



REDUCING  
INVESTIGATORS'  
ADMINISTRATIVE  
WORKLOAD FOR  
FEDERALLY FUNDED  
RESEARCH

NATIONAL SCIENCE BOARD



# REDUCING INVESTIGATORS' ADMINISTRATIVE WORKLOAD FOR FEDERALLY FUNDED RESEARCH



MARCH 10, 2014

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# CONTENTS

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|  |    |
|--|----|
| Memorandum   | iv |
| Acknowledgments                                      | v  |
| Executive Summary                                    | 1  |
| Introduction   | 5  |
| Overview of RFI Responses                            | 7  |
| Findings and Recommendations                         | 8  |
| I. Focus on the Science                              | 8  |
| Grant Proposals                                      | 8  |
| Progress Reports                                     | 9  |
| Recommendations                                      | 10 |
| II. Eliminate or Modify Ineffective Regulations      | 11 |
| Time and Effort Reporting                            | 11 |
| Human Subjects Research and IRBs                     | 11 |
| Animal Research and IACUCs                           | 13 |
| Financial Conflict-of-Interest                       | 14 |
| Laboratory Safety and Security                       | 14 |
| Recommendations                                      | 15 |
| III. Harmonize and Streamline Requirements           | 16 |
| Harmonization  | 16 |
| Financial Management and Audit                       | 16 |
| Recommendations                                      | 17 |
| IV. Increase University Efficiency and Effectiveness | 17 |
| Institutional Requirements and Support               | 17 |
| Recommendations                                      | 18 |
| Conclusion   | 19 |
| References   | 20 |
| Appendix A: Federal Regulatory Changes Since 1991    | 21 |
| Appendix B: Request for Information                  | 26 |
| Appendix C: Analysis of RFI Responses                | 31 |
| Appendix D: Response from OLAW                       | 77 |



March 10, 2014

**MEMORANDUM FROM THE CHAIRMAN OF THE NATIONAL SCIENCE BOARD**

**SUBJECT:** *Reducing Investigators' Administrative Workload for Federally Funded Research*

The National Science Board is pleased to present its report, *Reducing Investigators' Administrative Workload for Federally Funded Research*. For more than a decade, surveys and reports have highlighted an increase in administrative and compliance requirements associated with Federal research. There is now consensus that some of these requirements are interfering with the conduct of science out of proportion with the accepted need to ensure accountability, transparency and safety. To help address this issue, the Board created a Task Force on Administrative Burdens charged with examining the administrative workload of investigators that receive Federal funding.

This report contains the findings of the Task Force. It also describes a number of policy actions aimed at modifying and streamlining inefficient requirements while retaining necessary oversight of federally-funded research. The recommended policy actions are derived from the findings of a request for information and roundtable discussions with principal investigators and institutional administrative staff. In addition to key National Science Foundation staff, the Task Force engaged other Federal agencies, offices, working groups and non-governmental organizations in the development of the report.

The Board anticipates that these findings and recommended policy actions, if implemented, together with the findings and recommendations of existing reports and new initiatives stemming from recent Congressional inquiries, will strengthen the U.S. research enterprise. We live in an era of both limited resources and an economy that relies increasingly on knowledge intensive industries for growth. The Board believes these recommendations are timely, and will increase the impact of Federal investments in science and technology by allowing our Nation's researchers more time for discovery and innovation.

A handwritten signature in black ink that reads 'Dan E. Arvizu'.

Dan E. Arvizu  
Chairman

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**National Science Foundation**

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# EXECUTIVE SUMMARY

The past two decades have witnessed increasing recognition that the administrative workload placed on federally funded researchers at U.S. institutions is interfering with the conduct of science in a form and to an extent substantially out of proportion to the well-justified need to ensure accountability, transparency and safety. A 2005 Federal Demonstration Partnership (FDP) survey of investigators found that principal investigators (PIs) of federally sponsored research projects spend, on average, 42 percent of their time on associated administrative tasks. Seven years later, and despite collective Federal reform efforts, a 2012 FDP survey found the average remained at 42 percent.<sup>i</sup>

In December 2012, the National Science Board (NSB, Board) convened a Task Force on Administrative Burdens (Task Force).<sup>ii</sup> The Task Force issued a request for information (RFI) to identify which Federal agency and institutional requirements contribute most to PIs' administrative workload and conducted a series of roundtable discussions with faculty and administrators. The most frequently reported areas associated with high administrative workload were financial management; the grant proposal process; progress and other outcome reporting; human subjects research and institutional review boards (IRBs); time and effort reporting; research involving animals and institutional animal care and use committees (IACUCs); and personnel management. Other areas frequently addressed were subcontracts, financial conflict-of-interest (COI), training, and laboratory safety and security.

Investigators and institutions acknowledge their responsibility to ensure transparency, accountability and safety in the conduct of federally funded research and, thus, that rules and regulations are necessary. However, they also mentioned an array of areas where those rules and regulations could be eliminated, streamlined, or harmonized across agencies to significantly reduce unnecessary regulatory burden. Further, there is a perception that we have lost focus on the science and introduced requirements that are not necessary for the assessment of merit and achievement, accountability, or the protection of research subjects. These requirements often come at considerable cost to investigators and institutions and yield a loss of valuable research time, particularly when not harmonized across Federal agencies. Investigators and institutions perceive a lack of consideration for the cost and benefit of new regulations, suggesting that the cost is often far greater than the benefit, and that there were no means to assess their effectiveness. Once implemented, regulations are not easily modified or eliminated.

Investigators at many institutions suggested that a culture of overregulation has emerged around Federal research, which further increases their administrative workload. This overregulation was associated with a perceived increase in auditing practices and resulting institutional concerns about liability. Increased Federal reporting and compliance requirements, coupled with insufficient reimbursement of costs associated with federally funded research and a resulting decline in institutional administrative support at some universities, are reported to have added significantly to the faculty workload in tracking information, gathering administrative data, and preparing reports at the expense of performing research.

Many of the issues raised have been highlighted in previous surveys and reports for more than a decade. Failure to address these issues has resulted in wasted Federal research dollars. At a time of fiscal challenges and with low funding rates at many Federal agencies, it is imperative that these issues are addressed so that researchers can refocus their efforts on scientific discovery and translation. The Board offers several key, overarching, recommendations and a series of policy actions aimed at modifying and streamlining those requirements that are essential to ensure the proper performance of federally funded research.



## I. FOCUS ON THE SCIENCE

Investigators' administrative workload could be reduced significantly if requirements that are not critical to a proposals merit review were postponed until the proposal has been positively reviewed and is being considered for funding. Administrative work could be reduced further if progress reports were streamlined and focused solely on performance outcomes. The Board strongly encourages the National Science Foundation (NSF) Director and other Federal agencies funding scientific research to focus the peer-review process and post-award oversight on merit and achievement.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board recommends that agencies modify proposal requirements, so that they only include those essential to evaluating the merit of the proposed research and making a funding determination. This can be achieved through use of these or other mechanisms:
  - Preliminary proposals
  - Broadening just-in-time submission
  - Simplifying budget requirements
- B | Annual progress reports should be limited to research outcomes, reported in simplified formats and commensurate with the size of the award. Additional data requests should be limited to only what is essential for assessment of performance and compliance.
- C | The Board advises the NSF Director to fully review and consider the agency-specific comments received in response to the Board's RFI, as well as consideration of piloted modifications to the proposal process, and to report to the Board on review and progress within six months of the publication of this report.

## II. ELIMINATE OR MODIFY INEFFECTIVE REGULATIONS

In a number of areas, investigators and institutions have identified regulations that are ineffective or inappropriately applied to research time and again in surveys and reports. Effective action should be taken to eliminate or modify these requirements to avoid further waste of Federal research dollars and to accelerate the pace of scientific discovery and innovation.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board proposes that the Office of Management and Budget (OMB) identify appropriate means by which the piloted payroll certification approach for time and effort reporting can be used by universities and accepted by auditors and Inspectors General (IGs). Once resolved, a Memo of Clarification should be issued indicating that the payroll certification method is acceptable to the Federal Government.
- B | The Board supports a number of recently proposed reforms to regulations governing human subjects research, including:
  - Encouraging the use of a single IRB for multi-site studies.
  - Eliminating continuing review for all expedited/minimal-risk protocols.
  - Expansion and clarification of current exemption categories.

Further, the Board endorses the Association for the Accreditation of Human Research Protection Programs (AAHRPP) recommendation to declare all research involving minimal risk as eligible for review using the expedited procedure. The Board further recommends eliminating the requirement that IRBs review grant proposals and the requirement to submit IRB approved research protocols for review by agency IRB or peer review panel.

- C | An evaluation of the regulations, policies, guidance, best practices and frequently asked questions



(FAQs) of all regulatory, independent, and certification bodies governing animal research should be considered to identify policies and guidance that increase investigators' administrative workload without improving the care and use of animals.

- D | Proper balance between protection against COI and encouragement of university/industry partnership is needed to facilitate sound investment of Federal funding in innovative activities. The Board recommends an evaluation of recent changes to Public Health Services (PHS) COI regulations to assess cost and effectiveness and impact on entrepreneurial activities. The Board does not recommend adoption of the PHS COI regulations by other Federal agencies.
- E | The Board recommends re-examining safety and security requirements, or aspects of these requirements that target industry, but are also applied to research settings. Based on this examination, appropriate alternatives should be identified and implemented.

### III. HARMONIZE AND STREAMLINE REQUIREMENTS

Despite efforts on the part of OMB, Federal agencies and groups such as the Research Business Models Working Group (RBM) and FDP, a substantial lack of consistency and standardization remains within and among agencies in all aspects of grant management (i.e., regulations, policies, guidelines, and reporting requirements; terms and conditions; oversight; forms and formatting; electronic research administrative systems; and training). This lack of consistency comes at a high cost to investigators and institutions and must be addressed.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board urges Federal agencies to accelerate efforts to harmonize and streamline the grant proposal and submission processes and post-award requirements.
- B | The Board recommends that a mechanism be established to ensure uniform and consistent audit practices based clearly and directly on regulatory requirements. The Board further urges agencies and institutions to consider requiring receipts and justifications only for larger purchases.<sup>iii</sup> Audits that focus on larger expenditures, outcomes, and infrastructure for compliance and risk management, would significantly reduce investigators' workload while maintaining necessary oversight.
- C | To address the recommendations in this and other reports and to properly develop and implement new requirements affecting investigators and institutions, the Board recommends that a permanent high-level, inter-agency, inter-sector committee be created, with stakeholder and OMB/Office of Information and Regulatory Affairs (OIRA) representation. Stakeholders, either in concert with agencies as part of a committee or through a forum such as the National Academies, should create a priority list of regulations and policies that should be eliminated, modified, or harmonized to reduce the administrative workload of PIs and institutions. Implementation of the changes identified could occur, in part, through the recommended inter-agency, inter-sector committee.

### IV. INCREASE UNIVERSITY EFFICIENCY AND EFFECTIVENESS

University resources and the ability of institutions to manage Federal grants and comply with regulations vary widely, and this variance has real implications for investigators. Dissemination of effective practices and models can create efficiencies that reduce PIs' administrative workload. For research subject to IRB and IACUC review, effective practices and institutional assistance can result in significant time savings.

To achieve this goal, the Board proposes the following policy actions:

- A | The Board recommends that institutions communicate the origin of compliance requirements to researchers and avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so.
- B | The Board recommends that Federal agencies collaborate with research institutions, and organizations representing investigators and institutions to identify and disseminate model programs and best practices (e.g., for financial management and IRB/IACUC review) that could be adapted for use at other institutions. This effort could be aided by the recommended inter-agency, inter-sector committee.
- C | The time and effort involved in protocol preparation, revision, and review could likely be reduced if IRB and IACUC staff provided researchers with knowledgeable assistance in the preparation and modification of these protocols. The Board recommends that universities review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high-quality protocols that protect research subjects.

# INTRODUCTION

During the last two decades, a number of surveys, articles and reports have indicated that increased administrative and compliance requirements associated with federally funded research are consuming a significant proportion of the time that our Nation's scientists, engineers, and educators dedicate to this research. A 1999 report, *NIH Initiative to Reduce Regulatory Burden*, found that the system of regulation for each of five areas perceived to be of particular burden for researchers (COI, research integrity, human subjects protections, animal care and use, and disposal of hazardous wastes)<sup>iv</sup> was in need of change - "in some cases, dramatic change" - to reduce the regulatory burden on the research community. The report noted that many of the issues were "not new, often having been identified by other studies." Most of the findings cut across the Federal Government, and many still hold true today.

In 2005, a FDP survey of investigators found that PIs of federally sponsored research projects spend, on average, 42 percent of their time on associated administrative tasks. A 2009 National Research Council (NRC) report, *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*, stated that "the problem of excessive regulatory burdens...puts a drag on the efficiency of all university research," potentially costing "billions of dollars over the next decade."<sup>v</sup> It recommended that Federal agencies "reduce or eliminate regulations that increase administrative costs, impede research productivity, and deflect creative energy without substantially improving the research environment." A review of the Council on Governmental Relations' (COGR) November, 2013 list of Federal regulatory changes since 1991 (Appendix A) demonstrates the ongoing increase in regulations affecting PIs and research institutions.

The Federal Government, in concert with non-Federal organizations, has taken efforts to address these concerns. Congress, in response to the NRC report undertaken at congressional request, held hearings on this topic and requested that the Government Accountability Office (GAO) conduct a review of current regulations and reporting requirements imposed on research universities.<sup>vi</sup> In the past three years, the Obama Administration has issued two Executive Orders (EOs) aimed at reducing regulatory burden.<sup>vii,viii</sup> In addition, OMB has recently completed reforms to the administration and oversight of Federal research grants and contracts. The new guidance, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* (2 CFR 200), was issued in December 2013 following two periods of public comment.<sup>x</sup> In the area of human subjects research, an advanced notice of proposed rulemaking (ANPRM), *Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, was released in July 2011 by the Office of the Secretary of the Department of Health and Human Services (HHS), in coordination with the Office of Science and Technology Policy (OSTP).<sup>x</sup>

Collaborative efforts between the FDP and the RBM Working Group, a Federal interagency group under the National Science and Technology Council (NSTC) Committee on Science, have also aimed to reduce administrative work associated with Federal research grants. Among the items they have piloted are (a) alternative mechanisms for time and effort reporting requirements, and (b) the Science Experts Network Curriculum Vitae (SciENcv), a platform that enables researchers to generate and maintain biosketches for grant proposals and progress reports using existing information from agency databases.<sup>xi</sup> The RBM Working Group has also developed a standardized progress report, the Research Performance Progress Report (RPPR). OSTP and OMB require all Federal agencies to use the RPPR. The FDP aims to streamline the administration of federally sponsored research. It offers a forum for individuals from universities and nonprofits to collaborate with Federal agency officials to improve the national research enterprise.<sup>xii</sup> Other recent FDP efforts have included assessing the administrative impact of the American Recovery and Reinvestment Act (ARRA) reporting requirements on investigators and institutions.

