the process accelerate the rate at which needed regulatory revisions are proposed and adopted.

[11]See, e.g., National Research Council, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities* (Washington, DC: The National Academies Press, 2007); and National Research Council, *Beyond "Fortress America": National Security Controls on Science and Technology in a Globalized World* (Washington, DC: The National Academies Press, 2009).

12.2. The committee recommends that the Export Control Reform Initiative seek university input at all stages of the process. The Research Policy Board proposed in Part 1 of this committee's report would be an ideal vehicle for providing such input.

12.3. The committee recommends that the Export Control Reform Initiative work closely with universities and other stakeholders to specifically address the deemed export provisions[12] and vigorously support the spirit and letter of the fundamental research exclusion.

[12]As recommended by the report *The Deemed Export Rule in the Era of Globalization* [U.S. Deemed Export Advisory Committee, *The Deemed Export Rule in the Era of Globalization* (Washington, DC: U.S. Department of Commerce, 2007)].

13

Operationalizing the New Regulatory Framework for the Federal Investment in Research Institutions

In Part 1 of this report, the committee called for a new regulatory framework for the government–academic research enterprise. As envisioned, the framework would include a new entity, the Research Policy Board (RPB), and the establishment of a new associate director position (Academic Research Enterprise) at the White House Office of Science and Technology Policy (OSTP). The committee also offered a set of principles to guide the recalibration and future development of federal research regulations.

The committee's recommendations emanated from its assessment of the overall condition of the nation's academic research enterprise. In the course of the committee's investigation, analysis, and deliberations, it became clear that the absence of a body responsible for monitoring and optimizing the health and functioning of the nation's $65 billion annual investment in basic and applied research causes serious problems. Congress, the Administration, funding and regulatory agencies, research institutions, and the public lack a means of communicating with one another about their concerns and expectations regarding the regulation of research. Also lacking are the data needed to assess whether the government–academic research enterprise is operating as well as it might and the extent to which existing and proposed regulations, guidance documents, and policies are aiding or hindering that end. In the current regulatory framework, agencies face barriers to harmonizing research regulations and policies for optimal effectiveness.

The committee concluded that steps can be taken to improve the operational status of the government–academic research enterprise so as to maximize the benefits to science and society. The RPB will provide an environment where key participants can have candid conversations about their concerns, develop a shared understanding of the problems to be addressed, gauge the costs of proposed solutions, and make realistic assessments of the benefits and unintended consequences that result from new regulations. This forum would also facilitate anticipatory discussions about emerging fields of research that may require new or revised regulations or policies. Another facet of the new framework, the

OSTP Associate Director, Academic Research Enterprise, can see to it that data about regulatory benefits and burdens are collected and evaluated and that conflicts and redundancies in regulations and reporting requirements are eliminated. The committee's proposed framework thus provides the opportunity to create effective and proactive regulations geared to the needs of 21st century research.

The committee recognizes that creating and operationalizing a new regulatory framework will present challenges and that many questions must be answered in order to create an optimal model. Concerns of this type have been raised by readers of Part 1 of the committee's report. The committee believes it is unwise for it to attempt to address every mechanistic function of the proposed framework. Nonetheless, the committee believes that some additional clarifying remarks are appropriate. Therefore, in the current chapter, the committee offers a discussion of how the RPB and the associate director at OSTP might engage with the White House Office of Management and Budget (OMB), Congress, funding and regulatory agencies, and research institutions and associated organizations to optimize the research partnership. As the committee noted in Part 1 of this report, the goal of the framework is not to increase bureaucracy, but rather to make the federal regulatory regime simpler, more effective, and more harmonized across research funding agencies. A high-level forum that facilitates substantive dialogue about and collects and analyzes data on existing and proposed regulations will ultimately result in less bureaucracy as the members of the partnership, working together, streamline and harmonize those regulations governing the conduct of research. The committee recognizes that the RPB will require dedicated staff, including a full-time director, to convene meetings of senior officials, conduct detailed examinations of rules and regulations, and to formulate appropriate responses for congressional and agency consideration.

In the context of the committee's proposed regulatory framework, the committee envisions that the RPB will provide stakeholders with an opportunity to:

1. Consider, in an anticipatory fashion, issues, policies, concerns, and regulations that affect the multiple agencies that support or regulate federally funded research.
2. Consider, in an anticipatory fashion, new and emerging fields of research that may necessitate policy changes or new regulations.
3. Evaluate and assess the effects of existing, new, or proposed policies, regulations, and guidance documents.
4. Collect and evaluate appropriate data for the development of metrics that provide a quantitative assessment of the cost and benefit of specific regulations.[1]

[1]The importance of accurately estimating the costs of regulations cannot be overstated. As the committee noted in Chapter 2 of Part 1, while there are many ways to estimate the cost of regulations, there are no authoritative methodological approaches for calculating

Many of the recommendations in Parts 1 and 2 of the committee's report could be advanced through engagement with the RPB. The RPB could, for example, provide both a venue for discussion and a vehicle for the assemblage and analysis of the data needed to facilitate the committee's recommended consideration of, for example, a unified federal approach to the use and care of animals in research or select agent regulations.

Recognizing that the specific operational functionality of the RPB and the mandate of the proposed associate director will be defined through debate and negotiation, the committee provides, in the following section, a broad illustration of how the proposed framework might work.

The proposed OSTP-OMB annual report to Congress[2] is a key component of this new framework, as it affords Congress the opportunity to review, on a yearly basis, the progress made in optimizing the functioning of the research enterprise. It would also highlight current challenges and identify prospective issues of regulatory concern. The importance of the annual report will be illustrated in the following text.

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such costs. The American Council on Education, in its February 2015 report, *Recalibrating Regulation of Colleges and Universities*, observed that:

> Calculating the precise benefits and costs of regulation is both difficult and time-consuming. One reason for this is that duties and functions associated with a new regulation are usually absorbed by staff who already perform other duties, simply adding to their workload. Similarly, estimates of the cost of complying with a new regulation may fail to take into account the complicated interplay between new and existing requirements. Regulations do not exist independently of each other, and the interplay of multiple requirements can add exponentially to the cost of compliance.

To take the example of one regulation, the National Institutes of Health estimated annualized burden hours for compliance with the 2011 Public Health Service financial conflict-of-interest rule at 676,130 hours at an estimated cost of $23 million across roughly 2,000 awardee institutions. In contrast, a survey undertaken by the Association of American Medical Colleges indicated that just 70 institutions spent $22.6 million to implement the rule (see Chapter 5, p. 91). For a further discussion of agency cost estimates, see Appendix F: *A Brief Primer on the Paperwork Reduction Act*.

[2]Given the nature and magnitude of the issues that affect the research enterprise, it is expected that, in addition to its annual report, the proposed Research Policy Board would issue supplementary reports to relevant congressional committees, including the U.S. Senate Committee on Health, Education, Labor and Pensions; U.S. Senate Committee On Commerce, Science, and Transportation; U.S. House Committee on Science, Space and Technology; and U.S. House Committee on Oversight and Government Reform.

HOW THE PROPOSED RESEARCH POLICY BOARD MIGHT SERVE AN ANTICIPATORY FUNCTION

As an anticipatory body, the RPB will convene representatives from the research funding and regulatory agencies, the White House Office of Information and Regulatory Affairs (OIRA), inspectors general, and the research community routinely, and not simply in response to agency actions. The purpose of these meetings would be to identify agenda items, set project priorities, and engage in horizon-scanning. Such meetings would provide an opportunity for research funding agencies to raise concerns. By enabling agencies to give early voice to their concerns, problematic issues could be addressed in a preemptive (rather than in a reactive) manner, and actions could be taken proportionate to the magnitude of the concern. Regulatory action need only be taken if an identified problem is found to be systemic and beyond the willingness or capacity of research institutions to manage.

Additionally, the RPB could convene meetings with legislative staff to discuss proposed legislative actions affecting federally funded research.

Regular meetings will be used to discuss advances in research so as to provide the RPB with information on emerging trends and disruptive technologies (e.g., gene editing, autonomous technologies, synthetic biology, massive data on social networks) that may require new thinking about the governance of research as well as reconsideration of existing and proposed regulations and policies.

Research institutions will be expected to raise issues of regulatory importance, that is, regarding laws, general and permanent rules published in the *Federal Register*, agency policies and policy guidance (including FAQs), and executive actions, and identify best practices for facilitating a strong government–research university partnership.

It may be desirable, on occasion, based upon discussions with stakeholders, for the RPB to recommend the initiation of rulemaking to correct problems in existing regulations. Existing mechanisms for retrospective review of regulations (e.g., Executive Order 13563[3]) can be used for this purpose.

The RPB will explore mechanisms that would allow agencies to engage with the RPB prior to initiating a rulemaking. Issues that affect multiple agencies' policies and programs (such as conflicts of interest, human subjects, or animal care) will be subject to particular consideration.

[3]Improving Regulation and Regulatory Review, Executive Order No. 13563, 2011.

HOW THE PROPOSED FRAMEWORK MIGHT WORK IN THE ISSUANCE OF A NEW REGULATION

Before a Notice of Proposed Rule Making

Prior to initiating rule making, a draft Advance Notice of Proposed Rulemaking (ANPRM) on a subject area of significant interest to the research community will be placed on the agenda of the RPB at the request of the Associate Director, Research Enterprise (ADRE), OSTP, a federal agency, or the leadership of the RPB.

The RPB will convene a meeting to hear from the research community and invite the Associate Director, OSTP; OMB-OIRA administrator; issuing agency staff, and other relevant agency staff to informally discuss with the research community concerns about the draft ANPRM.[4]

OIRA would review subsequent revisions to the draft ANPRM to assess whether an agency has been responsive to concerns raised and meet with the RPB to hear any remaining concerns about the revised ANPRM so as to assure that these concerns had been appropriately considered *before* the proposal would be opened to public comment.

Following the OIRA-RPB meeting, in collaboration with the ADRE, the RPB will issue a report to the OSTP director and the OMB-OIRA administrator, identifying remaining unresolved issues of concern to the research community. Such reports will be included as an appendix in the annual OSTP-OMB report to Congress.

Between a Notice of Proposed Rulemaking and a Final Rule

If an agency issues a Notice of Proposed Rulemaking (NPRM)[5] that has not responded to the concerns raised by the academic research community through the process described above, then the following will occur.

The RPB will convene a meeting to discuss the agency response with the participants described above while ensuring that agency policies on ex parte communication during the rulemaking process are not violated.

Following the meeting, the RPB will issue a report describing problematic issues remaining in the NPRM and highlighting, as appropriate, that the issues with the NPRM were raised at the ANPRM stage. If, in the preamble to the NPRM, the responsible agency explains why it did not make changes, the RPB will detail, in its report to OSTP and OMB-OIRA, the reasons why the research community believes that the responses given are insufficient.

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[4]The committee recognizes that Federal Advisory Committee Act issues will need to be considered with regard to such discussions.

[5]If an NPRM is not preceded by an ANPRM, then the NPRM would be subject to review in a manner consistent with the process described above for an ANPRM.

OMB-OIRA would be expected to take into account the concerns raised in this report during its review of the agency final rule.

The RPB report will be included as an appendix in the OSTP-OMB annual report to Congress. The report will identify problematic final rules and document solutions offered by the research community to redress these concerns and, in so doing, provide Congress with an opportunity to conduct additional necessary information gathering.

After a Final Rule

The RPB will evaluate and comment on:

1. Guidance documents interpreting regulations and the associated burden that such documents might impose on research institutions.
2. Requests for new information collections, the associated burdens that such collections might create for universities, and the application of the Paperwork Reduction Act to minimize such burdens.
3. The enforcement of regulatory provisions by agencies and their inspectors general.
4. Internal retrospective reviews of current agency regulations.

Following the issuance of a final rule, the RPB will engage in ongoing communications about the implementation of the associated regulations with agency liaisons and the research community.

HOW THE PROPOSED RESEARCH POLICY BOARD MIGH ASSIST IN THE DEVELOPMENT OF METRICS, THE COLLECTION OF DATA, AND IN EVALUATING AND ASSESSING DATA

The RPB will work with the research community, research policy organizations, and federal agencies to identify and, as necessary, develop appropriate metrics to be used to assess the impact of regulations on the conduct of research. This should include defining appropriate methodologies for assessing the costs, benefits, and burdens associated with regulations.

The RPB will routinely request, in collaboration with organizations such as the Federal Demonstration Partnership, the Council on Governmental Relations, the American Association of Universities, the Association of Public and Land-grant Universities, the Association of American Medical Colleges, and the Federation of American Societies for Experimental Biology, data from research institutions regarding regulations currently under review as part of retrospective reviews of agency regulations required under Executive Order 13563. This information would be provided to the government.

The RPB will compile data on the costs of proposed and actual regulations. This information would be provided in the OSTP-OMB annual report to

Congress. For any significant new proposed regulations where the agency and research community's calculations of the costs, benefits, and burdens of the regulation significantly diverge, the RPB will convene a meeting with OIRA, the research community, and the issuing agency. Information regarding these meetings and the data collected should be included in the OSTP-OMB annual report to Congress.

Ultimately, the strength of the RPB will be its ability to contribute, through the vital role it will play in creating and shaping a meaningful dialogue among all stakeholders in the government–academic research partnership, to a more responsive and efficient regulatory structure that optimizes the nation's investment in academic research by better serving the interests of government, universities, investigators, and the public.

Appendixes

Appendix A

Biographical Information of Committee and Staff

Chair

LARRY R. FAULKNER is president emeritus of the University of Texas at Austin and is a retired president of Houston Endowment, a private philanthropy established by Jesse H. and Mary Gibbs Jones. Dr. Faulkner was born in Shreveport, Louisiana, in 1944. He earned a BS degree from Southern Methodist University in 1966 and a Ph.D. in chemistry from the University of Texas at Austin in 1969. Dr. Faulkner served on the chemistry faculties of Harvard University (1969–1973), the University of Illinois (1973–1983, 1984–1998), and the University of Texas (1983–1984, 1998–2006). At Illinois he was head of the Department of Chemistry, dean of the College of Liberal Arts and Sciences, and provost and vice chancellor for academic affairs. In 1998, he returned to the University of Texas at Austin as the 27th president, and served into 2006. Dr. Faulkner became president of Houston Endowment Inc. immediately thereafter and ultimately retired in 2012.