Despite collective reform efforts, a 2012 survey of FDP faculty members (seven years after the first survey) found that the average time that PIs of federally sponsored research projects spend on associated administrative tasks remained at 42 percent. Significant challenges still have to be addressed, and reform efforts are often limited in scope due to agency-specific requirements and systems and competing interests. Investigators and institutions are continually subject to new requirements that lack Federal inter-agency coordination and that are often implemented without consideration for their cost and effectiveness. There is a continued need to harmonize and streamline existing requirements, forms, and systems.

In March 2013, the Task Force issued a request for information (Appendix B), inviting PIs with Federal research funding to identify which Federal agency and institutional requirements contribute most to their administrative workload and to offer recommendations for reducing that workload. The Task Force also conducted a series of roundtable discussions with investigators and administrators. In concert with the numerous reports that increasing Federal regulatory requirements are impeding research, responses from investigators and institutions suggest that administrative requirements associated with federally funded research continue to increase. It was suggested that Federal requirements and their institutional counterparts continue to divert researchers' time and effort for science to administration and oversight. Increased Federal requirements and oversight, with no increase in cost reimbursement, have focused resources away from faculty. At the same time, a decline in funding rates for scientific proposals at some agencies and the size of awards relative to costs have PIs spending additional time preparing and submitting multiple proposals to support their research and less time conducting research and mentoring students.

The Board would like to emphasize that the term "burden" is used in this and other reports to describe excess regulations and requirements that slow the pace of research and do not improve either scientific or regulatory outcomes. The Board wants to be clear that America's researchers, their institutions, and the Federal agencies that support them all take seriously their roles as stewards of taxpayer funding and in the responsible conduct of research. The focus of this report, and of ongoing reform initiatives, therefore, is to address Federal requirements that do not improve scientific or regulatory outcomes but rather result in wasteful Federal spending and loss of valuable research time.

# OVERVIEW OF RFI RESPONSES

Individual and aggregate responses to the RFI represent the views of over 3,100 individuals, most of whom identified themselves as faculty. The largest number of individual responses (44 percent) received funding from the NSF. Thirty percent received funding from the National Institutes of Health (NIH). Concurrent with the RFI, the Task Force conducted a series of roundtable discussions with over 200 faculty and administrators.

The most frequently reported areas associated with high administrative workload, in order of prevalence, were financial management; the grant proposal process; progress and other outcome reporting; human subjects research and IRBs; time and effort reporting; research involving animals and IACUCs; and personnel management. Finances, personnel, effort reporting, and research involving human and animal subjects (IRB and IACUC) requirements were similarly identified as among the most time-consuming administrative responsibilities by investigators responding to the 2012 FDP Faculty Workload Survey (FWS). Other areas frequently addressed include subcontracts, COI, training, and laboratory safety and security. Many investigators suggested that NSF requirements were reasonable and favorable to those of other agencies. Investigators responding to the 2012 FDP FWS indicated that NSF administrative requirements take the least (36) percent time from Federal research.

A full report on the analysis and RFI respondent's recommendations (Appendix C) includes detailed methods and a full overview of responses. The Task Force sought to qualify RFI and roundtable comments and recommendations with data and reports, and with feedback from Federal agencies and working groups and pertinent organizations. Feedback from these entities is reflected in this report.

# FINDINGS & RECOMMENDATIONS

## I. FOCUS ON THE SCIENCE

In recent years, new requirements (some legislatively mandated) have been added to grant proposals. These requirements, although important, are often not critical to a proposals merit review. Investigators' administrative workload could be reduced significantly if materials that are not essential to establish the merit of the science being proposed were not required until the proposal has been favorably reviewed and is being considered for funding. Administrative work could be reduced further if progress reports were streamlined and if these reports focused on performance outcomes. The Board strongly encourages the NSF Director and other Federal agencies funding scientific research to focus the peer-review process and post-award oversight on merit and achievement.

### Grant Proposals

RFI respondents and roundtable participants indicated that they considered the preparation of scientific proposals to be an important part of research and peer-review to be an essential basis for funding decisions. The “burden” regarding proposals is primarily associated with declining funding rates and with new requirements that many perceive to be secondary to the science being proposed. Detailed budget requirements, formatting, and other requirements - which vary greatly by agency - and difficulties with proposal submission systems all increase the workload further.

Investigators questioned the need for detailed budgets for initial proposal submission and peer review, particularly since many programs negotiate the proposed budget downward after a decision to fund<sup>1</sup>. It was also suggested that supplemental information required at proposal submission is not necessary for review. The administrative workload of both the proposer and the reviewer could be substantially reduced through use of preliminary proposals, broadening use of “just-in-time” (JIT) submission for information that is not essential for review, and use of simplified budgets. JIT allows elements of a grant proposal to be deferred until a proposal has been peer reviewed and is being considered for funding and is currently used primarily for IRB and IACUC approval.

Investigators suggested that funding rates under 10 percent at a number of NIH institutes require the preparation of more grant proposals and resubmissions. Many RFI and roundtable respondents suggested that the NIH requirement that biosketches include a personal statement tailored to each proposal is highly burdensome and does not enhance review. Several also suggested that projects funded and budgeted under modular guidelines should be funded without modification and that NIH raise the threshold for the modular budget from the current level of \$250K to reflect increases in salary and benefit costs.

Regarding grant proposals, a number of respondents stated a preference for FastLane over Grants.gov and seemed to be unaware that NSF accepts submissions from both systems. Respondents suggested that NSF outreach and broader impacts requirements are frequently misinterpreted and that it is difficult to justify this relevance at the level of individual projects that are often designed to “open new frontiers of knowledge” and therefore “have an uncertain future.”

Investigators and institutions recommended standardizing the proposal and submission process and developing a standard, centralized database for biosketches, curriculum vitae, licenses, and other documents. Most Federal research agencies use the SF-424 Research and Related (R&R) proposal forms for proposal

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<sup>1</sup> Note that detailed budgets often are not required in preliminary proposals.

submission, and institutions can submit proposals to multiple agencies through Grants.gov. However, many areas of the proposal process still require standardization. The RBM Working Group has developed SciENCv, which allows investigators to populate a biosketch using information from existing databases specific to an agency. SciENCv has been piloted by NIH since the summer of 2013 and will be piloted by NSF in 2014. However, it is not yet a centralized system, and is still under development. Investigators will continue to create a separate biosketch for each agency, subject to agency-specific requirements. A pre-populated form should reduce PIs' administrative workload; however, a centralized interagency system with uniform requirements and the capacity for additional common documents would represent a significant positive step in reform efforts.

The number of grant proposals submitted to NSF has increased by more than 50 percent over the last decade and NSF is currently engaged in efforts to reduce the administrative workload for PIs and agency program staff. The NSF Division of Integrative Organismal Systems (IOS) and the Division of Environmental Biology (DEB) within the Directorate for Biological Sciences (BIO) are midway through a 3-year pilot of preliminary proposals that are reviewed based on a 1-page project summary and 5-page project description and biosketches. Panel surveys completed in 2012 and 2013 found that reviewers generally did not feel that proposal quality was negatively affected by the program, and that from 2012 to 2013 reviewers increasingly thought the process improved quality for overall intellectual merit and broader impacts. Initial evidence suggests that funding rates, the number of investigators submitting proposals, and the number of specific group awardees have not been adversely affected. However, the PI community has expressed dissatisfaction with the move from biannual submission and review to the single, annual deadline associated with the pilot and use of preliminary proposals for grant renewals<sup>2</sup>

## Progress Reports

Most of the respondents suggested that progress reports were more extensive than necessary to judge the progress of the research. It was suggested that data requests should be limited to essential information. Several respondents suggested that the reports are not used effectively by agencies and that reporting that is too frequent (i.e., monthly or quarterly) or too extensive hinders productivity and discourages work on difficult, long-term problems.

The RPPR generated many comments. A major research university noted that agency implementation allows for selective inclusion and exclusion of data from the common dataset, that additional award-specific requirements can be added, and that multiple systems are used for submission, and it recommended a post-implementation review to identify further opportunities for standardization. Investigators suggested that the RPPR requires much more work than previous progress reports, noted that uploading the report into different sections rather than uploading the full report is time consuming, and questioned the need to report on non-paid collaborators.

A post-implementation review of the RPPR is underway. Federal agencies will continue to require that information be submitted in response to each question, rather than allowing PIs to upload a single full report, which was the previous practice. This practice will allow agencies to more effectively gather data and analyze responses. A standard system for submission is reportedly not feasible at this time. Changes that have been, or will be, implemented include reducing the number of questions and streamlining the report to reduce repetition, allowing investigators to indicate that a question is not applicable (as with the previous format), pre-populating the report with information, and allowing links to standard publication databases. Investigators should note which questions are mandatory. No penalty is assessed for not answering optional questions.

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<sup>2</sup> Additional pilots are underway at NSF that aim to reduce the level of administrative work necessary for initial proposals. The NSF Directorate for Social, Behavioral and Economic Sciences Geography and Spatial Sciences (GSS) program piloted a "one-plus" proposal evaluation process. This process included moving from two competitions annually to the "GSS One-Plus" annual submission, which allows some declined proposers to revise and resubmit based on projects that were rated as having a high and potentially transformative character.



Those overseeing some large NSF grants and centers and NIH grants and programs indicated that the level of reporting and oversight is excessive and questioned whether the extensive information collected is used. Detailed NSF-specific comments and recommendations from the RFI and roundtable discussions were sent to NSF staff. NIH-specific comments and recommendations were sent to the NIH Office of Extramural Research.

Investigators indicated that requests for additional information beyond the scope of progress reports are burdensome. The Paperwork Reduction Act of 1980, amended in 1995, requires that requests for additional information collection be approved by the OMB Office of Information and Regulatory Affairs following internal agency review and approval and a period of public comment. NSF has instituted a process whereby any program seeking to impose reporting requirements outside the scope, or in excess, of the frequency permitted by the RPPR must provide justification to the agency's Reports Clearance Officer and to the Policy Office prior to seeking OIRA clearance to determine if the additional reporting component is necessary for the successful oversight of the program.

A major research university suggested that ARRA, the potential institutional reporting effort associated with emerging initiatives such as Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science (STAR METRICS) and the Digital Accountability and Transparency Act (DATA) legislation "are, and will be, burdensome and costly to research institutions." The Grant Reform and New Transparency (GRANT) Act also has the potential to add significantly to institutional costs and investigator's workload. These initiatives aim to make transparent the use of Federal funds for scientific research. In the pursuit of transparency, however, it is necessary to balance associated costs and to preserve our Nation's intellectual property and innovations. ARRA allowed for a high-level of transparency, however, an FDP member survey to assess the administrative impact of ARRA found that administrative costs, representing both staff and PI time, totaled \$7,973 per ARRA award. Investigators and institutions questioned the value of the data collected relative to the administrative cost and loss of research time.

## Recommendations

A | The Board recommends that agencies modify proposal requirements, so that they only include those essential to evaluating the merit of the proposed research and making a funding determination. This recommendation can be achieved through use of these or other mechanisms:

- Preliminary proposals
- Broadening JIT submission
- Simplifying budget requirements for peer review

The Board strongly encourages NSF to continue to pilot preliminary proposals and to reduce requirements for full proposals by broadening use of JIT submission and by using simplified budgets. Where necessary for use of JIT, modification of legislation should be sought (e.g., the America COMPETES Act of 2007, which mandates that postdoctoral mentoring plans be evaluated under NSB's broader impacts merit review criterion). A simplified budget could consist of a basic narrative or description of the resources needed to complete the project and an estimated total budget figure. To effectively reduce investigators' workload, institutions should also not request a detailed budget at the time of initial proposal. NSF is encouraged to continue to solicit feedback on these approaches from the research community and to adjust its approach in response to this feedback.

B | Annual progress reports should be limited to performance outcomes, reported in simplified formats and commensurate with the size of the award. Additional data requests should be limited to those that are essential for assessment of performance and compliance. The rigor of agency and OIRA review of requests for additional data collection has significant implications for investigators' workload. The Board recommends that OIRA and the NSF Director continue to evaluate reporting requirements to minimize additional data requests.

C | The Board advises the NSF Director to fully review and consider the agency-specific comments received in response to the Board's RFI and also consider piloted modifications to the proposal process and then report to the Board on review and progress within six months of the publication of this report.

## II. ELIMINATE OR MODIFY INEFFECTIVE REGULATIONS

RFI respondents and roundtable participants described a number of regulations (some legislatively mandated) as ineffective, creating unnecessary work, or inappropriately applied to research settings. These regulations applied, in particular, to time and effort reporting, COI, human and animal research, and laboratory safety and security. Many of these requirements have been identified in previous surveys and reports. Effective action should be taken to eliminate or modify these requirements to avoid further waste of Federal research dollars and to accelerate the pace of scientific discovery and innovation.

### Time and Effort Reporting

Per OMB Circular A-21, faculty are required to regularly identify and certify the amount of time that they and their staff, including unpaid volunteers, expend on research related to individual grants. While indicating their support for the proper stewardship of Federal grant funds, most of the RFI respondents and roundtable participants indicated that time and effort reporting is quite ambiguous, time consuming, and not an effective measure of proper use of Federal funds. Perhaps most importantly, it 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).

Investigators and institutions responding to an RFI posted in June 2011 by the RBM's A-21 Interagency Task Force ranked effort reporting as the top area of concern, and suggested that it represented an "extreme burden to scientific staff" and a substantial expense to universities. The NRC Committee on Research Universities, the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), COGR, and others have suggested that time and effort reporting be eliminated. Recommendations in response to the Board's RFI and roundtable discussions included eliminating effort reporting in favor of performance outcomes and deliverables, tangible measures of effort, or use of existing payroll systems to provide automated information.