Dr. Faulkner has published more than 120 scientific papers and directed 40 doctoral theses. He also is coauthor (with Allen J. Bard) of the prominent text *Electrochemical Methods: Fundamentals and Applications* and is coinventor (with Peixin He and James Avery) of the cybernetic potentiostat, which had a lasting impact on the design of commercial analytical instruments. He has been recognized with the Electrochemical Society's Edward Goodrich Acheson Medal, the American Chemical Society Award in Analytical Chemistry, the U.S. Department of Energy Award for Outstanding Scientific Achievement in Materials Chemistry, and the Charles N. Reilly Award of the Society for Electroanalytical Chemistry. In 2003, he was elected to the American Academy of Arts and Sciences.

As president of the University of Texas at Austin, he oversaw a capital campaign that raised over $1.6 billion. He also appointed and supported the work of the Commission of 125, a citizens' group that provided guidance on the future of the university and its relationship to the public. Other significant achievements included the development of the Blanton Museum of Art, the acquisition of the

Suida-Manning Collection of European Art and the Woodward-Bernstein Watergate Archive, and the creation of innovative scholarship programs that helped to restore the University of Texas's minority student enrollment. As president of Houston Endowment, he oversaw grant making of more than $400 million to charities in Greater Houston, focusing on arts and culture, education, the environment, health, and human services. From 2006 into 2008, he chaired the National Mathematics Advisory Panel by designation of the president and the secretary of education. From 2011 into 2013, he chaired the American Chemical Society's Presidential Commission on Advancing Graduate Education in the Chemical Sciences. In 2014–2015, he was vice chair of the Texas Higher Education Coordinating Board's Higher Education Strategic Planning Committee, which produced the state's next 15-year plan, *60×30TX.*

He now serves on the boards of Exxon Mobil Corporation, Southern Methodist University, Discovery Green Conservancy, Houston Grand Opera, the Philosophical Society of Texas, and Al Akhawayn University in Ifrane, Morocco. He was previously on the boards of Temple-Inland, Sandia National Laboratories, and the Lyndon Baines Johnson Foundation; and he chaired the Board of Trustees of Internet2 for a 3-year period ending in 2007.

Vice Chair

HARRIET RABB, JD, is vice president and general counsel to The Rockefeller University. Ms. Rabb was previously vice dean and faculty head of the clinical program, as well as a professor at Columbia Law School during her affiliation of more than two decades there. In 1991, she was named the first George M. Jaffin Professor of Law and Social Responsibility.

In 1993, Ms. Rabb was confirmed by the United States Senate to serve as general counsel for the U.S. Department of Health and Human Services under Secretary Donna Shalala. As chief legal officer of the department, Ms. Rabb was responsible for legal matters involving, among other agencies, the National Institutes of Health, the Centers for Disease Control, the Food and Drug Administration, the Health Care Financing Administration (now the Center for Medicare and Medicaid Services), and the Administration for Children and Families. Ms. Rabb led the department's legal efforts on health policy issues, including human stem cell research, pandemic influenza, tobacco, assisted reproductive technology, tissue and organ allocation, fetal tissue and human embryo research, informed consent, and various aspects of vaccines. In 2001, Ms. Rabb was named to her current position as vice president and general counsel to The Rockefeller University.

Members

ILESANMI ADESIDA (NAE) is dean emeritus of the College of Engineering and Donald Bigger Willett Professor of Engineering at the University of Illinois at Urbana-Champaign. He served as the vice chancellor for academic affairs and provost from 2012 to 2015. As the university's chief academic officer, he oversaw the campus's academic programs, policies, and priorities, which have been designed to ensure the quality of the educational experience for students and to sustain an environment that encourages and supports academic excellence. As the chief academic officer, Provost Adesida worked closely with the chancellor, the other vice chancellors, the deans of academic colleges and other units, academic staff, the Faculty Senate, and various committees in setting overall academic priorities for the campus.

In June 2005, Provost Adesida became the 13th dean since the inception of the College of Engineering in 1870. He originally joined the Illinois faculty in 1987, and he is currently the Donald Biggar Willett Professor of Engineering, professor of electrical and computer engineering, and professor of materials science and engineering. He has previously served as the director of the Micro and Nanotechnology Laboratory and the associate director for education of the National Science Foundation's Engineering Research Center for Compound Semiconductor Microelectronics.

Provost Adesida's research interests include nanofabrication processes and ultra-high-speed optoelectronics. He has extensive experience in development of novel processes for wide bandgap materials such as silicon carbide and gallium nitride. He has also worked on ultra-high-speed photodetectors and photoreceivers in various materials systems. Provost Adesida has chaired many international conferences, including serving as the program and general chair of the Electronic Materials Conference, 2000–2003. He is a fellow of the Institute of Electrical and Electronic Engineers (IEEE), American Association for the Advancement of Science (AAAS), American Vacuum Society (AVS), and Optical Society of America. He won the 2016 TMS John Bardeen Award for excellence in electronic materials. He is past president of IEEE Electron Devices Society, and is a member of the National Academy of Engineering.

Provost Adesida received his B.S., M.S., and Ph.D. degrees in electrical engineering from the University of California, Berkeley. From 1979to 1984, he worked in various capacities at what is now known as the Cornell Nanofabrication Facility and the School of Electrical Engineering, Cornell University, Ithaca, New York. He was the head of the Electrical Engineering Department at Tafawa Balewa University, Bauchi, Nigeria, from 1985to 1987.

ANN M. ARVIN (NAM) is vice provost and dean of research at Stanford University and the Lucile Salter Packard Professor of Pediatrics (Infectious Diseas-

es) and professor of microbiology and immunology. Her responsibilities as vice provost include serving as the cognizant academic dean for Stanford's 18 major university-wide interdisciplinary laboratories, centers, and institutes and overseeing university research policies, compliance with research regulations pertaining to human and animal research and laboratory safety, the Office of Technology Licensing/Industry Contracts Office, and shared facilities. Her research laboratory investigates the molecular mechanisms of human herpes virus infections, focusing on varicella-zoster virus, and T cell immune responses to viral vaccines and has had continuous National Institutes of Health funding since 1985. Her work has been recognized by election to the American Academy of Arts and Sciences, the Institute of Medicine of the National Academy of Sciences (NAS), the American Association for the Advancement of Science, and the Association of American Physicians. She has received the Distinguished Graduate Award from the University of Pennsylvania's School of Medicine, the Walter Hewlett Award from Stanford University School of Medicine, the John F. Enders Award of the Infectious Diseases Society of America, and the E. Mead Johnson Award for Pediatric Research, among others. She was chief of the Pediatric Infectious Diseases Division at the Packard Children's Hospital from 1984 to 2006. Her recent and current national service includes the National Academy of Sciences Board on Life Sciences, the President's Council of Advisors on Science and Technology working group on H1N1 influenza, the Institute Director's Advisory Council of the National Institute of Allergy and Infectious Diseases and the NAS/National Research Council Committee on Responsible Science and the Committee on Science, Technology, and Law. Dr. Arvin is a graduate of Brown University, with an AB in philosophy; Brandeis University, with an M.A. in philosophy; and the University of Pennsylvania School of Medicine, and completed postdoctoral fellowship training at the University of California, San Francisco, and Stanford University.

BARBARA E. BIERER, MD, a hematologist-oncologist, is a professor of medicine at Harvard Medical School and the Brigham and Women's Hospital. Dr. Bierer cofounded and now leads the Multi-Regional Clinical Trials Center of the Brigham and Women's Hospital and Harvard, a university-wide and collaborative effort to improve standards for the planning and conduct of international clinical trials, with a particular focus in the developing world. In addition, she is the director of the Regulatory Foundations, Ethics, and the Law Program at the Harvard Catalyst, and is a recipient of the Harvard Clinical and Translational Science Award. From 2003 to 2014, Dr. Bierer served as senior vice president of research at the Brigham and Women's Hospital, where she was the institutional official for human subjects and animal research, for biosafety, and for research integrity. During her tenure in this role, Dr. Bierer initiated the Brigham Research Institute and the Brigham Innovation Hub (iHub), a focus for entrepreneurship and innovation in health care. She established and was the founding director of the Center for Faculty Development and Diversity.

Dr. Bierer, a graduate of Harvard Medical School, completed her internal medicine residency at the Massachusetts General Hospital and her hematology and medical oncology training at the Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Earlier in her career, Dr. Bierer served as vice president of patient safety and director of the Center for Patient Safety at the Dana Farber Cancer Institute (2002–2003) and chief of the Laboratory of Lymphocyte Biology at the National Heart, Lung, and Blood Institute of the National Institutes of Health in Bethesda, Maryland (1997–2002). She has held positions as director of pediatric stem cell transplantation at Dana-Farber Cancer Institute and Children's Hospital.

In addition to her current responsibilities, Dr. Bierer chairs the Board of Trustees of the Edward P. Evans Foundation, a foundation supporting biomedical research, and serves on the Boards of Directors of Public Responsibility in Medicine and Research (PRIM&R) and Management Sciences for Health (MSH). She is the immediate past chair of the Secretary's Advisory Committee for Human Research Protections. She has authored or coauthored more than 180 publications.

JONATHAN D. BREUL is an adjunct professor in Georgetown University's McCourt School of Public Policy. He also serves on the UNESCO's Oversight Advisory Committee and has also chaired a number of congressionally requested studies of federal agencies for the National Academy of Public Administration. Previously, he was executive director of the IBM Center for the Business of Government and a partner in IBM Global Business Services. The IBM Center annually sponsored two dozen independent research reports by top minds in academe and the nonprofit sector, produced a weekly Business of Government Hour radio show, and published the biannual *Business of Government* magazine, which is distributed to all government executives.

Formerly senior advisor to the deputy director for management in the Office of Management and Budget (OMB), Mr. Breul served as OMB's senior career executive with primary responsibility for government-wide general management policies. He also served for 8 years as the U.S. delegate and elected vice chair of the Paris-based Organization for Economic Cooperation and Development's (OECD) Public Management Committee. Mr. Breul is an elected fellow of the National Academy Public Administration (NAPA) and leads the Government Performance Coalition.

CLAUDE R. CANIZARES (NAS) is the Bruno Rossi Professor of Physics at the Massachusetts Institute of Technology (MIT). At MIT since 1971, he has served as vice president (2013–2015), vice president for research and associate provost (2006–2013), associate provost (2001–2006), and director of the Center for Space Research (1990–2002). He oversaw the MIT Lincoln Laboratory from 2001 to 2014. Professor Canizares is a principal investigator on NASA's Chan-

dra X-ray Observatory and associate director of its science center. He has also worked on several other space astronomy missions and is author or coauthor of more than 230 scientific papers.

Professor Canizares's service outside MIT has included the Department of Commerce's National Advisory Council on Innovation and Entrepreneurship and the Emerging Technology and Research Advisory Committee and the National Academies of Sciences, Engineering, and Medicine Committee on Science, Technology, and the Law. He served as chair of the Academies' Space Studies Board and was a member of the NASA Advisory Council and the Air Force Scientific Advisory Board, among others. He is also a member of the L-3 Communications, Inc., Board of Directors. Professor Canizares is a member of the National Academy of Sciences and the International Academy of Astronautics and is a fellow of the American Academy of Arts and Sciences, the American Physical Society, and the American Association for the Advancement of Science. He has also received several awards including decoration for Meritorious Civilian Service to the United States Air Force, the Goddard Medal, and two NASA public service medals.

ARTURO CASADEVALL (NAM), MD, Ph.D., is chair of the W. Harry Feinstone Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health. Formerly, he was Leo and Julia Forchheimer Professor of Microbiology and Immunology; chair of the Department of Microbiology and Immunology; and professor in the Department of Medicine at the Albert Einstein College of Medicine. He received his B.A. from Queens College, City University of New York, and MS, MD, and Ph.D. degrees from New York University. His laboratory is interested in the fundamental questions of how microbes cause disease and how the host protects itself against microbes. The laboratory has a multidisciplinary research program spanning several areas of basic immunology and microbiology to address these general questions, which has resulted in more than 650 publications. His laboratory studies are focused on two microbes: the fungus *Cryptococcus neoformans*, a ubiquitous environmental microbe that is a frequent cause of disease in immunocompromised individuals, *Bacillus anthracis*, which is a major agent of biological warfare and Mycobacterium tuberculosis, the cause of tuberculosis. He is a fellow of the American Academy of Microbiology and was elected to the American Society for Clinical Investigation, to the American Association of Physicians, and as a fellow of the American Association for the Advancement of Science. Dr. Casadevall has served on numerous advisory committees to the National Institutes of Health, including study sections, strategic planning for the National Institute of Allergy and Infectious Diseases (NIAID), and the blue ribbon panel on response to bioterrorism. He currently cochairs the Board of Scientific Counselors for the NIAID and is a former member of the National Science Advisory Board for Biosecurity (NSABB). He is editor in chief of *mBio*, serves on the editorial boards of several journals, and has been the recipient of numerous

awards, most recently the Solomon A. Berson Medical Alumni Achievement Award in Basic Science of the NYU School of Medicine, the IDSA Kass Lecturer, and the William Hinton Award from the American Society of Microbiology for his efforts in mentoring scientists from underrepresented groups. He is a member of the National Academy of Medicine.

JONATHAN R. COLE, Ph.D., is the John Mitchell Mason Professor of the University, and for 14 years, from 1989 to 2003, he was provost and dean of faculties of Columbia University. He has spent his academic career at Columbia. From 1987 to 1989 he was vice president of arts and sciences. His early scholarly work focused principally on the development of the sociology of science as a research specialty. He published many books and articles on this subject. More recently, his published work addresses issues in higher education. His three most recent books on that subject are *The Great American University: Its Rise to Preeminence, Its Indispensable National Role, Why It Must Be Preserved* (2011), *Who's Afraid of Academic Freedom?* (2015), and *Toward a More Perfect University* (2016). He lectures throughout the world on topics related to higher education. Dr. Cole was a fellow at the Center for Advanced Study in the Behavioral Sciences from 1975 to 1976. He was awarded a John Simon Guggenheim Foundation Fellowship (1975–1976). He spent the 1986–1987 academic year as a visiting scholar at the Russell Sage Foundation. In 1992 he was elected a fellow of the American Academy of Arts and Sciences. He is an elected member of the American Philosophical Society; elected member of the Council on Foreign Relations; and an elected fellow of the American Association for the Advancement of Science. He received his B.A. in American history from Columbia College in 1964 and his Ph.D. in sociology from Columbia in 1969. From 1968 until today, he has taught at Columbia. He was the Adolphe Quetelet Professor of Social Science, 1989 to 2001; professor of sociology, Columbia University, from 1976 until he became provost in 1989. He was adjunct professor at The Rockefeller University from 1983 to 1985.