The new OMB Uniform Administrative Requirements include revised guidance on time and effort reporting. The guidance, which will take effect in December 2014, requires greater accountability of institutions and calls for strong internal controls for documentation. It provides guidance to meet the new standards, but also removes specific examples, allowing for greater flexibility. Ongoing pilots that use institutions' payroll systems to provide automated information to be certified by the PIs, such as the FDP Payroll Certification Project, included in the Advance Notice, were not addressed in the final Guidance. IGs are currently reviewing the pilots.

### Human Subjects Research and IRBs

The Federal Policy for the Protection of Human Subjects (45 CFR Part 46) establishes policy for human subjects protection in federally funded research at HHS and other Federal departments and agencies. Proposed changes to these policies in the ANPRM addressed many of the recommendations from the RFI and roundtable discussions. No announcement has been made of an impending release of an NPRM or final rulemaking.

Virtually all researchers understand and agree on the necessity of clear rules to protect human subjects in research. However, Federal regulations and institutional requirements for human subjects protections have become increasingly complex and may not be appropriately calibrated to risks (i.e., the approach applied

across a broad spectrum of study types is too broad-brush). These regulations and requirements have resulted in additional work for investigators, without providing the most meaningful protections for subjects. Several investigators suggested that researchers avoid or have discontinued human subjects research due to excessive administrative requirements and IRB delays.

RFI respondents and roundtable participants suggested that the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules<sup>3</sup> are generally inappropriate for human subjects research and noted that HIPAA and HHS Office for Human Research Protections (OHRP) policies on privacy matters conflicted. On the topic of IRBs, many respondents expressed concern about the extensive, or “excessive,” time taken for IRB review and approval, as well as the difficulty of obtaining approval on the first submission. These extended time periods can delay research for several months. These issues can, in some instances, be attributed to a lack of IRB support staff or good communication with investigators prior to review and underuse of the expedited review process (a possible strategy for minimizing institutional risk).

Respondents suggested that documentation requirements have increased considerably with increasing regulatory and oversight requirements and that these requirements have increased their workload without providing an appreciable increase in subjects’ safety. For example, one respondent suggested that, “for non-invasive, behavioral data (i.e., language tests), for parents with limited education, it seems excessive and intimidating to have a two page, single spaced consent form.” It was suggested that the level of documentation is particularly excessive for studies exempt from IRB review, such as certain types of social and behavioral research, and that studies eligible for exempt status should have a streamlined submission review process. It was also suggested that more options be available for research that poses no potential harm to be defined as exempt. Concerns specific to social and behavioral research as they relate to proposed changes to the Common Rule are addressed in a recent NRC report.<sup>xiv</sup>

Investigators conducting multi-site studies cited increased administrative work when they were required to have multiple institutions review the same protocols and consent forms. Different institutional IRBs typically have different forms, procedures, and deadlines. An investigator indicated that these differences can result in delays of a year or more and that approval and disapproval of portions of the protocol by different IRBs can introduce “inconsistencies...that reduce the scientific value of the study and...create flaws in the study design.” Respondents indicated that a single IRB of record for multi-site studies, with one approval, would significantly reduce their administrative workload. Guidance on selecting an IRB that delineates the responsibilities and compliance requirements of the central and local IRB/institution (e.g., for continuing review or financial COI) for various types of research, would reduce liability concerns and facilitate use.

RFI respondents noted that grant proposals and human subjects protocols are sometimes reviewed by the funding agency and the institution. IRBs sometimes undertake scientific review—beyond what is perceived to be necessary to ensure human subjects protections—of proposals that have already been peer reviewed and approved by Federal agencies. Agencies have also performed research protocol reviews that go beyond what is required for ensuring scientific effectiveness. Such reviews must then be reconciled with local IRB review.

Investigators suggested that IRBs exceed the Federal requirements due to concerns about oversight and liability. PIs noted that practices aimed at mitigating liability impose a considerable burden, as they delay research by weeks or months. Institutions and organizations representing them suggested that these practices are due to individual auditor interpretation of regulations, focus on process, and dissonance between the regulations and the findings of those enforcing them. The responses highlighted significant institutional variability in the efficiency of IRBs and the systems and requirements that they have in place. Institutional efforts to comply with conflicting agency requirements may compound the issue.

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<sup>3</sup> HHS issued the Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) and the Security Rule (Security Standards for the Protection of Electronic Protected Health Information) to implement HIPAA.

## Animal Research and IACUCs

Researchers working with laboratory animals have been required to obtain approval of their research protocols by IACUCs since 1985.<sup>4, xv</sup> The legislation gives the U.S. Department of Agriculture (USDA) and PHS authority to govern the treatment of research animals. PHS Policy requires institutions that receive PHS funding for the conduct of animal activities to base their programs on the *Guide for the Care and Use of Laboratory Animals* (Guide).<sup>xvi</sup> The *Guide*, published by the Institute of Laboratory Animal Resources (ILAR) at the National Academy of Sciences, is a manual of best practices.

As with human subject research and IRBs, IACUC-related administrative work is performed mostly by PIs and their research staff. As a result, these administrative requirements directly impact their workload. Comments on animal research echoed the concerns expressed for human research, including escalating regulations and prescriptive guidance, duplicative agency and institutional review of grants and protocols, IACUCs exceeding Federal requirements, and institutional concerns about liability.

Investigators recognized the responsibilities associated with their use of animals in research. They underscored their dedication to minimize their use of animals and to ensure the proper care and treatment of those animals that they used. What investigators expressed frustration with were requirements that increased their administrative workload but were not perceived to improve the care and treatment of animals. These issues have significant implications for the day-to-day conduct of research and function of IACUCs.

On the topic of guidance, respondents suggested that “should” statements in the Guide are enforced as “must” statements by the NIH Office of Laboratory Animal Welfare (OLAW), which has the effect of imposing new rules rather than offering interpretations. Their concern is that in addition to the requirements in statutes and regulations, new requirements are being created through guidance and FAQs, which is not the intent or purpose of guidance. In a written response to the RFI comments, OLAW, which administers the PHS Policy, responded that departures from these statements should be reported, unless performance standards support the deviation. The full response from OLAW to this and other concerns is included in this report (Appendix D).

Respondents indicated that USDA’s policies and guidance, which require a literature search in response to an Animal Welfare Act (AWA) requirement that investigators consider alternatives to animals, create considerable administrative work for investigators and do not facilitate the reduction, replacement, or refinement of animals used in research. A major research university noted that, in their experience, the literature search has not produced real alternatives, and that failure to adequately perform it is one of the top 10 citations noted by the USDA each year. It was suggested that this requirement could be incorporated into the list of assurance statements that PIs typically affirm or as an alternative process determined at the IACUC level.<sup>5</sup> In response, the USDA’s Animal and Plant Health Inspection Service made the following comment: “We support the efforts to explore options that address the respondents concerns regarding: the AWA requirement to consider alternatives to procedures that may cause more than momentary or slight pain or distress; IACUC authority and responsibilities; grants and protocol reviews; regulations, guidelines, and standards of care; and other topics of mutual concern. We look forward to working with the research community to ensure regulatory compliance, reduced administrative burdens, and humane animal treatment and care.”

A number of respondents commented on annual and three-year reviews of animal research protocols by IACUCs. It was noted that many institutions require that protocols be completely rewritten at year 3 (though not required by agencies) and that the review is perceived to be unnecessary as protocols are continually amended. According to OLAW, PHS Policy does not require that the protocol be rewritten at year 3. OLAW

<sup>4</sup> With the passage of the Improved Standards for Laboratory Animals Act (ISLAA, amending the 1966 Animal Welfare Act) and the Health Research Extension Act (HREA).

<sup>5</sup> The 1999 report NIH Initiative to Reduce Regulatory Burden also suggested the USDA re-examine this requirement.

also noted that annual review is not required. Therefore, for species not covered by the USDA (i.e., mice, rats and birds), annual IACUC review is optional.

Several investigators concurred with comments from the American Association of Immunologists. These comments suggested that the Federal requirement that all experiments have to be predetermined and that exact animal numbers have to be statistically justified forces researchers to project these quantities years into the future, and then continually file amendments for any deviation. Researchers suggested that it is impossible to predict the direction their research will take and the precise number of animals they will need for the full period of a grant. PHS Policy, according to OLAW, requires “that proposals specify a rationale for the approximate number of animals to be used” and that “the IACUC may approve a range of animal numbers, rather than a specific animal number, if the range is appropriately justified.”

Responses to the RFI suggest that designated member review - a form of expedited review approved by the USDA and OLAW - may be underused by IACUCs. OLAW affirmed that it is a valid alternative to full committee review and also noted that PHS Policy allows small changes to be approved through an administrative process. Investigators indicated the need for standard training and for language, templates, and procedures for animal research. OLAW offers guidance about institutional training programs, which, it suggested, could facilitate harmonization, and provides [sample documents](#),<sup>6</sup> including a [sample protocol form](#),<sup>7</sup> which can be modified as needed by the institution.

### Financial Conflict-of-Interest

PHS and NSF financial disclosure regulations were implemented in the mid-1990s. PHS regulations were updated in 2011 following passage of The Consolidated Appropriations Act of 2010, which mandated that NIH amend its regulations to strengthen Federal and institutional oversight. Among the revised regulations are requirements that investigators disclose all significant financial interests related to their institutional responsibilities; lower the monetary threshold for disclosure from \$10,000 to \$5,000; and, require investigators to complete COI training.

RFI respondents and roundtable participants largely focused on the recent changes to PHS regulations. They noted that the new regulations have resulted in significant additional work for investigators and the hiring of additional institutional staff with limited perceived benefit. Roundtable participants were emphatic in recommending that NSF and other agencies not adopt PHS requirements and advocated for a risk-based approach that would target major income sources. It was also suggested that disclosures should not be required at the time of proposal submission (when collaborations can change significantly), that updates should only be required when significant changes are reported and that clearer guidance is needed to prevent institutions from requiring reporting in excess of regulations.

Investigators and institutions acknowledged the need for accountability and transparency but also noted that overly stringent COI policies can hinder entrepreneurial activities. Increasingly stringent Federal COI policies will further limit technology transfer and innovation, and could impact the desired goals of university-business partnerships, without instituting a measurable change in COI. The National Academies report, *Research Universities and the Future of America*, recommends that the role of business in the research partnership be strengthened, which would accelerate “time to innovation” to achieve national goals. Proper balance between protection against COI and encouragement of university/industry partnership is needed to facilitate sound investment of Federal funding in innovative activities.

### Laboratory Safety and Security

Although recognizing the importance of associated oversight for the safety of researchers, subjects, and the public at large, the overwhelming sense was that regulations and requirements are not properly calibrated

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<sup>6</sup> <http://grants.nih.gov/grants/olaw/sampledoc/index.htm>

<sup>7</sup> [http://grants.nih.gov/grants/olaw/sampledoc/animal\\_study\\_prop.htm](http://grants.nih.gov/grants/olaw/sampledoc/animal_study_prop.htm)

to risk. Respondents mentioned excess regulation associated with the Chemical Facilities Anti-Terrorism Standards (CFATS) and the Select Agent Program, with academic labs being held to industrial standards. Respondents suggested requirements for training; biosafety protocols; reports and certification; tracking use of chemicals; and frequent inspections were excessive and felt that these requirements do not improve laboratory safety. Respondents further suggested limiting biosecurity policies to research that poses the greatest risk and eliminating requirements to quantify biological agents present in a research setting.

## Recommendations

A | The Board proposes that OMB identify appropriate means by which the piloted payroll certification approach for time and effort reporting can be used by universities and accepted by auditors and IGs. Once resolved, a Memo of Clarification should be issued indicating that the payroll certification method is acceptable to the Federal Government.

B | The Board supports a number of recently proposed reforms addressed in the HHS ANPRM that aim to reduce administrative work for investigators while maintaining or enhancing necessary protection for research subjects, including:

- Encouraging the use of a single IRB for multi-site studies.
- Eliminating continuing review for all expedited/minimal-risk protocols.
- Expansion and clarification of current exemption categories.

Further, the Board endorses the AAHRPP recommendation to eliminate the expedited review categories and, instead, (1) declare all research involving minimal risk as eligible for review using the expedited procedure and (2) define which procedures involve no more than minimal risk.

The Board further recommends eliminating the requirement that IRBs review grant proposals and the requirement to submit IRB approved research protocols for review by agency IRB or peer review panel.

C | The regulatory environment governing animal research has grown increasingly complex. An evaluation of the regulations, policies, guidance, best practices, and FAQs of all regulatory, independent, and certification bodies governing animal research should be considered to identify policies and guidance that increase investigators' administrative workload without improving the care and use of animals. As an example, the task force or committee might consider efforts to align USDA requirements on continuing review with PHS regulations; requiring review at least every three years which is consistent with PHS requirements but allows for greater frequency as deemed necessary by the IACUC. This approach is similar to the risk-based approach proposed for human subjects in the ANPRM where minimal risk studies, such as behavioral or observational studies, would not be subject to annual review.

The Board observes that detailed regulations and policies requiring a literature search for alternatives to animals may considerably increase PIs' workload without a realization of measurable improvement in animal care and use. Federal agencies should consider, as a possible alternative to a literature search, investing in sponsored research that examines alternatives to animal models. Such research might offer alternatives that ensure scientific validity and is more likely to lead to the reduction, refinement, and replacement of animal models.

D | The Board recommends an evaluation of recent changes to PHS COI regulations to assess cost and effectiveness and impact on entrepreneurial activities. The Board does not recommend adoption of the PHS COI regulations by other Federal agencies.

E | The Board recommends reexamining safety and security requirements, or aspects of these requirements that target industry, but are also applied to research settings. Based on this examination, appropriate alternatives should be identified and implemented.



### III. HARMONIZE & STREAMLINE REQUIREMENTS

#### Harmonization

RFI respondents and roundtable participants noted a lack of harmonization and standardization within and among agencies in all aspects of grant management - from policies and guidance to formatting and electronic submission. Inconsistencies in financial audit were also cited as contributing to the administrative burden. Investigators and institutions noted that every new regulation adds associated training requirements that are often excessive and not coordinated across agencies. This lack of coordination can result in training for the same regulation multiple times.

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. Standardization, however, also implies the need to reduce and simplify requirements so that harmonization will not lead to over-extension if the most restrictive elements are implemented.