LEE M. ELLIS, MD, is professor of surgical oncology, and molecular and cellular oncology and the William C. Liedtke, Jr. Chair in Cancer Research, at the University of Texas MD Anderson Cancer Center, and SWOG vice chair of translational medicine. Dr. Ellis graduated from the University of Virginia School of Medicine in 1983, and completed his residency in surgery at the University of Florida in 1990. Dr. Ellis went on to complete a surgical oncology fellowship at the MD Anderson Cancer Center (MDACC), where he has been on the faculty since 1993. Dr. Ellis has a clinical practice in surgical oncology, focused on patients with colorectal cancer and liver metastases. Academically, Dr. Ellis has established a reputation for expertise in the area of angiogenesis and growth factor receptors in gastrointestinal malignancies and is funded by several grants for research in this area. He has served on numerous National Institutes of Health (NIH) study sections and is a consultant to the National Cancer Institute (NCI), where he currently serves on the NCI Investigational Drug Steering

Committee (IDSC), and is vice chair of the NCI Colon Task Force. Dr. Ellis serves as an inaugural cochair of the NCI National Clinical Trials Network Correlative Sciences Committee. In 2000, Dr. Ellis was awarded the Faculty Scholar Award from the MDACC, and he was also the inaugural recipient of a grant from the George and Barbara Bush Endowment for Innovative Cancer Research. In 2007 he was awarded the William C. Liedtke, Jr., Chair in Cancer Research. Dr. Ellis serves on eight editorial boards, including serving as a deputy editor for *JAMA Oncology*.

Dr. Ellis has also authored more than 230 peer-reviewed publications, 110 invited reviews and editorials, 4 books, and 30 book chapters. Dr. Ellis served as interim chair of the Department of Cancer Biology from 2008 to 2012, and he also served as director of the Metastasis Research Center from 2010 to 2012 at the MDACC. Dr. Ellis served as codirector for the ASCO/AACR Workshop on Methods in Clinical Cancer Research from 2010 to 2012, and now serves as codirector of the FLIMS Workshop on Methods in Clinical Cancer Research. In May 2013 he assumed the position of vice chair for Translational Medicine of SWOG and serves on the Executive Committee for this organization. He is also on the Board of the Hope Foundation, the philanthropic arm of SWOG. Dr. Ellis is a member of the Nominating Committee of ASCO, a position he will hold until 2016. He chaired the ASCO Cancer Research Committee from 2012 to 2013.

Dr. Ellis's interest in data reproducibility was highlighted by a comment in *Nature* in 2012, followed by a survey on data reproducibility from investigators at the MD Anderson Cancer Center. He participated in a replication workshop held in at NCI/NIH in September 2012 and has lectured on this topic at numerous international meetings.

GEOFFREY E. GRANT is president of Research Advocates. Mr. Grant has extensive management experience in public and academic institutions and has been recognized as an advocate for national research programs and the scientific community while promoting responsible stewardship of public funds. Mr. Grant worked 25 years at NIH, serving as director of the Office of Policy for Extramural Research Administration before he went to Stanford University as associate vice president for research administration. He returned to Washington, D.C., on a dual assignment at the National Science Foundation and the White House Office of Science and Technology Policy, where he worked with all federal research agencies to streamline and facilitate multidisciplinary and interdisciplinary research. Mr. Grant was later vice president for research administration of Partners HealthCare, one of the nation's leading biomedical research organizations with approximately $1 billion of research support. He has received many honors and awards for research administration, including appointment to the Federal Senior Executive Service, the Society of Research Administrators Distinguished Contribution to Research Administration award, and the Association

of Independent Research Institutes (AIRI) Public Service Award. He now consults with universities on matters of grant opportunities, research policy, regulation, and compliance.

JOSEPH R. HAYWOOD, Ph.D., is Professor of Pharmacology and Toxicology and Assistant Vice President for Regulatory Affairs at Michigan State University (MSU). Dr. Haywood received his Ph.D. at the University of Florida and did post-doctoral work at the Cardiovascular Center at the University of Iowa. He rose through the ranks at the University of Texas Health Science Center at San Antonio before joining the Department of Pharmacology and Toxicology at MSU as professor and chair in 2002. In 2008 he became assistant vice president for regulatory affairs and remained as department chair until 2011. Dr. Haywood's research interests have been in the area of neurohumoral control of arterial pressure, especially in experimental models of hypertension. He has focused on the action of circulating hormones and diet on neurotransmitter control in the hypothalamus in regulating the sympathetic nervous system.

Dr. Haywood is a former president of Federation of American Societies for Experimental Biology (FASEB). In 2012, he served as FASEB vice president for science policy and has also served as chair of FASEB's Animals in Research and Education Subcommittee and Public Affairs Committee. Dr. Haywood is an active member of two FASEB societies. He is a member of the American Physiological Society and has served on its Council, and he is a member of the American Society for Pharmacology and Experimental Therapeutics. He has also been active in the leadership of the American Heart Association Council for High Blood Pressure Research. Dr. Haywood has served on the Council on Accreditation for the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and the Board of Governors of the International Council for Laboratory Animal Science (ICLAS). He co-chaired the committee that revised the CIOMS-ICLAS International Guiding Principles for the use of Animals in Research.

STEVEN JOFFE, MD, MPH, is the Emanuel and Robert Hart Associate Professor of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School. He serves as vice chair of the department and directs the Fellowship in Advanced Biomedical Ethics. He is also associate professor of pediatrics at the Perelman School of Medicine. Dr. Joffe attended Harvard College, received his medical degree from the University of California, San Francisco (UCSF), and received his public health degree from the University of California, Berkeley. He trained in pediatrics at UCSF and undertook fellowship training in pediatric hematology/oncology at the Dana-Farber Cancer Institute and Boston Children's Hospital. His clinical work is in the area of stem cell transplantation in children. His research addresses the many ethical challenges that arise in the conduct of clinical and translational investigation, both in pediatric oncology and other areas of medicine and science. He has led studies that examine the

roles and responsibilities of principal investigators in multicenter randomized trials, accountability in the clinical research enterprise, return of individual genetic results to participants in epidemiologic cohort studies, the integration of genomic sequencing technologies into the clinical care of cancer patients, and the governance of learning activities within learning health care systems. He currently serves as chair of the Children's Oncology Group Bioethics Committee and as a member of the U.S. Food and Drug Administration's (FDA) Pediatrics Ethics Subcommittee. In addition, he recently completed a term as a member of the Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections (SACHRP).

DAVID KORN (NAM), MD, Harvard University, is professor of pathology of Massachusetts General Hospital and Harvard Medical School. From November 15, 2008, to June 30, 2011, he was the inaugural vice provost for research at Harvard University. Prior to joining Harvard, Dr. Korn had served as the chief scientific officer of the Association of American Medical Colleges (AAMC) in Washington, D.C., since January 15, 2007, and before that as the senior vice president for biomedical and health sciences research at the association since September 1, 1997.

Dr. Korn served as Carl and Elizabeth Naumann Professor and Dean of the Stanford University School of Medicine from October 1984 to April 1995, and as vice president of Stanford University from January 1986 to April 1995. Previously, he had served as professor and founding chairman of the Department of Pathology at Stanford, and chief of the Pathology Service at the Stanford University Hospital, since June 1967. Dr. Korn has been chairman of the Stanford University Committee on Research; president of the American Association of Pathologists (now the American Society for Investigative Pathology), from which he received the Gold-Headed Cane Award for lifetime achievement in 2004; president of the Association of Pathology Chairs, from which he received the Distinguished Service Award in 1999; a member of the Board of Directors and of the Executive Committee of the Federation of American Societies for Experimental Biology; and a member of the Board of Directors of the Association of Academic Health Centers.

Dr. Korn served on the Board of Directors of the Stanford University Hospital from October 1982 to April 1995, the Children's Hospital at Stanford from October 1984 to its closure, and the Lucile Salter Packard Children's Hospital at Stanford from October 1984 to April 1995. He was a member of the Board of Directors of the California Society of Pathologists from 1983 to 1986. Dr. Korn has been a member of the editorial boards of the *American Journal of Pathology*, *The Journal of Biological Chemistry*, and *Human Pathology*, and for many years was an associate editor of the latter. He has sat on many society councils and boards. His nearly 200 publications range from bacteriophage biochemistry and genetics to the biochemistry and molecular biology of DNA replication in

human cells, and more recently, concern issues of academic values and integrity, research integrity, health and science policy, and financial conflicts of interest in academic medicine.

CHARLES F. LOUIS, Ph.D., is professor of neuroscience and cell biology emeritus at the University of California, Riverside, and former vice chancellor for research. Dr. Louis previously served as vice president for research at Georgia State University and served on the faculty at the University of Minnesota for more than 20 years, where he held a number of administrative positions that included head of the Department of Biochemistry, Molecular Biology and Biophysics from 1998 to 2000 and assistant vice president for research and associate dean of the Graduate School from 1994 to 1998. He previously held faculty appointments at the University of Connecticut Health Center and Leeds University in England.

Dr. Louis's biomedical research on the role of calcium as an intracellular signaling molecule, which was funded by the National Institutes of Health for more than 25 years, used a range of different approaches, including cell physiology, molecular biology, biochemistry, cell biology, and biophysics. Dr. Louis is former chair of the Executive Committee of the Council of Research Policy and Graduate Education (CRPGE) of the Association of Public and Land-grant Universities (APLU), and a member of the Boards of Directors of APLU and the Council on Government Relations (COGR); he has served on many peer-review grant committees as well as the boards of biotech industry associations in both Minnesota and Georgia. Dr. Louis received his B.A. in chemistry from Trinity College, Dublin, Ireland, his Ph.D. in biochemistry from Oxford University, and postdoctoral training at Stanford University.

DAVID W. ROBINSON, Ph.D., is currently professor and executive vice provost at Oregon Health and Science University (OHSU) in Portland, Oregon. He obtained a BSc in physiology at University College London and a Ph.D. at Cambridge University. In 1992 he moved to the United States to do postdoctoral training at the University of California, Davis, where he subsequently became a research track faculty member before moving to OHSU in 1997.

Dr. Robinson's research interests have been directed toward gaining a better understanding of the role retinal development plays in the maturation of the circadian and visual systems. Dr. Robinson also led the OHSU participation in the NCRR funded eagle-i Consortium, which was established to build a prototype of a national research resource discovery network to help biomedical scientists search for and find previously invisible, but highly valuable, research resources. He currently is the program director for the HRSA-funded Oregon Area Health Education Center at OHSU.

Dr. Robinson holds a faculty appointment as professor in the Department of Physiology and Pharmacology with joint appointments in the Department of Ophthalmology and the Oregon Institute of Occupational Health Science. At OHSU, Dr. Robinson's administrative work began as the senior technology advisor for research and education in 2000. Subsequent to that, he served as vice provost for academic technology (2006), director of educational communications (2006), interim university librarian (2008), vice provost for academic technology and information services (2008), interim provost for education and research (2009), and interim provost and vice president for academic affairs (2010) before receiving his current appointment in 2011. Dr. Robinson has also been the OHSU faculty representative to the Federal Demonstration Partnership since 2002. In 2008, Dr. Robinson was elected for a 3-year term to the position of vice chair and, as a member of the Executive Committee, continues to work closely with senior staff members from the FDP's Federal Agency partners, the Office of Science and Technology Policy, and the National Academies to improve the administrative processes involved with receiving funding from the federal government.

THOMAS J. ROSOL, DVM, Ph.D., is professor of veterinary biosciences at The Ohio State University. He served as the senior associate and interim senior vice president for research (2002–2005) and dean of the College of Veterinary Medicine (2005–2008) at The Ohio State University. Dr. Rosol currently serves as a senior advisor of life sciences for the university's Office of Technology Commercialization and Knowledge Transfer.

Dr. Rosol served on advisory boards to the National Institutes of Health, Department of Agriculture, American Veterinary Medical Association, and Morris Animal Foundation. He is a consultant for industry in preclinical safety, toxicology, and animal models of cancer.

The Rosol laboratory investigates the pathogenesis of animal models of human cancer, mechanisms and treatment of bone metastasis, and endocrine-responsive cancers, and has been funded by the National Institutes of Health for 30 years. Recent work focuses on prostate, breast, head, and neck cancer, and lymphoma. Dr. Rosol has more than 280 publications and served as the mentor for 23 Ph.D. students and 20 postdoctoral trainees. The laboratory specializes in molecular investigations and mouse and dog in vivo studies using state-of-the-art imaging using bioluminescence, microCT, high-resolution ultrasound, MRI, and PET. Dr. Rosol is a fellow of the American Association for the Advancement of Science and was recognized by Ohio State University as a Distinguished Scholar, which is one of the universities' highest honors. In 2015, Dr. Rosol was awarded the Annual Distinguished Mentor Award from the Society of Toxicologic Pathologists.

STUART SHAPIRO is an associate professor and director of the Public Policy Program at the Bloustein School of Planning and Policy at Rutgers University. He studies the process by which the federal government and the states issue regulations. His particular interest is the role that economics, science, and most importantly, politics play in regulatory decision making. In his 2016 book, *Analysis and Public Policy: Successes, Failures, and Directions for Reform*, he looked at the role that various types of analysis played in regulatory decisions. He found that politics, law, bureaucracy, and the limits of analysis itself placed bounds on the role of analysis but that, within these bounds, there was room for analytical influence on policy.