#### Financial Management and Audit

RFI respondents referenced financial tracking and reporting, including monthly and quarterly reports to agencies, as a significant administrative burden. This burden can result from agency requests that exceed standard regulations or legislatively mandated reporting requirements such as ARRA. In addition, investigators noted that the inability to access timely data on the financial status of their grants makes it difficult to plan expenses. Delays of one month or more for institutional budget reports have required some PIs to opt to separately track their finances.

PIs reported having to justify and seek approval for research supply and equipment purchases, including for low-cost supplies such as pens and paper towels, from university administrators. Several commented that greater institutional demands for financial details and justifications result from auditor requests and/or institutions' concerns about auditing. A major research university suggested that the current audit environment "takes an entirely risk averse approach, auditing well beyond regulatory requirements." COGR, AAU, and APLU, while offering that institutions should consider opportunities for streamlining processes, noted that IGs are seeking greater levels of certification and review. Respondents suggested that the cost of compliance far outweighs the incidences of abuse.

Another area frequently mentioned was the requirement to seek agency approval to transfer funds from one budget category to another. NSF does allow grantees to transfer funds between categories except in two instances: (a) moving funds out of the participant support category and (b) budget transfer in excess of \$25K for alterations or improvements (construction).

Many respondents noted that the management and necessary paperwork associated with sub-recipient monitoring are a "huge administrative burden" and where possible best avoided. The Federation of American Societies for Experimental Biology (FASEB) survey report produced in response to the Board's RFI noted the "lengthy finalization process for subcontracts due to institutional and agency requirements as well as state and Federal laws." It was suggested that the NSF collaborative research proposal reduces this burden. Separately submitted collaborative proposals to NSF allow two or more institutions to manage separate awards for a single, unified project.

A number of responses addressed travel reimbursement. Many respondents indicated that their institution requires receipts for even very small purchases, rather than using a per diem system for reimbursement.



## Recommendations

- A | The Board urges Federal agencies to accelerate efforts to harmonize and streamline the grant proposal and submission process and post-award requirements. Standardized requirements should be limited to the minimum necessary to assess merit, progress, and compliance and not default to the most restrictive elements. Agency-specific requirements should be identified and eliminated where possible to allow for a single standard.
- B | The Board recommends that a mechanism be established to ensure uniform and consistent audit practices based clearly and directly on regulatory requirements. The Board further urges agencies and institutions to consider requiring receipts and justifications only for larger purchases. Audits that focus on larger expenditures, outcomes, and infrastructure for compliance and risk management would significantly reduce investigators' workload while maintaining necessary oversight.
- C | NSB has direct responsibilities for NSF, but many of the findings in this report cut across the Federal Government and require high-level, multi-sector coordination. To address the recommendations in this and other reports and to properly develop and implement new requirements affecting investigators and institutions, the Board recommends that a high-level, inter-agency, inter-sector committee be created, with stakeholder and OMB/OIRA representation.
- The Board recommends that stakeholders, either in concert with agencies as part of a committee or through a forum such as the National Academies create a priority list of additional regulations and policies that should be eliminated, modified, or harmonized to reduce the administrative workload of PIs and institutions and propose detailed solutions or alternatives as appropriate. The list should include legislation that has resulted in significant cost and burden or impedes harmonization without substantially improving the research environment and its accountability and transparency. This harmonization will be most effective when institutions can be assured that adherence to these requirements will provide adequate risk avoidance.
  - A high-level, inter-agency, inter-sector committee is recommended to implement the necessary changes identified. The Board further recommends that the committee be made permanent, with rotating membership. The committee could coordinate with or otherwise advise OIRA on an ongoing basis to ensure that new regulations or changes to existing regulations that affect researchers, institutions, and other stakeholders are efficient, performance-oriented, and harmonized.

## IV. INCREASE UNIVERSITY EFFICIENCY AND EFFECTIVENESS

### Institutional Requirements and Support

Although 83 percent of respondents who identified a perceived source of burden saw the Federal Government as a major source, 77 percent also perceived the institution as a source of burden. Many researchers have the impression that the preponderance of compliance requirements are placed upon them by their own institution. Although institutional practices do exist, most compliance mandates are rooted in Federal or state law or policy. An additional complication arises for public institutions since they generally must comply with state regulations involving travel, reporting, purchasing, and sometimes human and/or animal subjects requirements. All of these requirements can be more restrictive than the Federal regulations and result in additional administrative burden on individual investigators. As an example, requirements associated with the Americans with Disabilities Act of 1990, which are important for accessibility, have resulted in excessive administrative and technical work, without associated funding, for investigators in some states due to state-level reporting requirements.

Three-quarters of RFI respondents addressed institutional administrative support. Some noted excellent support for a wide range of tasks, while others lamented the lack of support for areas such as budget preparation, proposal writing, IACUC and IRB protocol compliance, financial tracking and management, and general post-award support. A major research university stated that "the institutional administrative support that is available

to faculty has eroded as more and more staff time is consumed by addressing new requirements, and as more and more resources are diverted from faculty support to fund new staff to administer systems, programs, reviews, and other duties associated with ever changing reporting, regulatory, and monitoring requirements.” PIs at smaller or less research-intensive institutions may experience an even greater burden from Federal regulations as a result of having fewer administrative resources. The concern is that growing Federal regulations governing research will result in the concentration of research at fewer universities since only those with greater financial resources will be in a position to compete for Federal research funding.

Many respondents suggested that indirect cost reimbursement should be used to support PIs’ administrative needs directly. The general sense was that since PIs are bringing in funding for the university, institutions should be doing more to assist researchers with grant management. Indirect or Facilities and Administrative (F&A) cost recovery is reimbursement for costs already incurred by the institution to provide the facilities and infrastructure necessary to conduct research. Interestingly, most state agencies that fund research at universities within their states either do not pay indirect costs or do so well below the federally negotiated rate. The rationale is that because states already appropriate funding for public research institutions, paying indirect costs on individual grants and contracts would be seen as paying twice. It would appear unlikely that any action at the Federal level could address these issues.

## Recommendations

- A | The Board recommends that institutions communicate the origin of compliance requirements to researchers and avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so.
- B | The Board recommends that Federal agencies collaborate with research institutions, and organizations representing investigators and institutions, to identify and disseminate model programs and best practices (e.g., for financial management and IRB/IACUC review) that could be adapted for use at other institutions. This effort could be aided by the recommended interagency, inter-sector committee. Institutions might also consider mechanisms for surveying faculty on institutional burden. In response to this RFI, the University of California surveyed its faculty on Federal and institutional burden. Others have developed permanent mechanisms to address issues related to institution-level requirements and processes with the goal of reducing PIs administrative workload.<sup>8</sup>
- C | Developing human and animal research protocols in an appropriate format for IRB and IACUC review is a complex and often very time-consuming task. The time and effort involved could likely be reduced at many institutions, with consequent gains in research productivity and research subject protection if IRB and IACUC staff provided researchers with knowledgeable assistance in the preparation and modification of these protocols. Such assistance could lead to the development of high-quality protocols that are approved with minimal delay. As a consequence, research would commence much earlier. In addition, the workload of the researchers and IRB/IACUC staff and members might be reduced markedly. The Board recommends that universities review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high-quality protocols that protect research subjects.

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<sup>8</sup> As an example, Massachusetts General Hospital’s Continuous Research Operations Improvement Program.

# CONCLUSION

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.

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# APPENDIX A

FEDERAL  
REGULATORY  
CHANGES,  
SINCE 1991

# COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 750, Washington, D.C. 20005  
(202) 289-6655/(202) 289-6698 (FAX)

## Federal Regulatory Changes, Since 1991

*The regulations listed below have been implemented or amended since the imposition of the 26 per cent cap on administrative costs in the Facilities and Administrative Cost recovered under OMB Circular A-21. The listed regulations directly affect the conduct and management of research under Federal grants and contracts. The list of current regulations is in chronological order. Significant changes in the implementation or interpretation of regulations or management processes are listed below in a separate section. The list concludes with significant proposed regulations. **This list does not include the reporting requirements associated with the American Recovery and Reinvestment Act (ARRA) funding support.***

Federal Policy for the Protection of **Human Subjects (Common Rule)**, 1991)

Nonindigenous **Aquatic Nuisance Prevention & Control Act** of 1990 (Implemented, 1992)

NIH Guidelines for Research Involving **Recombinant DNA Molecules** (1994)

**Deemed Exports** (1994, EAR & ITAR)

**DFARS Export Control Compliance Clauses** (2010)

**Conflicts of Interest**

Public Health Service/NIH Objectivity in Research (1995; Amendments August 2012)

NSF Financial Disclosure Policy (1995)

**Lobbying Disclosure Act** of 1995 (Amended 2007; 2013)

Cost Accounting Standards (**CAS**) in OMB Circular A-21(1995)

Health Insurance Portability & Accountability Act of 1996 (**HIPAA**) Privacy Rule (Amendments January 2013)

OMB Elimination of **Utility Cost Studies (UCA)** (1998)

Data Access /**Shelby Amendment** (FY 1999 Omnibus Appropriations Act); related amendments to OMB Circular A-110

Policy on Sharing of **Biomedical Research Resources** (NIH, 1999)

**Misconduct in Science** (Federalwide Policy, 2000)

NEH, 2001

NSF, 2002

EPA, Directive, 2003

Labor, 2004

HHS/PHS, 2005

NASA, 2005

Energy, 2005

Veterans Affairs, 2005

Education, 2005

Transportation, 2005

USDA, 2010

HHS Centers for Medicare and Medicaid Services (**CMS National Coverage Determination for Routine Clinical Trials**) (Clinical Trials Policy), 2000

Health and Human Services/FDA **Clinical Trials Registry** (2000, Food and Drug Administration Amendments Act of 2007; Mandated Reporting, 2008)

**Executive Order 13224**, Blocking Property and Prohibiting **Transactions With Persons** Who Commit, Threaten to Commit or **Support Terrorism** (September 2001, also EO 12947, 1995)

**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

**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**

**CIPSEA** Confidential Information Protection and Statistical Efficiency Act (OMB Implementation Guidance 2007, Title V, E Government Act of 2002)

**Data Sharing** Policy (NIH, 2003)

Homeland Security Presidential Directive (**HSPD**) – **12**, Common Identification Standards for Federal Employees and Contractors (2004)

Higher Education Act, Section 117 Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)

**Model Organism** Sharing Policy (NIH, 2004)

**Constitution & Citizenship Day** (2005, Consolidated Appropriations Act FY 2005)

**Genomic Inventions** Best Practices (2005)

Office of Management & Budget Guidance for Governmentwide Debarment and Suspension [**Nonprocurement**] (2CFR Part 180, 2006) Consolidation of agencies' Governmentwide Debarment & Suspension Common Rule (2003).  
Federal Acquisition Regulations [FAR] Flowdown of Debarment/Suspension to Lower **Tier Subcontractors** (December 2010; amendment to FAR Subpart 9.4)

Combating Trafficking in Persons (2008)

**Code of Business Ethics & Conduct** (FAR 2008)

Homeland Security **Chemical Facilities Anti-Terrorism Standards (CFATS) (2008)**

**E-Verify** (2009)

**Military Recruiting** and ROTC Program Access (2008, Solomon Amendment, National Defense Authorization Act for FY 2005)

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)

National Institutes of Health **Public Access Policy** (2008, Consolidated Appropriations Act of 2008, Division G, Title II Section 218)

**Certification of Filing and Payment of Federal Taxes** (Labor, HHS, Education and Related Agencies Appropriations Act of 2008, Division G, Title V, Section 523)

National Institutes of Health Policy for **Genome-Wide Association Studies** (GWAS, 2008)

Federal Funding Accountability and Transparency Act (FFATA) Executive Compensation and **Subrecipient Reporting** (2006) (FAR, July 2010; OMB Open Government Directive, April 2010)

USAID **Partners Vetting System** (re: EO 13224 et al re: terrorist financing 2009; Extension to Acquisitions, 2012)

National Institutes of Health **Guidelines for Human Stem Cell Research** (2009)

National Science Foundation **Post-Doctoral Fellows Mentoring** (America COMPETES Act 2006; implemented 2009)

Executive Order 13513, Federal Leadership on Reducing **Text Messaging** While Driving (October 2009)

National Science Foundation **Responsible Conduct of Research** Training (America COMPETES Act 2006; implemented 2010)

National Science Foundation **Public Outcomes Reporting** (America COMPETES Act 2006; implemented 2010)



Federal Acquisition Regulations (FAR) and Office of Management & Budget Federal Awardee **Performance and Integrity Information System (FAPIS)** 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)

National Institutes of Health, **Budgeting for Genomic Arrays** for NIH Grants, Cooperative Agreements and Contracts (2010)

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; Inventor Oath or Declaration; 3rd Party Submission of Prior Art; Citation of Prior Art; Statutes of Limitation for Disciplinary Actions; Supplemental Examination; Post-Grant Review

NASA/OSTP **China Funding Restrictions** (2012, Under PL 112-10 § 1340(2) & PL 112-55 § 539)

**US Government Policy for the Oversight of Life Sciences Dual Use Research of Concern** (March 2012)

NIH, **Mitigating Risks of Life Science Dual Use Research of Concern** (2013)

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)

Office of Science and Technology Policy (OSTP), **Increasing Access to the Results of Federally Funded Scientific Research** (February 2013)

## **Implementation/Interpretation that Changes Business Practices, Since 1991**

**Foreign Nationals** (See COGR/AAU/FDP Troublesome Clause Report, 2008<sup>1</sup>)

**Publication Restrictions** (see COGR/AAU/FDP Troublesome Clauses, 2008)

**PL 106-107/Grants.gov**: Electronic Applications, Financial Reporting, Progress Reports, iEdison Invention Reporting, etc.

**CCR/DUNS** Registry requirements (Subrecipients implemented 2010)

**Research Performance Progress Report (RPPR)** (January 2010)

**Federal Financial Reporting (FFR)** (2011)

**Subrecipient Monitoring** (OMB Circular A-133, Compliance Supplement)

**Changes to A-21 F&A Proposal Format**

Federal Policy for the Protection of Human Subjects:

**Federalwide Assurance** (2004), mandatory training

**IRB Registration** (2008)

**Proposed Changes** (2011, see below)

**Title IX** of Education Amendments of 1972: Access to science and math educational programs (2007+)

**EPA Hazardous Waste**, Subpart K (2008)

**IRS 990 Reporting**

<sup>1</sup> The Report is available at: [www.cogr.edu/docs/COGRAAUTroublesomeClausesReport.pdf](http://www.cogr.edu/docs/COGRAAUTroublesomeClausesReport.pdf)

National Institutes of Health Trainee **Instruction in the Responsible Conduct of Research** (1989; 1994; Updated 2009)

Health & Human Services, Office of Grants and Acquisition Policy and Accountability **Guidance Regarding Funding of Contracts Exceeding One Year of Performance** (APM 2010-01, June 2010)

National Science Foundation, **Data Sharing Policy** (Updated 2011)

National Institutes of Health Implementation of the 2011 8th Edition of the National Academy of Sciences **Guide for the Care and Use of Laboratory Animals** (January 2012)

**Export Controls:** Export Administration Regulations (EAR) & International Traffic in Arms Regulations (ITAR) Reform (2013 Implementation)

Defense Federal Acquisition Regulations 252.204--7000 **Disclosure of Information** Clause Revised (2013)

National Institutes of Health, **Costing of Core Facilities** (2013)

National Institutes of Health Implementation of the American Veterinary Medical Association **Guidelines for Euthanasia**, 2013 Edition (2013)

National Science Foundation **Award Cash Management Service** (2012)

National Science Foundation Revised **Merit Review Criteria** (2013)

National Institutes of Health **Payment Management System Sub-Accounts** (2013)

## Significant Proposed Changes

Food and Drug Administration **Requirements for an Investigative New Drug (IND)** covering food and plants claiming therapeutic benefit

USDA **Animal Welfare Act, Contingency Planning** (2008)

Defense/DFARS **Safeguarding Unclassified Information** (ANPRM, May 2010; NPRM, 2011)

FAR **Organizational Conflicts of Interest** (NPRM April 2011)

HHS Office for Human Research Protections Human Subjects Research Protections: Enhancing **Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators**; proposed changes to 45 CFR 46 Subpart A (ANPRM, September 2011)

FAR **Privacy Act Training** (Proposed 2011)

OMB/COFAR **Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (Including Single Audit Act)** (Proposed February 2013)

OSTP **US Governmental Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern** (Proposed February 2013)

National Institutes of Health **Genome Data Sharing Policy** (September, 2013)

# APPENDIX B

REQUEST FOR  
INFORMATION

## **Request for Information (RFI): Reducing Investigators' Administrative Workload for Federally Funded Research**

### **Key Dates**

**Release Date: March 25, 2013**

**Response Date: May 24, 2013**

### **Issued by**

National Science Foundation (NSF)

### **Purpose**

This RFI offers principal investigators with Federal research funding the opportunity to identify Federal agency and university requirements that contribute most to their administrative workload and to offer recommendations for reducing that workload. Members of the National Science Board's Task Force on Administrative Burdens do not wish to increase your administrative workload with this request and you may choose to answer only those questions that are most pertinent to you. Your responses will provide vital input so that we can implement agency-level changes and offer recommendations to reduce unnecessary and redundant administrative requirements.

### **Background**

Over the past decade, two Federal Demonstration Partnership (FDP) Faculty Workload Surveys (2005 and 2012) indicate that administrative burdens associated with Federal research funding are consuming roughly 42% of an awardee's available research time, a figure widely cited in numerous articles and reports. To help address these issues, the National Science Board (Board) recently created a Task Force on Administrative Burdens. The Task Force is charged with examining the burden imposed on Federally-supported researchers at U.S. colleges, universities, and non-profit institutions. Responses to this RFI will be considered as the Board develops recommendations to ensure investigators' administrative workload is at an appropriate level.

### **Request for Information**

The Task Force is seeking a response to the questions below. In your response, please reference the question number to which you are responding.

## Sources of Administrative Work and Recommendations for Reducing Work

1. What specific requirements associated with your Federally funded grants require you personally to do the greatest amount of administrative work? Where possible, please indicate whether the origin of that administrative work is a requirement at your institution, a Federal requirement, or a requirement from another institution. What recommendations would you offer that might help to reduce the level of work?
2. Principal investigators responding to the FDP's 2012 Faculty Workload Survey identified the following sources of administrative work, in addition to human subject protection and animal care treated below, as particularly burdensome for Federal grantees:
  - Grant progress report submissions;
  - Finances (e.g. managing budget-to-actual expenses, equipment and supplies purchases, and other financial issues/requirements);
  - Personnel management, hiring, and employee evaluation, and visa issues;
  - Effort reporting;
  - Conflict of interest;
  - Responsible conduct of research;
  - Lab safety/security;
  - Data sharing; and,
  - Sub-contracts (e.g. overseeing: progress toward project goals and deadlines; budget expenditures, invoices, and other financial matters; and, compliance and safety/security issues).

If not addressed in question 1, for any of the areas listed, do you believe that the associated requirements significantly increase the amount of administrative work you personally need to perform? Where possible please indicate whether the source of the required administrative work is a requirement at your institution, a Federal requirement, or a requirement from another institution. What recommendations would you offer that might help to reduce the level of work?

3. Do you receive administrative support from your institution for Federal grants? If yes, for what specific preparation, reporting, and compliance requirements do you receive administrative support? Is the amount of support excellent, good, adequate, poor, or non-existent? Where does your administrative support come from within the institution (e.g. office of the vice president for research, office of sponsored programs, a department, a laboratory, others)? What additional administrative support would you like to receive from your institution?

## Institutional Review Boards (IRB)/Institutional Animal Care and Use Committees (IACUC)

4. If you are conducting human or vertebrate animal research requiring IRB or IACUC approval, what requirements (e.g. preparing protocols for initial review, annual reviews and re-writes, completing revisions requested by reviewers, and satisfying training and other Federal requirements) create the most administrative work? Is the work completed primarily by you or others? Are there particular practices used by your university's IRB/IACUC process that contribute to or subtract from

the administrative work you must perform to meet Federal and Institutional requirements? What recommendations would you offer that might help to reduce the level of work?

### Proposals

5. Investigators responding to the FDP 2012 Faculty Workload Survey indicated that 15 percent of their research time associated with a Federal award is devoted to proposal preparation. Are there administrative tasks associated with proposal preparation that increase your personal administrative workload? Please provide specific examples. What recommendations would you offer Federal agencies for reducing the level of administrative work necessary to submit a grant proposal while maintaining the details needed to evaluate the merit and feasibility of the proposed research?

### Agency-Specific Requirements and Multiple Agencies

6. From which agencies do you receive Federal funding? In your opinion, have you observed outcomes related to data or information that you have provided at the request of Federal agencies? If you receive funding from multiple agencies do you believe that there are overlapping or redundant interagency requests or requirements that increase your administrative workload? How might these requirements be streamlined across Federal agencies?
7. If you receive funding from NSF, are there NSF-specific requirements that you believe create significant administrative work for you? What steps would you suggest NSF take to reduce the level of work necessary to comply with the requirement(s)?

### Reform Efforts

8. The Office of Management of Budget (OMB) has recently proposed reforms to administrative requirements for Federal awards, including:
  - a. Guidance that clarifies the circumstances under which institutions may charge administrative support as a direct cost under certain conditions, including where the support is integral to a project or activity, can be specifically allocated to it, is explicitly included in the budget, and is not also recovered as indirect costs.
  - b. Reforms to effort reporting, including using employee payroll reports from institutional automated payroll systems to comply with effort reporting requirements.

What if any effect do you believe these proposed reforms would have on your administrative workload? Would you utilize direct charging if the guidance is finalized? To what extent would you utilize it (i.e., what % of funds)?

### Professional/Institutional Information

The following information will allow us to assess the influence of institution size/administrative capacity, academic rank, and field of study on the level and type of administrative work reported but is not required.

9. What is your academic rank? What is your field of study? Please indicate which of the following

best describes your institution:

- Public research institution with medical school
- Public research institution without medical school
- Private research institution
- Public master's institution
- Private master's institution
- Primarily undergraduate institution
- Minority-serving institution
- Non-profit/for profit institution

### **How to submit a response**

All responses and should be submitted by email to:

[Administrative-Reform@nsf.gov](mailto:Administrative-Reform@nsf.gov)

Responses to this RFI will be accepted through May 24, 2013. You will not receive individualized feedback on any suggestions. Individual or aggregate responses may be referenced in a final report; however the Board will not attribute any comments by name. Email addresses will be anonymized and responses kept confidential consistent with our obligations to comply with a judicial or administrative subpoena, or a FOIA request pursuant to 5 USC § 552. Please note that any personal information contained within the body of the email/response (i.e. signature lines) will be retained if not deleted by the sender. No basis for claims against the U.S. Government shall arise as a result of a response to this request for information or from the Government's use of such information. Any questions or inquiries should be sent to: [Administrative-Reform-Inquiries@nsf.gov](mailto:Administrative-Reform-Inquiries@nsf.gov).

### **Ann Bushmiller**

Senior Legal Counsel, NSB



# APPENDIX C

## ANALYSIS OF RFI RESPONSES

# CONTENTS

|   |    |
|---|----|
| Executive Summary   | 33 |
| 1. Introduction   | 35 |
| 2. Methods  | 36 |
| 3. Overview of Responses  | 37 |
| 4. Top Reported Burdens from the RFI                              | 39 |
| A. Financial Management   | 41 |
| B. Grant Proposal and Submission Process                          | 43 |
| C. Progress and Other Reporting                                   | 46 |
| D. Human Subjects Research and Institutional Review Boards (IRBs) | 48 |
| E. Effort Reporting   | 52 |
| F. Animal Research and IACUCs                                     | 54 |
| G. Personnel Management   | 58 |
| 5. Perceived Source of Burden                                     | 60 |
| A. Source of Burden   | 60 |
| B. Administrative Support   | 62 |
| 6. Agency-Specific Issues   | 65 |
| A. Cross-Agency Standardization                                   | 65 |
| B. NSF-specific comments  | 67 |
| C. NIH-specific comments  | 71 |
| 7. Comments on Additional Burdens                                 | 72 |
| A. Subcontracts   | 72 |
| B. Conflict of Interest   | 73 |
| C. Training   | 74 |
| D. Lab Safety and Security Requirements                           | 75 |
| 8. Conclusion   | 76 |

# EXECUTIVE SUMMARY

Over the past decade, a number of surveys, articles, and reports have indicated that administrative and compliance burdens associated with Federal research funding are consuming a greater proportion of the time that our nation's scientists, engineers, and educators are dedicating to research. The National Science Board's (NSB) Task Force on Administrative Burdens has been charged with examining the administrative burden imposed on federally supported researchers at U.S. colleges, universities, and non-profit institutions and offering recommendations for relieving it.

On March 25, 2013, the Task Force issued a request for information (RFI) to identify which Federal agency and institutional requirements contribute most to principal investigators' (PIs) administrative workload and to solicit recommendations for reducing the workload. While the majority of the 210 responses came from individuals (192), several organizations submitted aggregated responses (6) based on surveys of faculty or members or institutional responses (12) to the RFI. Together, the responses represent the views of 3,178 respondents, most of whom identified themselves as faculty. Forty-four percent of individual respondents indicated receiving National Science Foundation (NSF) support, and 30 percent indicated receiving funding from the National Institutes of Health (NIH). A smaller percentage of respondents indicated Department of Defense (DOD), Department of Energy (DOE), U.S. Department of Agriculture (USDA), or National Aeronautics and Space Administration (NASA) support. Many respondents reported receiving funding from more than one agency.

Concurrent with the RFI, the Task Force conducted a series of roundtable discussions with over 200 faculty and administrators. The comments received were consistent with those received for the RFI at large and are reflected in this report.

This report provides an analysis of the top-reported burdens, their perceived source, and recommendations offered by RFI respondents and roundtable participants for reducing their administrative workload. The major burdens cited in the RFI responses are as follows:

## **Financial Management**

Respondents indicated that financial reporting requirements, increased financial scrutiny, and detailed justifications for all purchases are a major source of administrative work. Many suggested that institutions are risk averse due to financial audits and that these institutions further contribute to burden through poor financial management software and use of different budget categories than those required by agencies. Respondent recommendations included reducing the frequency of reporting requirements and audits, developing consistent policies for audit, requiring receipts and justifications only for larger purchases, using electronic systems that track expenses in real time, and using per diem allowances for travel reimbursement.

## **Grant Proposal and Submission Process**

Most respondents indicated that they are spending a significant proportion of their time preparing and submitting grant proposals. A few individuals noted the increased need to prepare multiple proposals due to declining funding rates. Detailed budget requirements, increased requirements for supplementary materials, formatting requirements that vary by agency, and difficulties with proposal submission systems further increase the workload. Respondent recommendations included using preliminary proposals and broadening just-in-time (JIT) submission to include ancillary documents and detailed budgets; expanding use of modular budgets; standardizing the proposal and submission process; developing a centralized database for biosketches, curriculum vitae (CVs,) and other documents; and providing greater clerical support.

### **Progress and Other Reporting**

Responses noted burdens related to the frequency of reporting, formatting and length requirements, report submission, and recently implemented standardized reporting requirements. Respondents suggested that the reports were not effectively used by agencies and were, therefore, not a good use of PI time. Recommendations included eliminating progress reports (or at least reducing the scope of the reports) and improving the submission process.

### **Human Subjects Research and the Institutional Review Board (IRBs)**

Respondents who commented on human subjects research indicated that the length of time it takes to obtain IRB approval—typically on the order of several months—is excessive. Respondents suggested that it is difficult to get approval on first submission and that multiple rounds of review and revisions are often required. Several respondents suggested that the increased scrutiny does not affect participants' safety. Respondent recommendations included harmonizing guidelines across agencies, developing national standards and standardized templates, streamlining the exemption process and review of minimal risk research, and eliminating continuing review for expedited or minimal-risk protocols.

### **Time and Effort Reporting**

The majority of responses that addressed effort reporting indicated that it was time consuming, unnecessary, or both. Respondent recommendations included eliminating effort reporting or using existing payroll systems to provide automated information.

### **Research involving animals and Institutional Animal Care and Use Committees (IACUCs)**

Comments on research involving animals and IACUCs were similar to those for human subjects research. In addition, respondents noted that the multiple inspections required per year are disruptive, that the Federal requirement to project animal use for all years of a grant runs counter to the unpredictability of the scientific process, that the literature search requirement is of limited or no value, and that accrediting agencies increase the burden without improving animal care. Respondent recommendations included reducing reporting and inspections to what is necessary only for animal welfare, harmonizing regulatory requirements for IACUC approval across the funding agencies, and creating exempt and expedited review categories similar to those in human subjects regulations.