Dr. Shapiro also has a particular interest in cost-benefit analysis and teaches that subject to masters in public policy students. Before coming to Rutgers, he worked for the Office of Information and Regulatory Affairs in Washington, D.C., from 1998 to 2003, analyzing regulations from the Departments of Labor, Health and Human Services, Veterans Affairs, and numerous other agencies. He continues to be engaged in federal regulatory policy and has served as a consultant for the Administrative Conference of the United States.

STAFF

ANNE-MARIE MAZZA, Ph.D., is the senior director of the Committee on Science, Technology, and Law. Dr. Mazza joined the National Academies in 1995. She has served as senior program officer with both the Committee on Science, Engineering, and Public Policy and the Government-University-Industry Research Roundtable. In 1999 she was named the first director of the Committee on Science, Technology, and Law, a newly created activity designed to foster communication and analysis among scientists, engineers, and members of the legal community. Dr. Mazza has been the study director on numerous Academy activities and reports, including *International Summit on Human Gene Editing: A Global Discussion* (2016); *Identifying the Culprit: Assessing Eyewitness Identification* (2014)*; Positioning Synthetic Biology to Meet the Challenges of the 21st Century* (2013)*; Reference Manual on Scientific Evidenc*e, 3rd Edition (2011); *Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 Anthrax Letters* (2011); *Managing University Intellectual Property in the Public Interest* (2010); *Strengthening Forensic Science in the United States: A Path Forward* (2009); *Science and Security in A Post 9/11 World* (2007); *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (2005); and *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues* (2004). Between October 1999 and October 2000, Dr. Mazza divided her time between the National Academies and the White House Office of Science and Technology Policy, where she served as a senior policy analyst responsible for issues associated with a Presidential Review Directive on the government-

university research partnership. Before joining the Academy, Dr. Mazza was a senior consultant with Resource Planning Corporation. She is a fellow of the American Association for the Advancement of Science. Dr. Mazza was awarded a B.A., M.A., and Ph.D. from George Washington University.

THOMAS RUDIN is the director of the Board on Higher Education and Workforce at the National Academies—a position he assumed in mid-August 2014. Prior to joining the National Academies, Mr. Rudin served as senior vice president for career readiness and senior vice president for advocacy, government relations, and development at the College Board from 2006 to 2014. He was also vice president for government relations from 2004 to 2006 and executive director of grants planning and management from 1996 to 2004 at the College Board. Before joining the College Board, Mr. Rudin was a policy analyst at the National Institutes of Health in Bethesda, Maryland.

In 1991, Mr. Rudin taught courses in U.S. public policy, human rights, and organizational management as a visiting instructor at the Middle East Technical University in Ankara, Turkey. In the early 1980s, he directed the work of the Governor's Task Force on Science and Technology for North Carolina Governor James B. Hunt, Jr., where he was involved in several new state initiatives, such as the North Carolina Biotechnology Center and the North Carolina School of Science and Mathematics. He received a bachelor of arts degree from Purdue University, and he holds master's degrees in public administration and in social work from the University of North Carolina at Chapel Hill.

ELIZABETH O'HARE, Ph.D., was formerly a program officer with the Board on Higher Education and Workforce at the National Academies of Sciences, Engineering, and Medicine. Her portfolio included projects that addressed STEM workforce development, the higher education regulatory environment, and the competitiveness of American research universities. Dr. O'Hare left the National Academies in January 2016 to join Lewis-Burke Associates, a government relations firm specializing in advocating for the policy interests of higher education institutions and other research and education organizations. Prior to joining the National Academies, Dr. O'Hare served as a legislative assistant for Representative Rush Holt (NJ-12), where she handled energy, science, and education policy issues and staffed Rep. Holt in his role as the Senior Democrat on the Energy and Mineral Resources Subcommittee, House Committee on Natural Resources. Dr. O'Hare got her start in science policy after being selected by the Society for Research in Child Development as a 2010 American Association for the Advancement of Science (AAAS) Congressional Science Policy Fellow. She holds a Ph.D. in neuroscience from the University of California, Los Angeles, and an AB in psychology from Bryn Mawr College.

STEVEN KENDALL, Ph.D., is program officer for the Committee on Science, Technology, and Law. Dr. Kendall has contributed to numerous Academy reports, including *International Summit on Human Gene Editing: A Global Discussion* (2016); *Identifying the Culprit: Assessing Eyewitness Identification* (2014); *Positioning Synthetic Biology to Meet the Challenges of the 21st Century* (2013); the *Reference Manual on Scientific Evidenc*e, 3rd Edition (2011); *Review of the Scientific Approaches Used During the FBI's Investigation of the 2001 Anthrax Mailings* (2011); *Managing University Intellectual Property in the Public Interest* (2010); and *Strengthening Forensic Science in the United States: A Path Forward* (2009). Dr. Kendall completed his Ph.D. in the Department of the History of Art and Architecture at the University of California, Santa Barbara, where he wrote a dissertation on 19th century British painting. Dr. Kendall received his M.A. in Victorian art and architecture at the University of London. Prior to joining the National Research Council in 2007, he worked at the Smithsonian American Art Museum and The Huntington in San Marino, California.

NINA BOSTON is a research associate in the Policy and Global Affairs (PGA) Division at the National Academies of Sciences, Engineering, and Medicine. Ms. Boston supports the InterAcademy Partnership and the Development, Security, and Cooperation unit. She formerly supported the Board on Higher Education and Workforce. She has a B.A. in anthropology from Elon University and is currently pursuing an MPP from the University of Maryland School of Public Policy.

KAROLINA KONARZEWSKA is program coordinator for the Committee on Science, Technology, and Law. She is a master's student of economics at George Mason University. She holds a master's degree in international relations from New York University and a bachelor's degree in political science from the College of Staten Island, City University of New York. Prior to joining the National Academies, she worked at various research institutions in Washington, D.C., where she covered political and economic issues pertaining to Europe, Russia, and Eurasia.

Appendix B

Recommendations Table

OVERARCHING RECOMMENDATIONS	
RECOMMENDATION ONE:	The regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated.
RECOMMENDATION TWO:	To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, postdoctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community. Universities that deviate from or fail to enforce the norms of behavior should be sanctioned. The committee recommends that a newly established Research Policy Board (see Recommendation 7.1 below) should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions.
RECOMMENDATION THREE:	Inspectors general responsibilities should be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness. The relationship between inspectors general and research institutions should be based on a shared commitment to advancing the nation's interest through a dynamic and productive research enterprise.
RECOMMENDATION FOUR:	The committee recommends the creation of a new mechanism, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies (see Recommendations 7.1 and 7.2 below).
SPECIFIC RECOMMENDATIONS	
Topic:	*Proposal Preparation*
Policy / Statute / Regulation(s):	Specific Agency Requirements
Affected Parties:	Institutional Researchers Research Agencies
Actors:	Congress White House Office of Management and Budget Federal Agencies Funding Research
Relevant Report Section:	Part 1, Chapter 4
Recommended Actions:	4.1. The committee recommends that Congress, in concert with the White House Office of Management and Budget, conduct a transparent and comprehensive review of agency research grant proposal documents for the purpose of developing a uniform format to be used by all research funding agencies.

	4.2. The committee recommends that research proposal information should be limited to the minimal information necessary to permit peer evaluation of the merit of the scientific questions being asked, the feasibility of answering those questions, and the ability of the researcher/research team to carry out that research. For proposals demonstrating these characteristics, any supplementary information should, if requested, be provided *just-in-time*. 4.3. The committee recommends that research agencies develop a central repository to house assurances similar to the Single Audit Clearinghouse of the Federal Demonstration Partnership (FDP). 4.4. The committee recommends that Congress task a single agency with overseeing and unifying efforts to develop a central database of investigator information.
Topic:	*Progress Reporting*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Party:	Federal Agencies Funding Research
Actor:	White House Office of Management and Budget
Relevant Report Section:	Part 1, Chapter 4
Recommended Action:	4.5. The committee recommends that the White House Office of Management and Budget require that research funding agencies use a uniform format for research progress reporting.
Topic:	*Subrecipient Monitoring*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Party:	Institutional Administrators
Actor:	White House Office of Management and Budget
Relevant Report Section:	Part 1, Chapter 4
Recommended Action:	4.6. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education only to the extent necessary for prudent project and performance monitoring, and do not require more extensive monitoring of subrecipients' institutional compliance with all federal statues, regulations, policies, and institution-wide business practices.

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	As an immediate, interim measure, the committee recommends that the Office of Management and Budget permit research institutions to use subrecipients' publicly available Single Audit Reports to verify that subrecipients have not been otherwise debarred or suspended with respect to the receipt of federal funds. For those with a clean Single Audit Report, the prime institution should be allowed to rely on the Single Audit Act oversight process as an alternative to conducting a review of the adequacy of the subrecipient's institutional systems and business practices.
Topic:	*Conflicts of Interest*
Policy / Statute / Regulation(s):	Public Health Service Regulations[1]: 42 CFR Part 50, Subpart F (2011) NSF Grants Policy Manual, NSF 05-131 (2005)[2] Uniform Guidance[3]: 2 CFR Part 200 (2013)
Affected Parties:	Institutional Researchers Institutional Administrators
Actors:	Congress White House Office of Science and Technology Policy Research Institutions Federal Agencies Funding Research
Relevant Report Section:	Part 1, Chapter 5
Recommended Action:	5.1. The committee recommends that Congress, in concert with the White House Office of Science and Technology Policy and in partnership with research institutions, develop, within the upcoming fiscal year, a federal-wide financial conflicts of interest policy to be used by all research funding agencies.

[1]Public Health Service Agencies include: National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Health Resources and Services Administration (HRSA), and Indian Health Service (IHS)

[2]While the NSF adopted the 1995 PHS FCOI regulations, the agency chose not to adopt the changes in the new 2012 PHS FCOI regulation. Thus the NSF's policy is essentially identical to the former PHS policy.

[3]The Uniform Guidance applies to all federal agencies.

Topic:	*Human Subjects Research*
Policy / Statute / Regulation(s):	The Common Rule, codified at Protection of Human Subjects, 45 CFR 46 (2009). FDA Regulations "Federal Policy for the Protection of Human Subjects," Federal Register 80, no. 173 (September 8, 2015): 53933
Affected Parties:	Institutional Researchers Institutional Administrators Human Research Participants
Actors:	Congress The 18 Federal Agencies Following the Common Rule[4]
Relevant Report Sections:	Part 1, Chapter 5 Part 2, Chapter 9
Recommended Actions:	5.2. The committee recommends that Congress direct federal agencies following the Common Rule to institute a risk-stratified system of human subjects protections that substantially reduces regulatory burden on minimal-risk research while reserving more intensive regulatory oversight for higher risk research. 5.3. The committee recommends that Congress direct federal agencies following the Common Rule to require, for multisite research studies, that a single IRB with the necessary staff and infrastructure serve as the IRB of record for all domestic sites. 5.4. The committee recommends that Congress direct agencies, within a designated period of time, to align and harmonize their regulations (and definitions) concerning the protection of human subjects. 5.5. In instances of minimal-risk research where requiring informed consent would make the research impracticable, the committee recommends that Congress amend the FDA's authority so as to allow the FDA to develop criteria for waiver or modification of the requirement of informed consent for minimal-risk research. 5.6. The committee recommends that Congress instruct HHS to work with other agencies to ensure that research involving biospecimens is eligible for a waiver or modification of informed consent, so long as the proposed research meets the conditions for waiver or modification of informed consent as specified in the Common Rule.

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[4]These 18 agencies include: Departments of Agriculture, Defense, Education, Energy, Health & Human Services, Homeland Security, Housing & Urban Development, Justice, Transportation, Veterans Affairs, Consumer Product Safety Commission, Environmental Protection Agency, Agency for International Development, National Aeronautics & Space Administration, and the National Science Foundation.

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	9.1. The committee recommends that Congress authorize, and the President appoint, an independent, free-standing national commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. This commission was authorized by Congress under Public Law 95-622 in 1978, appointed by the President in 1979, and existed outside the structure of federal departments and agencies. The commission had a direct line-item appropriation from Congress, appointed its own staff, and set its own agenda. Congress should charge the proposed commission with examining and updating as necessary the ethical, legal, and institutional frameworks governing human subjects research. The commission should make recommendations to the President, Congress, and relevant federal agencies regarding how the basic ethical principles governing human subjects research should be applied to unresolved human research questions and novel human research contexts. The commission should have two broad charges: a. Recommend to the President and Congress ethically sound regulatory approaches for unresolved questions in human subjects research. b. Recommend to the President and Congress revisions in the legal and institutional structures for regulating research with human subjects. 9.2. To ensure that the proposed national commission can address the full range of unanswered questions regarding the protection of human subjects in federally funded research, the committee recommends that the executive branch withdraw the Notice of Proposed Rulemaking on the Federal Policy for the Protection of Human Subjects. The committee further recommends that the regulatory structure protecting human research subjects not be revised until the national commission has issued its report and the research community, patient groups, the public, and others have had an opportunity to consider and respond to the commission's recommendations.
Topic:	*Animal Research*[5]
Policy / Statute / Regulation(s):	The Laboratory Animal Welfare Act. Pub. L. No. 89-544 (1966); Animal Welfare Act Amendments of 1976, 7 USC, 2131-2159 (1976); 9 CFR Chapter 1, subchapter A, part 2 (2016); Health Research Extension Act of 1985. Pub. L. No. 99-158 (1985); Plan for Use of Animals in Research, 42 USC § 283E (1999; and Animals in Research, 42 USC § 289D (2010)

[5]The policies and statutes listed here are just a sampling of the many that govern the use of animals in research. For a more complete listing of the statutes, policies, principles, agency directives, and reference manuals that govern the use of animals in research, see Table 5-1 on pages 107-109 on Part I of this report.