### **Personnel Management**

Respondents noted that the hiring process is “time consuming” and “cumbersome” because of complicated immigration paperwork, uncertain visa timing, delays and inefficiencies in the creation of new positions funded by a grant, and extensive review of personnel actions. Recommendations included simplifying the hiring process, providing more flexibility to hire grant-funded staff, and increasing institutional support.

Several cross-cutting themes emerged from the responses. Growth in Federal requirements, lack of standardization across Federal agencies, increasing use of electronic systems that require PI input, and a lack of sufficient or high-quality administrative support has PIs spending a greater proportion of their research time on administrative tasks. Respondents also noted that postdocs, graduate students, and laboratory staff can spend considerable time addressing requirements. Most PIs and institutions suggested that new requirements do not improve the safety or conduct of science, or affect fraud and abuse.

# 1. INTRODUCTION

In 2009, Congress requested the National Academies develop a follow-up report to its *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future* to provide a more in-depth analysis of the health and competitiveness of the nation's research universities. The resulting report, *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*, stated that "the problem of excessive regulatory burdens ... puts a drag on the efficiency of all university research," potentially costing "billions of dollars over the next decade." It recommended that Federal agencies "reduce or eliminate regulations that increase administrative costs, impede research productivity, and deflect creative energy without substantially improving the research environment," and that they "harmonize regulations and reporting requirements across agencies."

Regulatory requirements consume a great deal of PI time allotted for federally sponsored research. Federal Demonstration Partnership (FDP) 2005 and 2012 surveys of its members found that PIs of federally sponsored research projects spend, on average, 42 percent of their time on associated administrative tasks. The FDP is a cooperative initiative among Federal agencies and 119 institutional recipients of Federal research grants.

On March 25, 2013, the Task Force issued an RFI inviting PIs with Federal research funding to identify which Federal agency and institutional requirements contribute most to their administrative workload and to offer recommendations for reducing that workload. Despite ongoing efforts to reduce requirements, respondents suggest that Federal requirements and their institutional counterparts are impeding the progress of research and diverting funding for science into administration and oversight. Increasing Federal requirements and oversight but not increasing administrative funding diverts resources away from faculty who spend more time administering grants. At the same time, a decline in agency funding rates for scientific proposals has PIs spending greater time preparing and submitting multiple proposals to support their research.

## **FROM A MAJOR RESEARCH UNIVERSITY:**

*While acknowledging the importance of regulatory oversight, compliance with the growing number and complexity of such regulations requires substantial administrative effort. This diverts faculty time and resources from active research. The steady stream of new Federal regulations and reporting requirements represents one of the fastest rising costs to research universities, results in inefficient use of Federal research dollars, and is deleterious to scientific productivity.*

## **FROM THE ENDOCRINE SOCIETY:**

*In addition to the burden on investigators, the excessive administrative workload wastes critical taxpayer dollars and delays the conduct and completion of life-saving research. The administrative and regulatory tasks are also prohibitively expensive and result in an increasingly unequal playing field for biomedical researchers at many institutions across the country.*

## 2. METHODS

National Science Board Office (NSBO) staff worked with researchers at the Institute for Defense Analyses (IDA) Science and Technology Policy Institute (STPI) to analyze the RFI responses. STPI researchers qualitatively coded each response with QSR's Nvivo 9 software to allow comments and recommendations to be reported by topic area. They defined categories that allow for comparison with those identified by both the 2012 FDP Faculty Workload Survey and faculty and administration roundtable discussions held by the Task Force.

The coding process was performed independently by different coders, with several iterations of cross-coder validation. During the coding process, the texts of the 210 sources were categorized for a number of factors, including: 1) the type of response (individual; aggregated group response; institution); 2) the attributes of the respondent (academic rank or position, support from funding agencies, type of institution); and 3) the burdens identified in the response. Within the burden types, the coders identified whether the respondent had suggested that any given requirement was a burden or not, the respondent's perceived source of the burden, and any recommendations for lessening the burden.

### 3. OVERVIEW OF RESPONSES

The RFI received a total of 210 responses, 192 responses from individuals and aggregated survey (Table 1) or institutional (Table 2) responses. The individual and aggregated responses<sup>1</sup> represent the views of 3,178 respondents, most of whom identified themselves as faculty. Concurrent with the release of the RFI, the Task Force conducted a series of regional roundtable discussions with over 200 faculty and administrators held at Stanford University, Tufts University, the Georgia Institute of Technology, an NSF Grants Conference, and at Council on Governmental Relations (COGR) and FDP meetings. The comments received were consistent with those received for the RFI at large and are also reflected in this report.

**Table 1: Aggregated Responses to the RFI**

| Organization   | Number of Individuals Surveyed/Represented |
|--|--|
| Cold Spring Harbor Laboratory (CSHL)   | 50   |
| The Endocrine Society (TES)  | Not Provided*                              |
| Federation of American Societies for Experimental Biology (FASEB) <sup>2</sup> | 1,324                                      |
| University of California   | 1,287                                      |
| University of Texas  | 313  |
| University of Idaho  | 12**                                       |

\* TES members participated in the FASEB survey but also submitted an institutional response.

\*\* The University of Idaho provided information (i.e., position and department) for only 12 individuals but indicated that 14 were surveyed. The university also held discussions on which their response is based, in addition to the faculty survey.

**Table 2: Institution Responses to the RFI**

| Organization   | Lead Office Responding  |
|--|---|
| Princeton University   | Research and Institutional Official                                 |
| The American Association of Immunologists  | AAI Committee on Public Affairs                                     |
| Cornell University   | Not Provided  |
| Stanford University  | Dean of Research; Dean of the School of Medicine                    |
| Government Transaction Services, Inc.  | Co-Founders   |
| Massachusetts Institute of Technology (MIT)  | Vice President for Research   |
| Public Responsibility in Medicine and Research (PRIM&R)  | Chair, PRIM&R Board of Directors                                    |
| University of California Academic Senate   | Not Provided  |
| University of Texas-Austin   | Associate Vice President for Research, Office of Sponsored Projects |
| COGR, the Association of American Universities (AAU), and the Association of Public and Land-grant Universities (APLU) | Not Provided  |
| American Physiological Society   | Director, Government Relations and Science Policy                   |

<sup>1</sup> Aggregated responses are single responses that explicitly represent the aggregated opinion of multiple individuals at an organization or institution (i.e., the faculty of a university or members of a professional society). Institutional responses represent a single institutional perspective.

<sup>2</sup> FASEB, in preparing their response, convened meetings of six of its key subcommittees and surveyed its society members and the general research community. FASEB provided a formal response and a report summarizing the survey findings.



Forty-four percent of respondents indicated receiving NSF support, and 30 percent were funded by NIH. A smaller percentage of respondents indicated DOD, DOE, USDA or NASA support. The FASEB response noted that 27 percent of respondents who identified a funding agency received funding from NSF, 86 percent received funding from NIH, and 21 percent from DOD. The data provided by the University of California survey indicated that 51 percent of respondents received NSF funding and 50 percent of respondents received NIH funding. Many respondents received funding from more than one funding agency.

Individual respondents were asked to identify their academic title or position, and 59 percent provided this information. Of these, 80 percent identified themselves as being university faculty, 14 percent identified themselves as being university administrators, 3 percent both faculty members and administrators, and 4 percent representatives from other institutions (e.g. nonprofits).

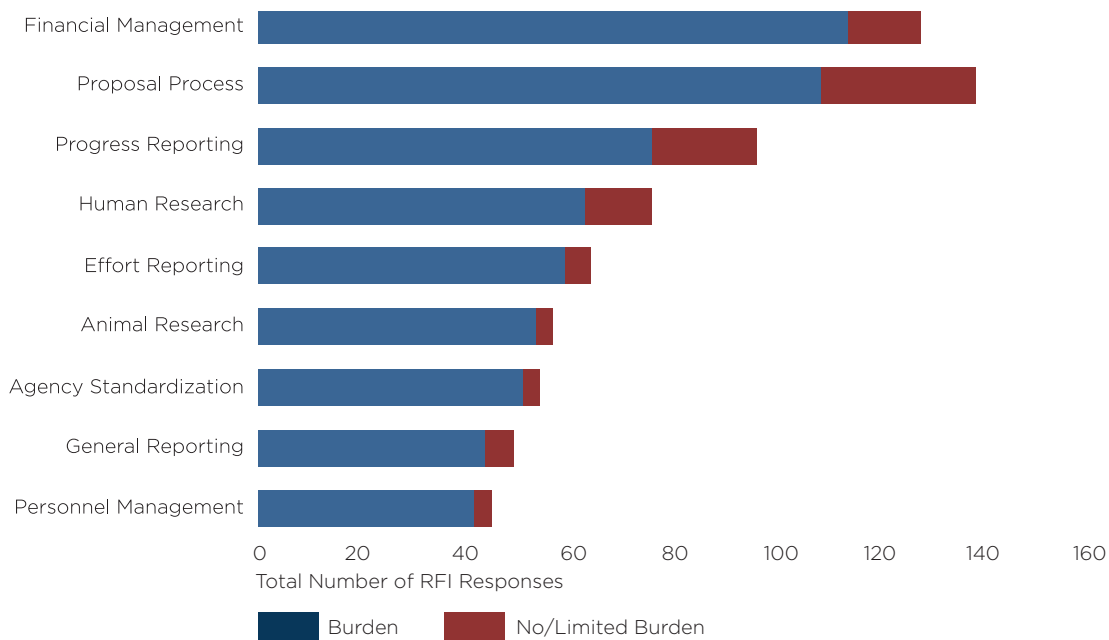
Respondents also were asked to provide a description of their institution. Of the respondents who included this information, 63 percent were affiliated with public research institutions, and 22 percent were affiliated with private research institutions. The remaining respondents represented for-profit or non profit organizations, primarily undergraduate institutions, minority-serving institutions, public master's institutions, or other types of institutions (e.g., hybrid public/private institutions).

In the following sections, we present the results and analysis from the RFI. The recommendations presented include direct recommendations offered in responses and inferences from comments on specific burdens and do not reflect the views of STPI, the NSBO, or the Task Force.

## 4. THE TOP REPORTED BURDENS FROM THE RFI

Figure 1 shows the count of RFI responses in the top 8 categories, representing the specific categories mentioned by 20 percent or more of the total coded responses. Note that these counts represent at least one mention of a specific burden anywhere in an individual response in either positive (red) or negative (blue) terms.<sup>3</sup> These counts do not represent the intensity of the experienced burden, only its prevalence in responses.

**Figure 1: Total number of responses that mention each type of burden, limited to those mentioned in 20 percent or more of the responses**



Note for Figure 1: Progress Reporting and General Reporting are treated in the single section “Progress and other reporting” in this report

The most prevalent burdens in the University of California and FASEB studies were similar to those from the RFI. However, as might be expected due to disciplinary differences, rankings are different between the populations. FASEB respondents ranked IACUC and IRB significantly higher than the broader populations in the University of California and overall RFI sample.

<sup>3</sup> An individual response may contain multiple mentions of a particular burden but is only counted once in Figure 1.

FASEB, the University of California, and other group responses are reflected in the overall summary of findings for each section, with unique viewpoints noted in the “aggregated responses” section.

The following sections explore in further detail the top burden types in Figure 1. These burdens include

- Financial management,
- Grant proposal and submission process,
- Progress and other reporting,
- Human subjects research and IRB,
- Effort reporting,
- Research involving animals and IACUC, and
- Personnel management.

For each section, we provide a general overview of the comments and main themes, followed by more detailed analysis of specific comment themes and recommendations suggested by respondents.

### I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

#### a. Overview

Some of the most frequently cited burdens were associated with financial management (60 percent of respondents), including budget preparation, financial tracking and reporting, purchasing approval and receipt submission, and travel requirements. Fourteen respondents indicated that they perceived minimal or acceptable financial management burden. These respondents noted that they received good administrative support for financial management from their institution.

#### b. Budget Preparation

Fifty-one percent of the responses in this category mentioned budget preparation and management as a major source of burden. Investigators expressed the futility of writing detailed budgets for proposals that may not be funded (or rebudgeted if they are), with some suggesting use of modular budgets, such as those allowed by NIH. Respondents noted that some institutions further increase this burden by requiring more detailed budgets than those requested by the funding agencies at the time of grant submission. Several respondents indicated that the cost-sharing requirements of some agencies are burdensome.

#### c. Financial Tracking and Reporting

Thirty-seven percent of responses in this category referenced financial tracking and reporting as a significant burden. Respondents mentioned the high frequency of required financial reporting, increased financial scrutiny, and the inability to access accounts or to generate financial reports using available financial management software. Many respondents indicated that their institutions also used different financial categories from those of Federal agencies, making it still more difficult to track funds.

#### d. Purchasing

Thirty-two percent of individual responses about financial management mentioned purchasing as burdensome. Respondents indicated that having to gain approval for every purchase made with grant funding, including subcontractor purchases and those already approved by agencies, is burdensome and that the requirement to list a business purpose for purchases contributes to this burden. Several respondents suggested that greater institutional demands for financial details and justifications resulted from requests from auditors, recent audits, or concern about audit. A major research university noted that the current audit environment “takes an entirely risk-averse approach, auditing well beyond regulatory requirements and extending findings to individual auditor interpretations of regulations, guidance, and other institutional practices.” COGR roundtable participants suggested that Inspectors General (IGs) and auditors have such a different interpretation of regulations that institutions have to be risk averse. Respondents described a seeming lack of cost/benefit analyses for new financial requirements and suggested that the cost of compliance far outweighs the incidences of abuse.

Several respondents suggested that splitting supply, animal, and equipment costs among grants was not realistic or efficient. One respondent suggested that demonstrating leveraging of resources is advantageous at the time of proposal but seemingly discouraged or not permitted once funds are granted. Other issues mentioned included providing sole-source justification and supplying vendor quotes for equipment purchases.

#### e. Travel

Fifteen percent of individual responses in this category mentioned travel issues related to financial management. Travel reimbursement was raised by a number of respondents who indicated that their institutions required receipts for all purchases, rather than using a per diem allowance, with some respondents indicating that receipts were subject to layers of review and audit. Respondents also mentioned the lack of ability to make travel arrangements and the lack of administrative support for travel planning.