	U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training Public Health Service Policy on Humane Care and Use of Laboratory Animals
Affected Parties:	Institutional Researchers Institutional Administrators
Actors:	Congress White House Office of Science and Technology Policy Federal Agencies Funding Animal Research Institutional Researchers Conducting Animal Research Research Institutions
Relevant Report Section:	Part 1, Chapter 5
Recommended Actions:	5.7. The committee recommends that Congress direct the White House Office of Science and Technology Policy to convene within one fiscal year representatives from federal agencies that fund animal research and representatives from the research community to assess and report back to Congress on the feasibility and utility of developing a unified federal approach for the development, promulgation, and management of policies and regulations pertaining to the care and use of research animals. 5.8 The committee recommends that reporting, assurances, and verifications to agencies should be reduced and streamlined. Agencies should adjust their requirements for reporting such that animal-related noncompliance reports are tiered to the level of significance or impact on animals and included in an annual report rather than submitted on an individual event basis. Annual reports to individual agencies about animal care programs should be replaced by a single annual report under the proposed Federalwide Assurance mechanism. Processes that are redundant to the IACUC approval process, such as the Vertebrate Animal section of PHS grant applications and the DOD central administrative protocol review, should be eliminated. 5.9. The committee recommends that research institutions should assess their own regulatory processes to determine where their compliance activities can be streamlined to ensure effective use of indirect research recovery costs, while still meeting the requirements of federal regulations.
Topic:	*Audits and Audit Climate*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)

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Affected Parties:	Inspectors General Agency Heads Institutional Researchers Institutional Financial Officers
Actors:	Congress Inspectors General Federal Agencies
Relevant Report Section:	Part 1, Chapter 6
Recommended Actions:	6.1. The committee recommends that Congress require inspectors general to: • Resolve issues regarding their interpretation of agency policies and priorities with the agency before conducting formal audits of research institutions, except for those situations in which the audit itself is directed toward inconsistent agency policy interpretations; • Include in their semi-annual reports, publish on their web sites, and highlight in their presentations to Congress examples of effective, innovative, and cost-saving initiatives undertaken by research institutions and federal research agencies that both advance and protect the research enterprise; • Provide to Congress, and make publicly available, information generated each year on the total costs (agency and institutional costs) of inspectors general audits of research institutions, the total amounts of initial findings, the total amounts paid by institutions after audit resolution, and any significant management, technology, personnel, and accountability steps taken by research institutions as the result of a completed audit; • Reexamine the risk-based methodology in identifying institutions as candidates for offices of inspectors general audits to take into account the existing compliance environment/oversight on campuses, recognizing that many research institutions have clean Single Audits, are well-managed, and have had long-standing relationships with the federal government; and • Encourage all federal inspectors general to report only final audit resolution findings on their websites and in their semi-annual reports to Congress.
Topic:	*Reporting of Compensation for Personnel Expenses*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Parties:	Institutional Researchers Institutional Financial Officers
Actors:	Congress White House Office of Management and Budget

Relevant Report Section:	Part 1, Chapter 6
Recommended Action:	6.2. The committee recommends that Congress and OMB affirm that research institutions may take advantage of the flexibility provided by the Uniform Guidance with regard to the documentation of personnel expenses.
Topic:	Procurement Standards
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Parties:	Institutional Researchers Institutional Financial Officers
Actor:	White House Office of Management and Budget
Relevant Report Section:	Part 1, Chapter 6
Recommended Action:	6.3. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance as follows: • Amend Section 200.329 to read: "Procurement by micro-purchases. Procurement by micro-purchase is the acquisition of supplies or services on a purchase order from a single vendor, the aggregate dollar amount of which does not exceed $10,000 (or $2,000 in the case of acquisitions for construction subject to the Davis-Bacon Act). OMB shall periodically revisit and adjust the $10,000 threshold to account for escalating costs of supplies and services." • Add the following sentence to the list of criteria for the permissible purchase of supplies and services through non-competitive bids (Section 200.320): "The procurement is necessary for research, scientific, or other programmatic reasons, such as instances where the purchase is for a specialized service or of a necessarily quality that is only available from a single vendor, or if only one vendor can deliver in the required time frame."
Topic:	*Financial Reporting*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Parties:	Institutional Researchers Institutional Financial Officers
Actor:	White House Office of Management and Budget
Relevant Report Section:	Part 1, Chapter 6
Recommended Action:	6.4. The committee recommends that White House Office of Management and Budget amend the Uniform Guidance to establish a mandatory 120 day timetable for the submission of all financial reports for all federal research funding agencies.

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Topic:	*Cost Accounting Standards*
Policy / Statute / Regulation(s):	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)
Affected Parties:	Institutional Researchers Institutional Financial Officers
Actor:	White House Office of Management and Budget
Relevant Report Section:	Part 1, Chapter 6
Recommended Action:	6.5. The committee recommends that the White House Office of Management and Budget amend the Uniform Guidance so that research universities are not required to submit a revised Cost Accounting Disclosure Statement (DS-2) each time they change their accounting practices, as long as those practices are in compliance with the Uniform Guidance and are posted promptly on the universities' web sites. Rather, the initial disclosure statement and revisions to it should be submitted to the research institution's cognizant agency in coordination with the institution's F&A proposal.
Topic:	*Intellectual Property and Technology Transfer*
Policy / Statute / Regulation(s):	Reporting on Utilization of Subject Inventions, 37 CFR 401.8
Affected Parties:	Institutional Researchers Federal Agencies Funding Research
Actors:	Congress National Institute of Standards and Technology
Relevant Report Section:	Part 2, Chapter 10
Recommended Actions:	The committee recommends that Congress: 10.1 Congress transfer responsibility for the operation of the invention report system (currently iEdison) to the Department of Commerce and allocate appropriate resources to the department for upgrading the invention reporting system so as to create a user-friendly interface for the input of data on inventions. `10.2The Department of Commerce, in consultation with the proposed Research Policy Board, should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act. 10.3. Authorize the Department of Commerce to require that the invention data reporting obligations imposed on recipients of federal funding by all agencies are aligned with agreed upon reporting requirements.

Topic:	*Select Agents and Toxins and Dual-Use Research of Concern*
Policy / Statute / Regulation(s):	Possession, Use and Transfer of Select Agents and Toxins, 7 CFR 331 (2005) Possession, Use and Transfer of Select Agents and Toxins, 9 CFR 121 (2005) Select Agents and Toxins, 42 CFR 73 (2005)
Affected Parties:	Institutional Researchers Federal Agencies Funding Research
Actors:	Executive Branch Federal Select Agent Program Federal Agencies Funding Research
Relevant Report Section:	Part 2, Chapter 11
Recommended Actions:	11.1. The committee recommends that the President assign the responsibility for regulating all microbes and toxins on the select agents and toxins list to a single agency.[6] 11.2. The committee recommends that the Federal Select Agent Program develop and promulgate a reasonable inventory management system for biological select agents and toxins that takes account of the living, self-replicating nature of biological agents. 11.3. The committee recommends that the regulations[7] governing select agents and toxins be amended to: a. Allow researchers to more readily access relevant select agents in times of public health emergencies. b. Increase the number of lower virulence strains of select biological agents available to researchers. c. Make more transparent the process by which materials are added to and removed from the select agents and toxins list.
Topic:	*Export Controls*
Policy / Statute / Regulation(s):	Export Control Reform Initiative

(Continued)

[6] The proposed Research Policy Board could take a leadership role in discussions about which agency should have responsibility for the regulation of the microbes and toxins on the select agents and toxins list.

[7] Possession, Use and Transfer of Select Agents and Toxins, 7 CFR 331 (2005); Possession, Use and Transfer of Select Agents and Toxins, 9 CFR 121 (2005); and Select Agents and Toxins, 42 CFR 73 (2005).

Continued

Affected Parties:	Institutional Researchers Department of Commerce Department of State
Actors:	Congress Executive Branch
Relevant Report Section:	Part 2, Chapter 12
Recommended Actions:	12.1. The committee recommends that Congress and the Administration support a robust continuation and renewal of the Export Control Reform Initiative. Even under current statutes, the initiative has the potential to make further, marked improvements (e.g., to the regulations, oversight process, and ease of compliance) that would bring significant benefits to national security, to commerce, and to the economy, as well as to federally funded university research. The lessons learned in the initiative over the past five years could help participants in the process accelerate the rate at which needed regulatory revisions are proposed and adopted. 12.2. The committee recommends that the Export Control Reform Initiative seek university input at all stages of the process. The Research Policy Board proposed in Part 1 of this committee's report would be an ideal vehicle for providing such input. 12.3. The committee recommends that the Export Control Reform Initiative work closely with universities and other stakeholders to specifically address the deemed export provisions[8] and vigorously support the spirit and letter of the fundamental research exclusion.
Topic:	*Regulatory Framework*
Policy / Statute / Regulation(s):	Requires New Legislation / Executive Action
Affected Parties:	Office of Information and Regulatory Affairs, White House Office of Management and Budget White House Office of Science and Technology Policy
Actor:	Congress
Relevant Report Section:	Part 1, Chapter 7

[8]As recommended by the report *The Deemed Export Rule in the Era of Globalization* [U.S. Deemed Export Advisory Committee, *The Deemed Export Rule in the Era of Globalization* (Washington, DC: U.S. Department of Commerce, 2007)].

Recommended Action:

7.1. The committee recommends the creation of a new mechanism, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research regulations of similar purposes across agencies.

Specifically, the committee recommends that Congress take the following actions:

- Establish a new entity, a Research Policy Board. The RPB would be a self-funded, government linked entity serving as the primary policy forum for discussions relating to the regulation of federally funded research programs in academic research institutions.
- Establish a new Associate Director, Academic Research Enterprise, in the White House OSTP, having responsibilities to:
  a. serve as one of two principal federal contact points for the RPB;
  b. oversee and facilitate the general health of the government-academic research partnership;
  c. work in partnership with OMB-OIRA to manage the overall regulatory burden; and
  d. jointly with the Administrator of OIRA, issue an annual report to Congress on regulatory issues and actions affecting the research partnership.

7.2. The committee recommends that participants in the government-academic research partnership adopt the…set of operational principles [articulated on pp. 14-15 of this report] as a part of the new regulatory framework for federally funded academic research.

The committee recommends that research institutions conduct a review of institutional policies developed to comply with federal regulations of research to determine whether the institution itself has created excessive or unnecessary self-imposed burden (see Chapter 7).

The committee recommends that research institutions revise self-imposed burdensome institutional policies that go beyond those necessary and sufficient to comply with federal, state, and local requirements (see Chapter 7).

Appendix C

Committee Meeting Agendas

MEETING 1
WASHINGTON, DC
FEBRUARY 12-13, 2015

THURSDAY, FEBRUARY 12, 2015

OPEN SESSION

10:15 am	Welcome and Opening Remarks
	Chair: Larry R. Faulkner, The University of Texas at Austin Vice Chair: Harriet Rabb, The Rockefeller University
10:30	Charge to the Committee
	Speaker: Jamienne S. Studley, U.S. Department of Education
11:00	Reforming Regulation and Reporting Requirements
	Speakers: Tobin L. Smith, Association of American Universities Lisa Nichols, Council on Governmental Relations Howard Gobstein, Association of Public and Land-Grant Universities
12:15 pm	Lunch
1:30	Reducing Investigators' Administrative Workload for Federally Funded Research: A Report from the National Science Board
	Speaker: Arthur I. Bienenstock, Stanford University

2:15 Regulations and Reporting Requirements Governing the Biomedical Research Enterprise

Speaker:
Yvette R. Seger, Federation of American Societies for Experimental Biology

2:45 Adjourn

FRIDAY, FEBRUARY 13, 2015

OPEN SESSION

8:30 am Continental Breakfast

9:00 Welcome and Opening Remarks

Chair:
Larry R. Faulkner, The University of Texas at Austin
Vice Chair:
Harriet Rabb, The Rockefeller University

9:15 Regulations and Reporting Requirements of Special Concern to Medical Schools

Speakers:
Heather H. Pierce, Association of American Medical Colleges
Stephen J. Heinig, Association of American Medical Colleges

9:45 Administration of Federal Research Grants and Contracts

Speaker:
Cynthia Hope, The University of Alabama and Federal Demonstration Partnership

10:15 Adjourn

MEETING 2
WASHINGTON, DC
APRIL 16-17, 2015

THURSDAY, APRIL 16, 2015

OPEN SESSION

8:30 Continental Breakfast

9:00	Welcome and Introductions / Meeting Overview
	Chair: Larry R. Faulkner, The University of Texas at Austin Vice Chair: Harriet Rabb, The Rockefeller University
9:15	Discussion with White House Office of Science and Technology Policy and Office of Information and Regulatory Affairs
	Speakers: Kei Koizumi, White House Office of Science and Technology Policy Howard Shelanski, White House Office of Information and Regulatory Affairs
10:30	Research Agency Panel I
	Speakers: Richard Buckius, National Science Foundation Marty Rubenstein, National Science Foundation Jean Feldman, National Science Foundation
11:45	Lunch
1:00 pm	Research Agency Panel II
	Speakers: Robin Staffin, U.S. Department of Defense Patrick Mason, U.S. Department of Defense Thomas Christian, Air Force Office of Scientific Research Walter Jones, Office of Naval Research
2:30	Break
2:45	Research Agency Panel III
	Speakers: Linda Blevins, U.S. Department of Energy Michael Zarkin, U.S. Department of Energy Ann Bartuska, U.S. Department of Agriculture Thomas Burke, U.S. Environmental Protection Agency

FRIDAY, APRIL 17, 2015

OPEN SESSION

8:30 am Continental Breakfast

9:00 Welcome and Opening Remarks

Chair:
Larry R. Faulkner, The University of Texas at Austin
Vice Chair:
Harriet Rabb, The Rockefeller University

9:15 Recalibrating Regulation of Colleges and Universities

Speaker:
William Kirwan, American Council on Education Task Force on Federal Regulation of Higher Education

10:00 Discussion with the National Science Foundation's Inspector General

Speaker:
Allison Lerner, National Science Foundation

MEETING 3
SAN FRANCISCO, CA
MAY 28-29, 2015

THURSDAY, MAY 28, 2015

OPEN SESSION

8:30 am Continental Breakfast

9:00 Welcome and Introductions

Chair:
Larry R. Faulkner, The University of Texas at Austin
Vice Chair:
Harriet Rabb, The Rockefeller University

9:15	Opening Remarks
	Speaker: Keith Yamamoto, University of California, San Francisco School of Medicine
9:45	University Panel I
	Speakers: Wendy Streitz, University of California Cindy Kiel, University of California, Davis Richard Seligman, California Institute of Technology
10:30	Discussion with Committee
11:15	Public Comments/Comments from the Floor
12:00 pm	Lunch
1:00	University Panel II
	Speakers: Mary Lidstrom, University of Washington Patrick Schlesinger, University of California, Berkeley
1:30	Discussion with Committee
2:15	Public Comments/Comments from the Floor

FRIDAY, MAY 29, 2015

OPEN SESSION

8:00 am	Continental Breakfast
8:30	Welcome and Opening Remarks
	Chair: Larry R. Faulkner, The University of Texas at Austin Vice Chair: Harriet Rabb, The Rockefeller University
8:45	University Panel III
	Speakers: Steven Beckwith, University of California

John Hemminger, University of California, Irvine
Randy Livingston, Stanford University

9:30 Discussion with Committee

10:00 Public Comments/Comments from the Floor

MEETING 4
WOODS HOLE, MA
JULY 6-8, 2015

MEETING CLOSED IN ITS ENTIRETY.

MEETING 5
WASHINGTON, DC
JULY 21-22, 2015

TUESDAY, JULY 21, 2015

OPEN SESSION

8:30 am Welcome and Introductions

Chair:
Larry R. Faulkner, The University of Texas at Austin
Vice Chair:
Harriet Rabb, The Rockefeller University

9:00 Vanderbilt Federal Regulatory Cost Study

Speakers:
Brett Sweet, Vice Chancellor for Finance and Chief Financial Officer, Vanderbilt University
Tejus Kothari, Principal, The Boston Consulting Group

10:00 Research Regulation (Policy and Guidance) at the National Institutes of Health

Speaker:
Sally J. Rockey, Deputy Director for Extramural Research, National Institutes of Health

11:00 OMB Perspective – The Future is NOW… for the Uniform Grant Guidance (2 CFR 200).

Speakers:
Gil Tran, Senior Policy Analyst, White House Office of Management and Budget
Daniel Werfel, former Controller, White House Office of Management and Budget

12:00 pm Lunch

1:00 Views from Accrediting Bodies

Speakers:
Christian E. Newcomer, Executive Director, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International
Sarah Kiskaddon, Director, Global Business Development and Public Affairs, Association for the Accreditation of Human Research Protection Programs (AAHRPP), Inc.

2:00 Department of Commerce Export Controls Impacting Academic Research

Speaker:
Kimberly Orr, Senior Biologist, Chemical and Biological Controls Division, Bureau of Industry and Security, U.S. Department of Commerce

2:30 Patient Research Advocacy

Speaker:
Frances Visco, President, National Breast Cancer Coalition

3:15 Perspectives from the U.S. Department of Health and Human Services' Office of the Inspector General

Speaker:
Julie K. Taitsman, Chief Medical Officer, Office of the Inspector General, U.S. Department of Health and Human Services

WEDNESDAY, JULY 22, 2015

OPEN SESSION

8:00 am Welcome and Introductions

Chair:
Larry R. Faulkner, The University of Texas at Austin

Vice Chair:
Harriet Rabb, The Rockefeller University

8:15 Breakfast Discussion with Senator Lamar Alexander (R-TN)

MEETING 6
HOUSTON, TX
OCTOBER 29-30, 2015

THURSDAY, OCTOBER 29, 2015

OPEN SESSION

8:30 am Continental Breakfast

9:00 Welcome and Introductions

Chair:
Larry R. Faulkner, The University of Texas at Austin
Vice Chair:
Harriet Rabb, The Rockefeller University

9:15 Opening Remarks

Speaker:
Paul Klotman, Baylor College of Medicine

9:45 Human Subjects Research and the Common Rule

Speakers:

Barbara Evans, University of Houston Law School
John Cornwell, Rice University
Ellen Wright Clayton, Vanderbilt University

10:30 Discussion with Committee

11:00 Break

11:15 Issues in Science and Security

Speakers:
Gerald Epstein, U.S. Department of Homeland Security (overview of DURC policy)
James W. Le Duc, Galveston National Laboratory, University of Texas Medical Branch, (select agents)

	David Ivey, University of Texas, Austin (export controls)
12:00 pm	Discussion with Committee
12:30	Comments from the Public
12:45	Lunch
1:45	Data Sharing HIPPA, Privacy, and Academic Research Speakers: Amy McGuire, Baylor College of Medicine Laura Beskow, Duke University
2:30	Discussion with Committee
3:30	Research Policy Board: A Discussion with Neal Lane Speaker: Neal Lane, Rice University
4:30	Comments from the Public
5:00	Adjourn

FRIDAY, OCTOBER 30, 2015

8:30 am	Continental Breakfast
9:00	Welcome Chair: Larry R. Faulkner, The University of Texas at Austin Vice Chair: Harriet Rabb, The Rockefeller University
9:15	Opening Remarks Speaker: David Leebron, Rice University
9:30	Discussion with Committee
10:00	Managing University Technology Transfer (Intellectual Property, Material Transfer Agreements, Licensing) Speakers:

Jilda Garton, Georgia Institute of Technology
Valerie McDevitt, University of South Florida

10:45 Discussion with Committee

11:15 Comments from the Public

12:00 pm Adjourn to Closed Session

MEETING 7
WASHINGTON, DC
JANUARY 14-15, 2016

THURSDAY, JANUARY 14, 2016

OPEN SESSION

1:00 pm Research Policy Board

Speaker:
Howard Shelanski, White House Office of Information and Regulatory Affairs

2:00 Break

2:15 Regulatory Framework for Human Subjects Research

Speaker:
Jeffrey R. Botkin, University of Utah (via videoconference)

3:15 Adjourn to Closed Session

FRIDAY, JANUARY 15, 2016

CLOSED SESSION

Appendix D

Federal Obligations for Science and Engineering to the 100 Universities and Colleges Receiving the Largest Amounts

TABLE 4. Federal obligations for science and engineering to the 100 universities and colleges receiving the largest amounts, ranked by the total amount received in FY 2013: FYs 2005–13
(Dollars in thousands)

Rank	Institution	2005	2006	2007	2008	2009[a]	2010[a]	2011	2012	2013
	All institutions	27,937,016.0	28,157,286.0	28,186,803.0	28,386,839.0	35,504,174.6	35,371,728.6	31,459,956.9	30,847,687.1	29,034,304.1
1	Johns Hopkins U.	1,182,277.0	1,239,503.0	1,162,196.0	1,115,411.0	1,513,904.1	1,599,409.2	1,672,208.0	1,606,900.5	1,538,502.6
2	U. WA	656,046.0	673,068.0	660,316.0	615,965.0	746,866.4	790,901.8	694,703.6	718,605.0	662,920.7
3	U. MI	516,320.0	565,121.0	549,399.0	587,193.0	771,468.6	743,530.5	694,653.7	674,228.1	609,859.1
4	U. CA, San Francisco	473,518.0	466,350.0	470,405.0	524,066.0	551,947.9	573,860.6	560,303.4	571,435.5	573,638.4
5	U. CA, San Diego	427,948.0	444,964.0	476,109.0	518,357.0	653,799.4	671,553.2	583,216.7	621,620.4	565,551.1
6	U. PA	557,961.0	532,610.0	536,396.0	519,703.0	664,576.7	663,325.2	551,527.3	533,791.8	540,124.2
7	Stanford U.	484,273.0	489,229.0	458,646.0	419,485.0	497,306.1	558,256.9	502,460.6	504,206.5	495,617.1
8	U. CA, Los Angeles	523,528.0	504,824.0	514,317.0	513,695.0	613,082.9	616,781.4	521,260.1	502,660.4	481,135.1
9	Columbia U. in the City of New York	460,131.0	566,335.0	547,591.0	438,888.0	561,545.3	552,513.7	490,265.4	510,402.7	477,051.2
10	U. Pittsburgh	427,071.0	442,524.0	447,443.0	430,490.0	541,369.7	548,900.8	494,269.3	518,820.8	465,624.9
11	Harvard U.	442,119.0	450,024.0	466,397.0	438,380.0	544,385.1	564,593.0	485,550.1	497,138.1	458,699.7
12	Duke U.	458,558.0	496,265.0	495,701.0	430,935.0	539,979.8	534,953.3	457,108.7	493,369.8	454,284.4
13	U. CO	366,908.0	371,695.0	362,936.0	358,640.0	463,414.1	492,890.7	443,395.2	443,048.7	448,386.8
14	U. NC, Chapel Hill	363,018.0	374,542.0	382,264.0	411,714.0	494,485.3	460,030.6	448,831.3	451,434.3	441,716.6
15	U. WI, Madison	476,673.0	473,508.0	435,874.0	455,767.0	599,277.6	528,988.8	479,600.9	472,408.6	440,354.1
16	Yale U.	384,170.0	389,947.0	417,835.0	419,807.0	481,232.0	508,044.8	449,577.3	434,000.7	412,470.3
17	U. MN	362,361.0	369,870.0	412,624.0	393,509.0	496,935.5	485,982.6	539,510.3	430,149.3	410,565.5
18	PA State U.	295,329.0	323,361.0	349,530.0	366,047.0	451,058.4	491,218.0	524,843.7	465,691.1	392,831.6
19	GA Institute of Technology	149,066.0	155,997.0	194,561.0	211,059.0	279,644.8	264,935.3	332,834.8	416,065.6	385,229.9
20	Vanderbilt U.	303,357.0	334,302.0	351,931.0	341,502.0	417,407.8	437,966.4	374,030.1	385,951.0	373,566.4
21	Washington U., St. Louis	427,789.0	434,013.0	438,079.0	425,623.0	492,997.9	485,009.3	408,944.7	419,207.1	372,133.8
22	Cornell U.	360,472.0	332,225.0	372,491.0	373,858.0	492,720.8	404,678.8	387,144.6	374,924.2	368,553.3
23	MA Institute of Technology	359,401.0	374,403.0	399,416.0	405,802.0	439,379.6	385,828.6	336,355.1	375,057.1	339,998.9
24	U. CA, Davis	238,643.0	257,281.0	269,980.0	291,869.0	367,433.4	367,943.3	327,780.0	312,699.3	333,824.9
25	Northwestern U., Evanston	230,021.0	240,310.0	271,900.0	261,680.0	346,223.9	310,413.1	301,087.9	319,442.1	314,781.9
26	Emory U.	240,287.0	241,448.0	261,996.0	277,246.0	323,720.8	328,619.4	324,740.0	318,548.6	305,765.4
27	U. Southern CA	316,139.0	275,017.0	269,286.0	270,662.0	355,696.4	388,512.1	337,527.0	321,380.8	300,322.6
28	Case Western Reserve U.	303,267.0	290,365.0	289,746.0	279,388.0	307,091.0	303,553.8	287,025.2	288,001.3	287,673.8
29	U. IL, Urbana-Champaign	209,595.0	212,885.0	270,675.0	247,188.0	308,576.4	354,860.1	351,180.9	361,820.7	284,676.7
30	U. CA, Berkeley	270,571.0	254,445.0	251,482.0	266,642.0	317,505.6	331,304.0	296,407.4	292,144.9	283,842.5
31	NY U.	192,824.0	182,863.0	193,916.0	189,525.0	235,086.4	272,310.6	254,866.8	256,733.1	249,004.8
32	OH State U.	244,280.0	236,428.0	245,606.0	262,411.0	307,603.1	356,569.7	259,702.9	260,904.2	248,612.0
33	Baylor C. of Medicine	262,968.0	252,729.0	239,994.0	264,302.0	290,042.5	280,373.4	243,296.4	274,404.1	244,067.7
34	U. Rochester	261,637.0	267,323.0	267,071.0	260,685.0	317,282.9	313,691.7	261,863.9	262,852.5	237,345.7
35	U. AZ	220,643.0	227,883.0	237,948.0	232,974.0	296,560.3	273,194.2	258,540.0	283,473.2	231,903.2
36	Scripps Research Institute	254,235.0	221,678.0	199,031.0	212,416.0	258,200.1	264,550.2	237,256.5	244,149.9	231,333.0
37	U. MD, College Park	140,168.0	151,135.0	154,520.0	174,639.0	203,533.3	215,193.1	174,171.3	240,585.4	227,283.7
38	U. AL, Birmingham	254,207.0	255,985.0	251,394.0	225,306.0	283,777.6	254,895.0	251,875.8	240,434.8	223,512.3
39	Rutgers, State U. NJ	271,697.0	274,060.0	230,146.0	277,227.0	345,807.8	343,931.8	315,401.2	276,610.8	222,426.4
40	U. FL	218,908.0	204,171.0	207,304.0	202,859.0	258,890.1	271,567.1	224,620.5	229,985.6	221,513.8
41	Icahn School of Medicine at Mt. Sinai	195,201.0	194,275.0	220,711.0	195,887.0	246,205.8	235,514.2	193,220.9	196,922.5	213,885.6

TABLE 4. Federal obligations for science and engineering to the 100 universities and colleges receiving the largest amounts, ranked by the total amount received in FY 2013: FYs 2005–13
(Dollars in thousands)