### II. AGGREGATED RESPONSES

Four of six aggregated responses made similar comments related to financial management. The FASEB response mentioned complex and error-prone financial tracking systems and a lack of administrative support from institutions.

## Recommendations

- Employ modular budgets (like those of NIH)<sup>4</sup> at more Federal agencies and raise them to \$350K or \$400K to reflect rising personnel costs.
- Require institutions to provide budgets that exactly match grant/agency categories.
- Institutions should use an electronic system that tracks expenses in real time, with the ability to upload invoices and documentation related to each expense.
- Institutions should give faculty more control over budgets.
- Institutions should implement a website that generates budget amounts for different line items based on university rates and simple inputs from the PI (e.g., number of students requested, months of summer salary desired, and so forth).
- Simplify reporting justification under a certain monetary threshold (e.g., \$100).
- Require receipts and justification only for purchases greater than \$1,000.
- Use a per diem allowance for travel reimbursement.
- Institutions should have fewer staff involved, and fewer signatures should be required in the process of purchasing and grant administration.
- Institutions should have the spending and hiring reports generated by the institution's sponsored programs office, and these reports should have to be approved only by the PI.
- Agencies/programs should not require financial reporting more frequently than quarterly.
- Federal agencies should reduce the frequency of audits and allow more flexibility.
- Eliminate reporting of travel by investigators funded by the Public Health Service (PHS).
- Encourage greater administrative support for financial management requirements.
- Clarify, at an institutional level, what items are covered by overhead.
- Agencies should eliminate the need for administrative approval/justification to reallocate funds between budget categories and to request no-cost extensions.
- Federal funding should be considered an encumbrance and permanently taken out of consideration toward future Federal budgets.
- Agencies should reduce cost-sharing requirements.
- Allow no cost-extension periods greater than one year.
- Establish one Federal payment system and common costing rules.
- Verbal estimates for equipment and services should suffice for proposals, with written quotes needed only for awards.
- The Office of Management and Budget (OMB) should minimize the number of forms that investigators are required to complete; increase reporting intervals where feasible; and assess the need for and impact of new reporting requirements, including a proposed quarterly reporting requirement for all Federal research grants and contracts. In addition, OMB should review all existing mandatory, financially related Federal reporting requirements to evaluate for institutional and researcher burden, volume and purpose of the data, duplication, and cost.
- OMB should engage institutions to develop for all reporting requirements approval criteria that ensure continuation and approval of only those requirements whose benefits significantly outweigh costs, provide substantiated government and public value for which no alternative Federal data source is available, and impose no additional burden directly on researchers and little or no additional cost and burden on institutions.

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<sup>4</sup> Modular budgets are part of NIH's modular research grant applications. see FAQ [here](#).

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

## a. Overview

Sixty-five percent of individual and institutional responses commented on the grant proposal and submission process, most frequently on proposal writing, which was often described as being overly lengthy and time consuming. Respondents suggested that low funding success rates require PIs to submit multiple proposals to multiple agencies to fund their research. The next most cited burden related to supporting documentation and formatting requirements, which included comments on agencies' collection of duplicative information and use of different requirements. Other widely cited burdens included detailed budget requirements, difficulties with grant submission websites, and lengthy proposal review time. Twenty-nine responses stated that the grant proposal process did not impose significant burden or represented an acceptable administrative workload.

## b. Proposal Writing

Forty-eight percent of the responses in this category commented on proposal writing, which respondents described as time consuming and often the highest burden within their administrative activities. One theme that emerged was that with declining funding rates, PIs find it necessary to write and submit many more proposals to fund their research, leading to even greater competition and still lower success rates. This situation, in conjunction with a growing number of required supplementary documents (e.g. conflict of interest (COI) and data management plans), makes the grant proposal process particularly burdensome and, it was suggested, marginalizes the science. Respondents suggested that this ancillary information is not necessary for review and should only be required once the proposal has been recommended for funding. They suggested that this burden could be alleviated through preliminary proposals or expanding the use of JIT submission. TES applauded NIH's JIT procedures and suggested that Federal agencies apply them more broadly. However, regarding the use of preliminary proposals, one respondent cautioned that "a low rating should not prevent submission of a full proposal, but will inform the PI of chances."

*The supplemental requirements are now nearly twice the size of the actual proposal.*

*The basic problem with proposal preparation is the time required to develop a full proposal, with only a small proportion of proposals funded. Obviously, the vast majority of PIs simply waste the entire effort. It would be infinitely better if there was a pre-proposal stage with simple budget and shorter project description.*

*AAU/APLU/COGR: The use of JIT procedures in some agencies and for some aspects of the applicant process should be extended across agencies and for all requirements. If institutions could focus their activities on those proposals most likely to be funded, the broad burden for investigators and institutions would be significantly reduced.*

## c. Forms and Formatting Requirements

The next most referenced burden in this category was forms and formatting requirements (34 percent). Respondents suggested that the instructions for proposal preparation are excessive and unclear and that the rules and systems seem to change annually, requiring PIs and administrators to continually learn new requirements. They noted that unique formatting and informational requirements between agencies and programs requires PIs and staff to, as one response phrased it, "review and apply a myriad of rules for different solicitations and to reformat and change standard information so it is presented as required." They recommended standard forms and requirements. They also suggested that biographical information, CVs, and other forms could be stored in a centralized database that is accessible to all agencies and updated as needed. A number of respondents suggested that too much emphasis was placed on procedure and that in this competitive climate a proposal could be rejected due to formatting errors.

*Actual research seems to have taken second place to a lot of peripheral activities that, while important, have become litmus tests for proposals and grant assessment.*

#### d. Grant Submission Systems

Twenty-six percent of responses in this category commented on the grant submission technology used by funding agencies, suggesting that the submission process is overly complex and time consuming due to inefficient systems and requirements that vary by agency. Many of the comments were directed toward Grants.gov, which was described as “cumbersome,” “inefficient,” “redundant,” and “incomplete.” Respondents also expressed that they preferred the NSF FastLane system to Grants.gov, and several indicated that they were being required to use Grants.gov.<sup>5</sup> However, one major research university suggested that Grants.gov made the proposal submission process more unified and that agencies should require its use.

*The new requirement to use Grants.gov is a very poor choice. I have been required to submit three proposals via Grants.gov in the past, and this grant system is inefficient and takes significantly more time than the NSF FastLane system.*

*Streamline the electronic systems and forms required across agencies! Not only do research administrators have to be experts in OMB circulars, institutional procedures, and agency requirements, we also have to be experts in IT [Information Technology], S2S systems, eRA [electronic Research Administration] systems, FastLane, Grants.gov, FedConnect, eGrants, PMS [Payment Management System], eRACommons, and the list goes on.*

#### e. Data Management Plans

Four percent of individual responses in this category and two aggregated group responses indicated that they perceived issues with data management plans to be burdensome. Respondents suggested that the plans were time consuming, that requirements were vague and did not apply to certain fields, and noted the lack of standardization across agencies. Several respondents suggested that the plans often dwarf the grant proposal itself. Group responses from two major research universities echoed concerns that data management plans were often too open ended and unnecessarily added to investigators' workload.

#### f. Other Burdens

Other burdens addressed included the length of the review period (10 percent), the length of proposals (7 percent), and the burdens associated with specific forms and plans (e.g. postdoctoral mentoring plans and broader impact statements). Individual responses and the FASEB survey report noted that delays in funding decisions cause PIs to submit more “backup” proposals. While some respondents indicated that proposals should not be longer than 5 pages, others suggested that proposals shorter than 10–12 pages could not receive adequate scientific review or that shorter proposals actually took them more time to complete. Respondents suggested that they would benefit from greater pre-award administrative support, which one respondent suggested was “presently way overburdened by the large numbers of proposals PIs must submit.” Many suggested that they performed much of the work themselves, in part, due to a lack of scientific expertise among support staff. One respondent suggested that the workload impedes institutions' ability to retain good support staff.

## II. AGGREGATED RESPONSES

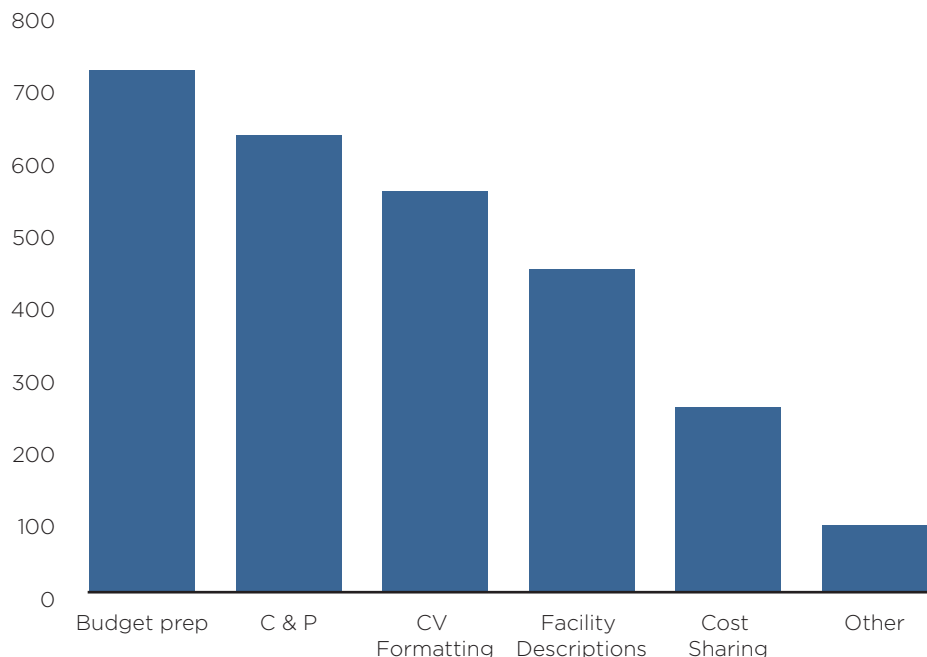
Five aggregated responses included information on burdens associated with the grant proposal and submission process. The FASEB response noted that these two areas were ranked as the highest burdens by nearly half of the respondents, in part, due to a reported lack of administrative support. AAI reported that members find the current process rigid, detailed, and time consuming.

Similar to the FASEB response, a major research university reported that investigators who were surveyed perceived proposal preparation and submission as their most significant burden. They described the same cycle of less funding, more applications, more competition, and lower success rates. In response to the follow-up question, “What administrative tasks associated with proposal preparation increase your personal administrative workload?” faculty members stated that budget preparation, current and pending (C&P) support, and CV formatting (indicative of inconsistencies at different funding agencies) create workload (Figure 2). Faculty also frequently mentioned the requirement to describe available facilities.

<sup>5</sup> NSF has not required a switch to Grants.gov, and FastLane is still available.



**Figure 2: Faculty responses to a follow-up question on proposal-preparation burdens**



## Recommendations

- Forms, formatting, requirements, and electronic systems should be standardized across agencies. When standardization is not possible, provide summary tables and documents highlighting important differences.
- Employ modular budgets at more Federal agencies.
- Allow parts (e.g., detailed budgets and data sharing plans) of a grant proposal to be submitted JIT once the proposal is being recommended for funding or a preliminary proposal stage with a simple budget and shorter project description.
- Minimize ancillary documents (e.g., postdoc mentoring plans or C&P support).
- Agencies should publish model grant proposals.
- Good proposals should be held until funding becomes available.
- Agencies should expand grant writing and management training for researchers and administrators and provide web-based training guides to communicate agency expectations and goals.
- Allow forms to be updated rather than completely reentered.
- Have a secure [Federal] electronic centralized database for biosketches, CVs, licenses, Resources and Environment Statements, COI Disclosures, and other requirements that can be linked to PubMed, eCommons, FastLane, and so forth and is updated annually/as needed.
- The personal statement should be dropped from the [NIH] biosketch so that one does not need a different biosketch for each proposal.
- Agencies should post the calls for proposals further in advance of the due date.
- Reduce matching requirements, especially if all PIs are soft-money funded.
- Agencies should institute mid-career and senior “awards” that provide funding for 5–7 years based on a record of accomplishment. These awards should not be based on specific proposals but on the idea of funding people who have been successful and influential. Perhaps analogous to the Canada Research Chairs.
- Reduce or eliminate the requirement for data management plans.
- Agencies should provide clear guidelines and policies for data sharing.
- Reduce the number of open-ended descriptions in data management plans, potentially through the creation of a standard template.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Forty-five percent of individual and institutional responses addressed progress reporting. Twenty-one percent of these responses indicated that these reports are necessary, useful, and appropriate. The majority framed them as a burden, with some suggesting that the length could be reduced and that the forms could be streamlined to eliminate redundancies. Some respondents also suggested that published or submitted manuscripts or grant renewals would provide the necessary information on progress and that time spent on progress reports would be better spent on research and publications. A few respondents indicated that they did not feel that the information provided in progress reports was used, or even read, by agencies, and most indicated they had never received feedback. One respondent asked that agencies consider what they actually need and use.

*I have yet to see any recommendation about the research or even funding being changed based on these reports. The asymmetric relationship here is prone to abuse by the funding agencies, who understandably want to be seen as responsible stewards of taxpayer dollars. But there is no visible impact of these reports, in which case they are having a negative effect on productivity.*

A major research university noted that a new requirement for progress reports is to indicate all individuals who worked on the project, their percent time, and their funding source, regardless of whether their funding was from the project in question. They suggested that this is an additional burden for faculty and that it was unclear why it is now required. This requirement was also cited as burdensome by a new investigator who noted that this information is included with the proposal.

### b. Frequency and Timing

Forty-seven percent of the individual responses in this category made reference to the frequency of progress reporting as the source of burden. Some respondents indicated that their funding agency required monthly or quarterly reports, which were considered excessive and burdensome, with one respondent noting that annual and final reports can be redundant and suggesting that all reports should be a minimum of 12 months apart.

### c. Standardized Progress Reports

Several responses explicitly mentioned the Research Performance Progress Report (RPPR), a standardized report that is currently being implemented by all Federal research agencies. The response from a major research university recommended a post-implementation review of the RPPR to identify further opportunities for standardization. It indicated that additional award-specific data requirements can be added to the common dataset and that multiple agency-specific systems are used for submission of the RPPR, adding further complexity. A major research university noted that its researchers are finding Research.gov cumbersome, that uploading the report in the many different sections is time consuming and difficult to navigate, and that the section on non-paid collaborators could be scaled back since this was felt to be outside the scope of the project. While some respondents noted that they liked the ability to retrieve information, others noted that the RPPR as implemented in Research.gov for NSF awardees requires more detail than previous reporting forms, with one noting that the new report was “unwieldy” and others indicating that it was “inefficient” and a “huge amount more work.” Respondents also noted errors with the Research.gov system.