Rank	Institution	2005	2006	2007	2008	2009[a]	2010[a]	2011	2012	2013
42	U. Chicago	246,241.0	236,915.0	268,322.0	291,585.0	340,171.5	281,205.5	262,268.2	251,813.7	213,015.2
43	U. UT	162,979.0	178,286.0	177,273.0	181,189.0	222,689.9	250,999.4	211,674.4	220,261.2	207,313.8
44	OR Health and Science U.	192,916.0	203,155.0	200,064.0	186,343.0	247,661.7	245,557.8	215,582.1	212,969.1	206,186.7
45	MI State U.	166,922.0	148,748.0	161,531.0	149,604.0	186,050.2	198,419.1	209,429.7	197,516.3	204,047.2
46	Boston U.	212,981.0	229,510.0	218,040.0	238,130.0	286,345.5	239,739.4	237,166.9	227,469.2	203,567.5
47	U. CA, Irvine	177,856.0	172,908.0	227,497.0	183,327.0	224,251.9	220,254.7	194,882.2	191,427.3	197,778.4
48	U. IA	197,454.0	207,940.0	223,184.0	225,288.0	238,935.9	237,020.8	218,252.8	216,977.8	190,436.3
49	CA Institute of Technology	171,043.0	163,634.0	166,729.0	187,618.0	237,463.8	236,169.7	206,825.1	196,965.6	186,915.1
50	U. TX, Austin	141,540.0	167,695.0	166,033.0	172,328.0	241,903.8	206,253.3	226,983.9	303,760.2	178,484.2
51	U. IL, Chicago	172,886.0	182,528.0	188,891.0	167,448.0	186,418.9	219,809.4	177,547.1	166,172.9	170,992.9
52	U. Miami	136,847.0	127,448.0	146,867.0	151,430.0	198,009.6	233,101.5	183,613.0	175,046.6	169,160.0
53	U. MD, Baltimore	189,360.0	183,359.0	210,472.0	175,085.0	204,035.3	214,494.3	215,034.2	186,600.6	166,991.2
54	Purdue U.	139,396.0	143,411.0	148,648.0	162,535.0	227,969.0	261,517.0	191,480.1	176,625.7	166,956.2
55	Yeshiva U.	160,165.0	146,850.0	136,160.0	141,447.0	153,302.4	200,420.2	171,671.8	165,410.7	162,472.2
56	Consortium for Ocean Leadership	1,164.0	469.0	9,671.0	39,170.0	202,973.4	94,855.6	140,715.1	188,772.8	156,734.1
57	AZ State U.	95,008.0	99,687.0	112,835.0	122,887.0	163,994.8	130,676.4	146,157.8	174,022.4	153,975.6
58	U. VA, Charlottesville	200,789.0	190,993.0	213,596.0	190,002.0	254,402.8	215,759.9	176,230.5	173,993.5	152,452.2
59	Carnegie Mellon U.	84,624.0	97,890.0	122,307.0	104,934.0	126,427.7	139,640.5	137,923.0	133,587.2	151,524.5
60	U. TX, Southwestern Medical Ctr.	178,233.0	180,796.0	198,303.0	170,058.0	201,663.3	216,964.4	185,991.7	178,825.5	151,363.0
61	VA Polytechnic Institute and State U.	105,159.0	79,096.0	102,497.0	103,884.0	181,211.1	137,951.7	158,032.9	139,453.2	150,271.4
62	U. MA, Medical School	124,465.0	112,002.0	127,217.0	127,875.0	159,014.9	183,726.2	164,647.6	149,503.3	142,528.5
63	NC State U.	106,725.0	114,777.0	110,222.0	115,651.0	135,815.6	146,598.6	151,914.7	140,047.9	141,260.1
64	Princeton U.	116,059.0	128,517.0	115,525.0	131,198.0	167,236.3	152,541.8	137,760.8	148,789.7	136,881.1
65	U. TX, M. D. Anderson Cancer Ctr.	160,662.0	169,091.0	171,339.0	155,309.0	196,137.6	201,134.7	159,906.7	162,742.9	132,734.1
66	U. KY	151,351.0	147,418.0	141,802.0	141,622.0	176,334.0	173,518.5	143,312.8	133,852.3	125,605.5
67	CO State U., Ft. Collins	129,254.0	117,905.0	110,364.0	111,240.0	132,660.1	132,587.5	122,699.1	119,609.7	124,785.8
68	Wake Forest U.	132,547.0	125,828.0	117,468.0	125,109.0	170,167.1	133,937.8	131,174.3	129,264.2	123,616.2
69	IN U.-Purdue U., Indianapolis	111,588.0	117,688.0	116,727.0	123,335.0	144,602.7	159,219.4	133,071.6	125,299.9	114,773.6
70	U. CA, Santa Barbara	100,764.0	103,469.0	102,170.0	106,643.0	147,519.8	117,215.3	128,185.9	107,062.3	110,682.1
71	Dartmouth C.	110,824.0	105,876.0	103,949.0	102,587.0	132,983.7	133,737.8	104,974.5	98,830.8	106,692.9
72	OR State U.	96,916.0	95,766.0	90,313.0	101,746.0	110,589.1	127,631.8	110,824.7	101,375.8	105,649.5
73	U. CT	123,461.0	117,811.0	113,880.0	115,298.0	130,127.7	137,918.3	114,858.1	107,137.5	105,461.3
74	Woods Hole Oceanographic Institution	88,795.0	88,270.0	105,234.0	97,478.0	133,677.8	115,624.3	117,591.6	115,739.6	105,134.1
75	U. KS	98,243.0	102,952.0	115,619.0	114,293.0	149,093.9	178,733.1	128,309.3	135,265.1	102,349.4
76	IA State U.	107,993.0	97,786.0	90,413.0	103,360.0	115,964.8	123,117.8	129,289.2	97,290.3	100,576.9
77	LA State U.	148,528.0	130,551.0	99,096.0	100,995.0	127,216.6	119,990.3	113,953.6	92,921.1	99,780.7
78	Brown U.	83,338.0	95,467.0	99,990.0	99,734.0	128,524.8	122,823.8	106,759.6	101,850.4	98,647.9
79	VA Commonwealth U.	86,205.0	77,060.0	81,414.0	92,965.0	119,225.3	107,965.4	99,564.1	99,146.2	96,944.0
80	U. NM	110,968.0	108,473.0	116,241.0	108,952.0	147,754.3	149,011.4	113,885.6	106,448.9	96,634.1
81	FL State U.	78,205.0	82,361.0	81,484.0	89,165.0	117,014.4	143,509.8	88,208.0	92,333.6	95,804.8
82	U. GA	98,758.0	90,386.0	100,075.0	103,853.0	116,361.4	118,716.3	97,073.7	102,838.6	93,795.2
83	Medical U. SC	117,018.0	95,866.0	97,224.0	100,576.0	132,850.5	122,755.2	107,800.0	97,827.3	92,103.9

TABLE 4. Federal obligations for science and engineering to the 100 universities and colleges receiving the largest amounts, ranked by the total amount received in FY 2013: FYs 2005–13
(Dollars in thousands)

Rank	Institution	2005	2006	2007	2008	2009[a]	2010[a]	2011	2012	2013
84	Medical C. WI	86,713.0	88,343.0	99,111.0	95,625.0	107,317.7	108,784.9	94,958.5	103,764.0	91,773.1
85	Tufts U.	88,094.0	98,701.0	86,282.0	81,256.0	108,701.9	118,965.5	80,184.5	90,372.7	91,590.4
86	SUNY, Stony Brook U., Stony Brook	104,166.0	104,299.0	103,076.0	98,948.0	119,030.5	128,467.0	99,167.2	95,718.7	91,507.5
87	George Washington U.	72,531.0	59,944.0	79,731.0	89,162.0	112,643.9	105,565.1	72,087.9	101,325.2	91,284.8
88	TX A&M U., College Station	112,960.0	99,167.0	97,571.0	129,239.0	172,176.8	157,992.6	109,867.6	118,945.5	91,190.2
89	U. HI, Manoa	121,124.0	124,730.0	118,241.0	114,184.0	123,372.5	131,046.1	111,262.0	96,423.2	89,833.4
90	U. TX, Health Science Ctr., Houston	112,328.0	103,979.0	102,112.0	114,385.0	136,587.6	134,380.4	98,349.0	86,477.1	89,376.2
91	U. TX, Medical Branch	117,596.0	115,404.0	103,395.0	118,637.0	123,111.8	105,654.1	86,618.0	95,354.5	86,088.3
92	U. CA, Santa Cruz	62,938.0	66,976.0	72,844.0	65,726.0	85,423.2	91,647.5	72,502.3	76,756.9	85,721.9
93	Georgetown U.	91,283.0	92,508.0	90,502.0	95,230.0	93,844.0	124,359.6	95,203.2	98,022.3	84,017.2
94	UT State U.	58,740.0	61,873.0	66,760.0	77,823.0	71,454.7	97,067.4	91,469.7	81,722.1	81,125.9
95	U. MA, Amherst	72,379.0	80,974.0	86,789.0	89,943.0	130,090.9	93,420.0	86,344.2	85,256.0	80,945.7
96	U. DE	71,909.0	77,799.0	82,676.0	89,738.0	116,584.5	104,421.8	112,591.8	78,326.1	80,445.0
97	U. MO, Columbia	99,937.0	110,069.0	105,047.0	101,041.0	130,494.2	110,739.6	101,243.4	85,912.4	79,637.7
98	NM State U.	89,720.0	101,749.0	57,284.0	60,647.0	64,015.6	61,687.7	44,618.4	70,794.8	78,835.4
99	U. TX, Health Science Ctr., San Antonio	88,801.0	89,883.0	108,191.0	128,939.0	109,899.2	103,233.8	86,698.4	79,650.7	78,126.7
100	Temple U.	46,932.0	57,353.0	53,070.0	60,026.0	74,673.6	85,955.5	72,754.5	84,667.2	77,571.2
	All other institutions	6,039,050.0	6,011,936.0	5,632,272.0	5,854,212.0	7,529,973.9	7,394,363.9	6,037,648.6	5,473,138.0	5,221,562.4

[a] Includes American Recovery and Reinvestment Act of 2009 obligations.

NOTES: Because of rounding, detail may not add to totals. Institution order is based on total actual dollars received before amounts are rounded; institutions receiving the same amount of actual dollars are listed alphabetically.

SOURCE: National Science Foundation, National Center for Science and Engineering Statistics, *Survey of Federal Science and Engineering Support to Universities, Colleges, and Nonprofit Institutions*.

Appendix E

Federal Research and Development Spending

Table 19–1. FEDERAL RESEARCH AND DEVELOPMENT SPENDING
(Budget authority, dollar amounts in millions)

	2014 Actual	2015 Enacted	2016 Proposed	Dollar Change: 2015 to 2016	Percent Change: 2015 to 2016
By Agency [1]					
Defense [2]	66,018	67,451	72,121	4,670	7%
Health and Human Services	30,685	30,475	31,040	565	2%
Energy	11,996	11,736	12,597	861	7%
NASA	11,906	12,145	12,238	93	1%
National Science Foundation	5,827	5,999	6,309	310	5%
Agriculture	2,380	2,446	2,884	438	18%
Commerce	1,556	1,526	2,127	601	39%
Veterans Affairs	1,101	1,090	1,147	57	5%
Transportation [3]	853	900	1,115	215	24%
Interior	840	904	985	81	9%
Patient-Centered Outcomes Research Trust Fund	297	506	578	72	14%
Homeland Security [4]	1,032	1,032	569	−463	−45%
Environmental Protection Agency	539	523	559	36	7%
Education	315	333	279	−54	−16%
Smithsonian Institution	227	245	261	16	7%
Other	763	758	885	127	17%
TOTAL	**136,335**	**138,069**	**145,694**	**7,625**	**6%**
Basic Research					
Defense	2,112	2,292	2,101	−191	−8%
Health and Human Services	15,862	15,482	15,966	484	3%
Energy	4,095	4,120	4,245	125	3%
NASA	3,371	3,198	3,198	0	0%
National Science Foundation	4,752	4,834	5,062	228	5%
Agriculture	992	1,004	1,114	110	11%
Commerce	205	210	239	29	14%
Veterans Affairs	451	429	450	21	5%
Transportation	.....	.....	.....	.....	.....
Interior	52	53	61	8	15%
Patient-Centered Outcomes Research Trust Fund	.....	.....	.....	.....	.....
Homeland Security [4]	41	41	41	0	0%
Environmental Protection Agency	.....	.....	.....	.....	.....
Education	27	6	7	1	17%
Smithsonian Institution	200	209	225	16	8%
Other	27	19	19	0	0%
SUBTOTAL	**32,187**	**31,897**	**32,728**	**831**	**3%**
Applied Research					
Defense	4,664	4,775	4,819	44	1%
Health and Human Services	14,621	14,791	14,864	73	0%
Energy	4,550	4,363	4,683	320	7%
NASA	2,358	2,402	2,480	78	3%
National Science Foundation	678	728	802	74	10%
Agriculture	1,090	1,105	1,251	146	13%
Commerce	1,053	919	1,086	167	18%
Veterans Affairs	583	564	597	33	6%
Transportation	635	673	766	93	14%
Interior	665	701	785	84	12%
Patient-Centered Outcomes Research Trust Fund	297	506	578	72	14%
Homeland Security [4]	210	210	176	−34	−16%
Environmental Protection Agency	456	442	474	32	7%
Education	179	199	159	−40	−20%
Smithsonian Institution	.....	.....	.....	.....	.....
Other	507	533	626	93	17%
SUBTOTAL	**32,546**	**32,911**	**34,146**	**1,235**	**4%**

Table 19–1. FEDERAL RESEARCH AND DEVELOPMENT SPENDING—Continued
(Budget authority, dollar amounts in millions)

	2014 Actual	2015 Enacted	2016 Proposed	Dollar Change: 2015 to 2016	Percent Change: 2015 to 2016
Development					
Defense[2]	58,986	60,366	65,036	4,670	8%
Health and Human Services	30	30	30	0	0%
Energy	2,559	2,322	2,621	299	13%
NASA	6,004	6,481	6,423	–58	–1%
National Science Foundation	.....	.....	.....	.....	.....
Agriculture	179	177	181	4	2%
Commerce	85	164	400	236	144%
Veterans Affairs	67	66	67	1	2%
Transportation	198	199	304	105	53%
Interior	107	110	113	3	3%
Patient-Centered Outcomes Research Trust Fund	.....	.....	.....	.....	.....
Homeland Security[4]	348	348	344	–4	–1%
Environmental Protection Agency	78	76	80	4	5%
Education	109	128	113	–15	–12%
Smithsonian Institution	.....	.....	.....	.....	.....
Other	235	215	264	49	23%
SUBTOTAL	**68,985**	**70,682**	**75,976**	**5,294**	**7%**
Facilities and Equipment					
Defense	256	18	165	147	817%
Health and Human Services	172	172	180	8	5%
Energy	792	931	1,048	117	13%
NASA	173	64	137	73	114%
National Science Foundation	397	437	445	8	2%
Agriculture	119	160	338	178	111%
Commerce	213	233	402	169	73%
Veterans Affairs	.....	31	33	2	6%
Transportation	20	28	45	17	61%
Interior	13	39	2	–37	–95%
Patient-Centered Outcomes Research Trust Fund	.....	.....	.....	.....	.....
Homeland Security[4]	433	433	8	–425	–98%
Environmental Protection Agency	5	5	5	0	0%
Education	.....	.....	.....	.....	.....
Smithsonian Institution	27	36	36	0	0%
Other	–3	–8	.....	.....	.....
SUBTOTAL	**2,617**	**2,579**	**2,844**	**265**	**10%**

[1] Some numbers in the chapter text include non-R&D activities and thus will be different from the R&D numbers in this table.
[2] In this Budget, Department of Defense began reporting development activities from three additional accounts, adding $1.9 billion in FY 2014, $1.8 billion in FY 2015, and $1.5 billion in FY 2016.
[3] Classification of R&D activities at the Federal Avaiation Administration have been recently updated.
[4] As of the date the 2016 Budget was released, final 2015 appropriations for the Department of Homeland Security were not yet enacted. Therefore, the 2015 column of this table reflects amounts requested for the Department of Homeland Security in the 2015 Budget.

SOURCE: *Fiscal Year 2016 Analytical Perspectives of the U.S. Government*, U.S. Government Printing Office, 2015, pp. 298–9, https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/spec.pdf.

Appendix F

A Brief Primer on the Paperwork Reduction Act

When an agency wishes to collect information from 10 or more people, it must follow steps outlined in the Paperwork Reduction Act (PRA) and the implementing regulations for the PRA.[1] An agency must publish a notice in the *Federal Register* and provide 60 days for public comment on the information collection request. After the comment period, the agency submits the information collection request to the Office of Information and Regulatory Affairs [OIRA, a part of the White House Office of Management and Budget (OMB)] with a supporting statement.[2] Concurrent with this submission, the agency publishes a second notice in the *Federal Register* asking the public to submit any comments on the information collection to OMB. After waiting 30 days for public comments, OIRA has an additional 30 days within which to approve or disapprove the information collection. The agency must seek re-approval (and repeat the entire process) of all information collections every 3 years (or sooner as required by OMB).

As part of the information collection request process, the agency must calculate the burden of the information collection and demonstrate its "practical utility." The standards for information collection are found at 44 U.S.C.[3] § 3506(c)(3)(A). Each agency must certify that the information collection, "is necessary for the proper performance of the functions of the agency, including that the information has practical utility and that its efforts, "reduce(s) to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency."[4] OIRA must "minimize the Federal information collection burden, with particular emphasis on those individuals and entities most adverse-

[1]Controlling Paperwork Burdens on the Public, 5 CFR 1320 (2010).

[2]The supporting statement must include answers to 18 questions. For collections of information collections employing statistical methods, an additional five questions must be answered. The questions and cover sheet may be found at http://www.whitehouse.gov/sites/default/files/omb/inforeg/83i-fill.pdf.

[3]United States Code. The U.S. Code is a consolidation and codification by subject matter of the general and permanent laws of the United States.

[4]See Federal Agency Responsibilities, 44 U.S.C.§ 3506(c)(3)(C).

ly affected," and "maximize the practical utility of and public benefit from information collected by or for the Federal Government."[5]

APPROVAL OF AGENCY GRANT APPLICATION FORMS

National Institutes of Health

National Institutes of Health (NIH) grant application forms are approved by OMB under OMB Number 0925-0001. Burden hours to complete the documents are estimated by NIH in Table F-1.

The agency also specifies the cost associated with this burden using a dollar value of $35/hour (this implies the agency assumes that much of the information collection is performed by administrative personnel).

NIH is also listed as one of the users of grants.gov form SF-424 (Application for Federal Assistance). The OMB Number is 4040-0001 for the basic form and 4040-0004 for supplemental information (each form is approved separately by OMB). The online grants.gov approvals are approved for 1 hour per application. The physical version of the primary form lists the burden as varying by agency [(from 15 minutes for the U.S. Agency for International Development to 4.4 hours for the Department of Health and Human Services (HHS)]. The physical version of the supplemental form lists the burden as varying from 1.07 hours [Department of Defense (DOD)] to 120 hours [National Science Foundation (NSF) and the Department of Homeland Security (DHS)]. HHS lists burden hours as 58 hours.

It is unclear how this 58-hour estimate (or the 4.4-hour estimate for completing the SF-424 for HHS grants) relates to the 24-hour estimate approved for HHS by OMB or whether HHS has OMB approval for this estimate.

National Science Foundation

NSF grant application forms are approved by OMB under OMB Number 3145-0058. NSF estimates that applicants expend an average of approximately 120 burden hours for each proposal submitted. NSF expects to receive approximately 51,600 proposals in FY 2015, which would result in a total of 6,192,000 burden hours.

This is the extent of the detail that NSF provides on its estimates. The agency does not monetize its estimate.

For NSF, the 120-hour estimate matches the approved burden estimate for form SF-424 that appears on grants.gov.

[5]See Federal Agency Responsibilities, 44 U.S.C.§ 3505(c).

TABLE F-1 National Institutes of Health Estimates of Hour Burden to Complete Paper and Electronic Versions of Grant Application Form PHS 395

Estimates of Hour Burden				
Information Collection Number or Form	**Number of Respondents**	**Frequency of Response**	**Average Time (hours) Per Response**	**Annual Burden Hours**
PHS 398 [paper]	8,389	1	35	293,615
PHS 398 [electronic]	76,312	1	22	1,678,864

SOURCE: Courtesy of Stuart Shapiro.

Other Agencies

Other agencies rely, in part, on the grants.gov approval for their PRA approval. However, it appears that there is variation amongst agencies with regard to the approval of supplemental materials. For example, the Department of Energy requires a "budget justification" for its grants. Under OMB Number 1910-5162, the agency has approval for 24 burden hours. However, the actual supplemental burden for form SF-424 is listed as 1.5 hours. It is unclear whether these numbers refer to different things.

On form SF-424, DOD burden hours are listed as only 1.07 hours. However, DOD grant websites contain numerous DOD forms that do not have OMB Numbers on them,[6] suggesting that these forms have not been approved for information collection by OMB as required by the PRA.

[6]For example, the Office of Naval Research, Science, and Technology website, http://www.onr.navy.mil/Contracts-Grants/submit-proposal/contracts-proposal/cost-proposal.aspx or the Army Research Laboratory website, http://www.arl.army.mil/www/default.cfm?page=218.

Appendix G

The Grants Process at the National Science Foundation and the National Institutes of Health

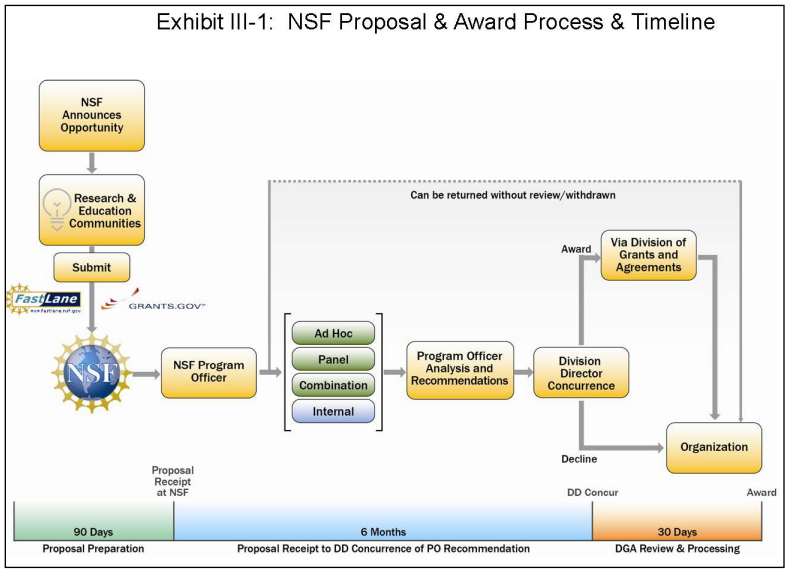

FIGURE G-1 National Science Foundation proposal and award process and timeline. SOURCE: National Science Foundation, "Exhibit III-1: NSF Proposal & Award Process & Timeline," *Proposal and Award Policies and Procedures Guide, Part I: Grant Proposal Guide*, December 2014, p. III-3, http://www.nsf.gov/pubs/policydocs/pappguide/nsf15001/gpg_print.pdf.

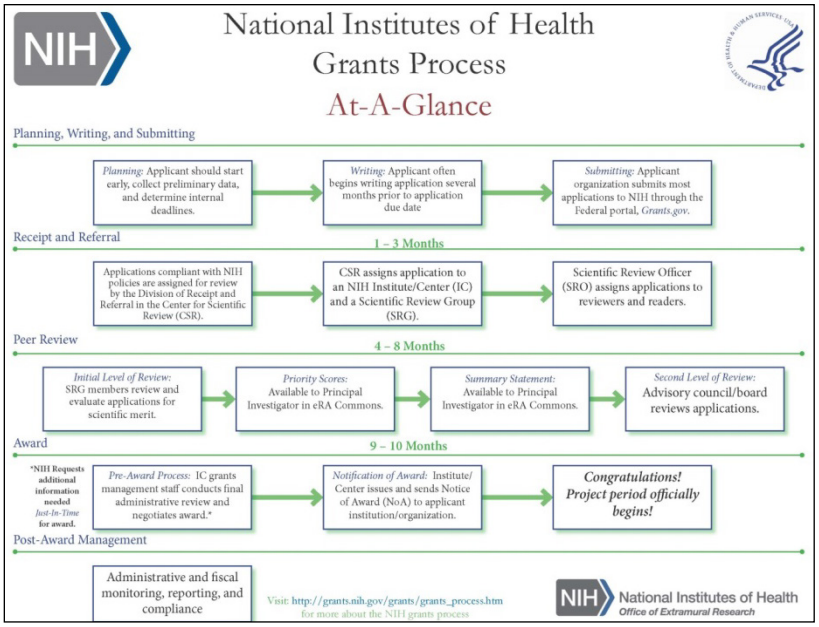

FIGURE G-2 National Institutes of Health Grants Process At-A-Glance.
SOURCE: National Institutes of Health Office of Extramural Research, "National Institutes of Health Grants Process At-A-Glance," 2015, http://grants.nih.gov/grants/2014%20NCURA%20OER%20Grant%20Process%20At-A-Glance.pdf.

Appendix H

HHS and USDA Select Agents and Toxins

7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
Abrin	*Bacillus anthracis**
Botulinum neurotoxins*	*Bacillus anthracis Pasteur strain*
Botulinum neurotoxin producing species of *Clostridium**	*Brucella abortus*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]	*Brucella melitensis*
Coxiella burnetii	*Brucella suis*
Crimean-Congo haemorrhagic fever virus	*Burkholderia mallei**
Diacetoxyscirpenol	*Burkholderia pseudomallei**
Eastern Equine Encephalitis virus[3]	Hendra virus
Ebola virus*	Nipah virus
*Francisella tularensis**	Rift Valley fever virus
Lassa fever virus	Venezuelan equine encephalitis virus[3]
Lujo virus	
Marburg virus*	**USDA SELECT AGENTS AND TOXINS**
Monkeypox virus[3]	African horse sickness virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	African swine fever virus
Ricin	Avian influenza virus3
Rickettsia prowazekii	Classical swine fever virus
SARS-associated coronavirus (SARS-CoV)	Foot-and-mouth disease virus*

Saxitoxin	Goat pox virus
South American Haemorrhagic Fever viruses:	Lumpy skin disease virus
Chapare	*Mycoplasma capricolum*[3]
Guanarito	*Mycoplasma mycoides*[3]
Junin	Newcastle disease virus[2,3]
Machupo	Peste des petits ruminants virus
Sabia	Rinderpest virus*
Staphylococcal enterotoxins A,B,C,D,E subtypes	Sheep pox virus
T-2 toxin	Swine vesicular disease virus
Tetrodotoxin	
Tick-borne encephalitis complex (flavi) viruses:	**USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS**
Far Eastern subtype	*Peronosclerospora philippinensis*
Siberian subtype	*(Peronosclerospora sacchari)*
Kyasanur Forest disease virus	*Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
Omsk hemorrhagic fever virus	*Ralstonia solanacearum*
Variola major virus (Smallpox virus)*	*Rathayibacter toxicus*
Variola minor virus (Alastrim)*	*Sclerophthora rayssiae*
*Yersinia pestis**	*Synchytrium endobioticum*
	Xanthomonas oryzae

*Denotes Tier 1 Agent. These agents present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety. (See *http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/select-agent-regulations.html*).

[1]C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[2]A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[3]Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious

caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category. 9/10/13

SOURCE: Federal Select Agent Program, "Select Agents and Toxins List," available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html.

Appendix I

Report Briefings[1]

2015

Monday, September 21, 2015

Staff from offices of Senators Lamar Alexander (R-TN) and Patty Murray (D-WA) and staff from U.S. Senate Committee on Health, Education, Labor & Pensions

Staff from Subcommittee on Space, Science, and Competitiveness, U.S. Senate Committee on Commerce, Science, and Transportation

Staff from U.S. House Committee on Science, Space, and Technology

White House Office of Science and Technology Policy and Agency Briefing

Tuesday, September 22, 2015

Senator Lamar Alexander (R-TN)

Official Public/Media Release

Tuesday, October 20, 2015

Association of American Universities (AAU) presidents

Wednesday, October 21, 2015

Committee on Science, Technology, and Law

Thursday, October 22, 2015

Council on Governmental Relations (COGR) members

[1]On Part 1.

Thursday, November 19, 2015

National Science Board (NSB)

Association of Public and Land-grant Universities (APLU) senior staff

Friday, November 20, 2015

Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, White House Office of Management and Budget

President's Council of Advisors on Science and Technology (PCAST)

Tuesday, December 1, 2015

National Science and Technology Council (NSTC)

2016

Monday, January 11, 2016

Federal Demonstration Partnership (FDP)

Friday, March 11, 2016

Association of American Medical Colleges (AAMC), Group on Research Advancement and Development,

Thursday, March 31, 2016

Public Responsibility in Medicine and Research (PRIM&R), Institutional Animal Care and Use Committee Conference

Friday, April 1, 2016

Experimental Biology 2016

UPCOMING

Monday, August 6, 2016

National Council of University Research Administrators (NCURA) Annual Meeting