Some respondents indicated that it was much more time consuming to type text into individual boxes with the new progress report format and wanted to return to uploading full reports. One respondent noted that word limits for each box made it difficult to respond in a meaningful way, and several noted that entering publications and presentations is tedious. Many stated a preference for NIH’s (previous) 2-page report.

*The annual report interface is extremely burdensome to the PI: we become data entry specialists instead of scientists.*

*The basic idea of the reports is excellent, but the number of questions and the interface for entering information make this a process difficult to learn and more time consuming than necessary.*

#### **d. General Reporting Requirements**

Twenty-four percent of responses in this category noted burdens associated with general reporting requirements (other than annual progress reports). For example, two institutional responses described a multi-year increase in Federal reporting requirements and resulting burden through programs such as the Federal Funding Accountability and Transparency Act (FFATA), the American Recovery and Reinvestment Act of 2009 (ARRA), and Science and Technology for America's Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science (STAR METRICS). A private company, citing the FDP ARRA Administrative Impact Report, noted that ARRA alone added \$7,973 per grant in additional costs to post-award administration. Commenting on the proliferation of reporting requirement, the joint response from the AAU, APLU, and COGR stated:

*With each new regulation or policy requirement, recipient institutions have implemented numerous policies and procedures to address both the investigator's responsibilities and the institutional obligations, including increased reporting and monitoring of research activities, ensuring information security and access controls, implementing mandatory training, and complying with restrictions and reporting on foreign nationals and business ethics, hazardous wastes, and so forth .... Unfortunately, agencies have increasingly requested more information, defending the increase as necessary for assessing the achievement of programmatic goals. Some requests seem appropriate and in line with the program; others feel like sweeps for any and all possible outcomes without a rationale for the collection.*

#### **Recommendations**

- Eliminate progress reporting in favor of performance-based outcomes (i.e., scientific achievements such as published or submitted manuscripts).
- Scale back the RPPR section on non-paid collaborators.
- Require reporting no more frequently than annually, increase its uniformity, and clearly explain the necessity to researchers. If reports do not influence continuing funding or programmatic decision making, further reduce the scope or frequency.
- Coordinate timing of progress reports so that PIs are not required to submit progress and final reports in rapid succession.
- Streamline and standardize progress report forms, formatting, and submission.
- Reduce progress report length.
- Agencies should provide feedback on submitted progress reports.
- Encourage greater administrative support for reporting requirements.
- Agencies should provide deadlines that are sensitive to faculty schedules.
- Agencies should provide examples and templates for progress reports.
- Where data already exist, institutions and investigators should not be required to resubmit these data.
- Programs should justify any requests beyond standard reporting requirements and obtain approval for such additions from an independent oversight body/individual.
- Non-value added and duplicative data requests should be eliminated.
- Eliminate annual co-PI reports.
- Allow links to standard publication databases.
- Allow PIs to cut and paste conference presentations.
- Keep the reports succinct and clear.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Thirty-eight percent of the total responses addressed human research requirements (30 percent directly mentioned IRB-related burdens). Of these, 17 percent noted that they do not perceive aspects of the IRB process as unduly burdensome. For the remaining respondents, the greatest burdens were preparing initial protocols (24 percent), completing the IRB review process (21 percent), and getting revisions approved (17 percent). The University of California, TES, FASEB, and University of Idaho aggregated responses all noted that IRBs ranked among the highest burdens indicated by the PIs they surveyed.

### b. IRB Review

Respondents indicated that the majority of administrative work is in drafting and submitting initial protocols and completing revisions and renewals. Most indicated that the length of time it takes to obtain IRB approval was excessive and typically required several months due to multiple rounds of revision and review. Many suggested that it is difficult to get approval on first submission, even for previously approved protocols and that time-consuming revisions are often required. Several respondents suggested that the increased scrutiny has not improved participant safety.

The consensus among roundtable participants was that IRB and IACUC burdens arose more from the guidance and interpretations of regulatory bodies than from the regulations themselves. RFI respondents suggested that institutional boards/ committees, in turn, go well beyond the Federal requirements, resulting in additional burdens. This going beyond the Federal requirements is thought to be due to concerns about liability and audit and, as one response suggested, “dissonance between the regulations and the findings of audits,” which results in risk intolerance. It was suggested that this situation is exacerbated by additional agency-specific regulations or policies, including duplicative agency-based protocol reviews. Respondents noted variability in IRBs, with some indicating that they were helpful and others a hindrance. A few respondents suggested that IRB oversight/accountability was needed.

Respondents suggested that the level of oversight is excessive for qualitative social and behavioral research and that exemptions for research that poses no potential harm to subjects should be increased. Several respondents indicated that developing protocols and other documents for exempt studies was burdensome. One respondent suggested that exempt research should not have the same regulatory requirements for submission as non-exempt research and that only a letter of intent identifying the study’s aims and plan for data use be required for administrative approval.

*Our IRB requirements are onerous given that this is innocuous behavioral research without a participant complaint in over 40 years ... the research is complex, and we are required to maintain about 15 separate consents, renewing and reporting on their use yearly.*

### c. Multi-site Studies

Respondents conducting multi-site studies indicated that submission to multiple IRBs, using different forms and procedures, was very time consuming and frequently results in research being delayed. They recommended use of a central IRB or federated model, which allows IRBs to defer their approval to the IRB of the primary site. Further, the response from the AAU, APLU, and COGR suggested that the role of IRBs in human subjects research can be met or supplemented by an equivalent international/national body but that many Federal sponsors insist on duplicative reviews by a U.S.-based IRB.

*The number of IRB approvals necessary to proceed with a multi-site study that uses each site’s IRB may involve waiting periods of a year or more as each institution reviews the application and has a separate dialogue with each site’s PI. This process delays the progress of the study, discourages the investigator(s) involved, and is highly cost ineffective.*

*A central IRB is able to incorporate the major concerns that institutions have about liability risk and COI and may better facilitate the progress of multicenter clinical research studies. Several successful CIRBs [Central IRBs] are already in place, including CIRBs facilitated by the Veterans Administration, National Cancer Institute, and independent committees such as the Western, Independent, and Sterling IRBs.*

#### **d. Regulations and Requirements**

Respondents indicated that Federal and institutional requirements for human subjects research have become increasingly complex. These complex requirements impose a significant burden on affected investigators, many of whom complete IRB-related administrative work themselves. Several respondents indicated that they avoided human subjects research, were considering quitting, or have quit due to excessive administrative requirements.

The AAI and a major research university noted that Department of Health and Human Services (DHHS) regulations<sup>6</sup> state that “changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review” and noted that such language has caused many IRBs to implement local policies requiring that any change to research protocols must be reviewed and approved by the IRB. In their response, they suggested that this requirement could delay researchers seeking to implement even minor, inconsequential changes. This concern was also raised by a number of individual respondents. Both institutions suggested changing the DHHS regulatory language so that only *significant* changes in research activity would require IRB approval.

#### **e. Other**

Respondents suggested that IRB training requirements are excessive and that the application of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules to research is confusing and frustrating. Roundtable participants noted that these rules, enforced by DHHS, contradict the policies of the DHHS Office of Human Research Protection (OHRP) but that institutions are subject to both. RFI respondents noted that IRBs are increasingly undertaking scientific review of peer or agency reviewed protocols and that agencies are also reviewing IRB approved research protocols.

Several respondents indicated that their IRBs use burdensome paper systems. Among those whose institutions use electronic systems, some noted that using electronic systems has made the process more efficient while others noted that their electronic systems have not reduced burden. Participants noted inefficiencies with particular systems, and one respondent suggested that NIH’s online system was preferable. One aggregate response suggested identifying IRBs and software packages that function well and encouraging their replication or adoption.

## **II. AGGREGATED RESPONSES**

TES noted that many human subjects requirements “are unnecessarily cumbersome and cause substantial delays ... [and] they do not affect patient safety.” TES noted wording changes in regulations due to liability concerns—changes that can delay research by weeks or months, delays due to IRB review of scientific aspects that have already “successfully navigated peer review,” and the “redundant” requirement to notify both the funding agency and IRB of changes to clinical research protocols. Two participants from the Georgia Tech roundtable discussion suggested that determination letters (from NIH’s Office of Human Protection) drove stricter standards. Participants from the COGR roundtable discussion noted that the Association for the Accreditation of Human Research Protection Programs (AAHARP) forbids accredited institutions from deferring to non-accredited institutions, regardless of the quality or rigor of their standards.

The FASEB response and a university response noted that PIs were frustrated with the amount of time needed for IRB approval, the difficulty of multi-site protocol approval, a lack of standardization, and low risk

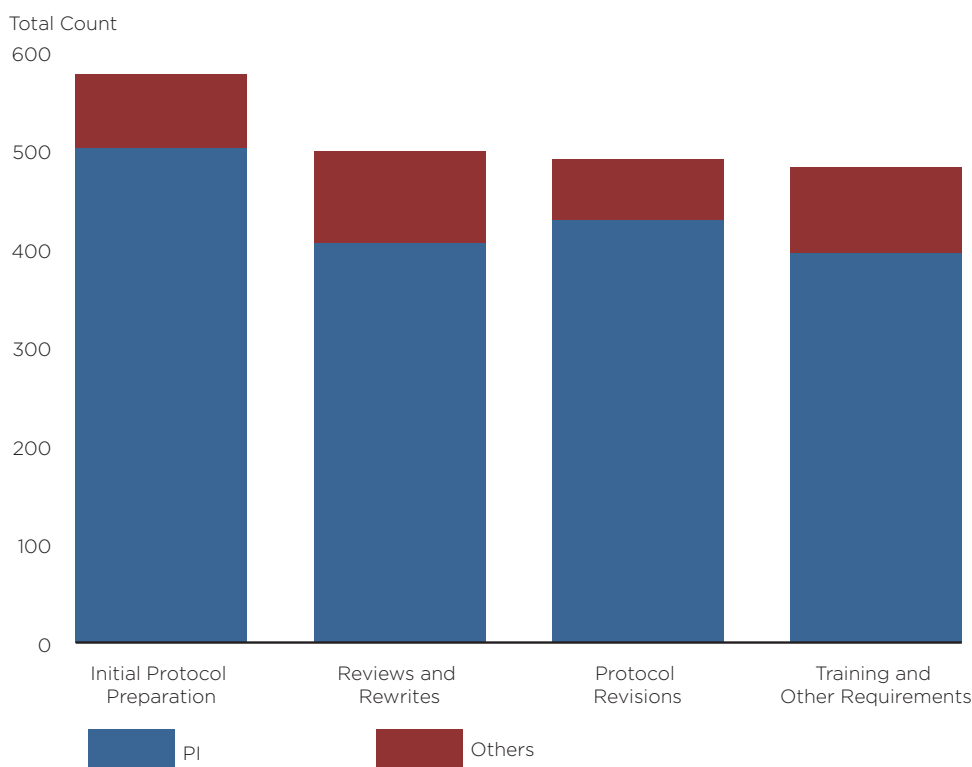
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<sup>6</sup> 45 C.F.R. § 46.103(b)(4)(iii) (2009).

tolerance. FASEB noted that the lack of harmonization among the 19 departments and agencies that do not participate in the Common Rule, failure to calibrate regulations to risk, and institutional practices aimed at mitigating liability rather than protecting participants impose a considerable burden on PIs. A university response also highlights the concern that protocol revision requests often stem from the IRB's "lack of understanding of non-clinical research."

In addition, a major research university asked respondents who performed human or animal research requiring IRB/IACUC approvals for additional detail on which activities created the most administrative work and who performed each task. Figure 3 shows the total number of responses to this question. Similar to the preceding results, most PIs identified preparation of initial protocols as contributing to administrative work, with relatively similar numbers identifying protocol reviews and rewrites, protocol revisions, and training requirements as burdensome. Interestingly, for each of these tasks, over 80 percent of PIs reported that the activity was performed by the PI rather than staff, reflecting the general sentiment in individual responses to the RFI.

**Figure 3: Faculty responses to follow-up questions on IRB and IACUC requirements and whether they are fulfilled by the PI or others**



### Recommendations

- Harmonize guidelines across agencies.
- Develop national standards for IRB approval.
- Institutions should conduct 24-month reviews of protocols instead of 12-month reviews.
- Create standardized informed consent templates and other IRB forms that can be shared by all institutions engaged in human subjects research.

- As proposed in the DHHS Advanced Notice of Proposed Rule Making (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, mandate that all domestic sites in a multi-site study rely upon a single IRB as their IRB of record.
- Develop clearer guidance as to what constitutes exempt research, and streamline the exemption process.
- Adopt a standard process for low-risk IRB review that would be acceptable to all Federal agencies.
- Eliminate continuing review for expedited or low-risk protocols.
- Permit appropriately trained staff to perform expedited review instead of using IRB members.
- Automate linkage or facilitate communication of local IRB applications and approvals to Federal funding agency databases.
- Encourage open lines of communication between the IRB and investigator during the protocol review and revision process.
- IRBs should reduce the time to approval.
- Reduce and standardize human subjects training requirements.
- IRBs should tier review and focus on higher risk studies.
- Review studies that are in “analysis-only” phase to every two or three years instead of annually.
- Limit the number of documents and pages required in IRB submissions.
- Replace annual renewals with protocols that last for the duration of the project.
- Use the methodology provided in proposals rather than rewriting it for IRB applications.
- Clarify, streamline, and delineate the responsibilities of IRBs, institutions, and Federal agencies in reviewing the human subjects sections of grant applications.
- Identify research areas where guidelines for determining the criteria for protocol review and exemption could be improved.
- Exempt research from the HIPAA Privacy Rule and strengthen data security and privacy protections through the Common Rule. In the absence of a full exemption, modify the Privacy Rule to allow more data elements. More closely align institutional systems with Federal compliance guidelines.
- Reduce HIPAA and Federal Educational Rights and Privacy Act (FERPA) training to once every five years.
- Identify those IRBs and software packages that function well and encourage adoption and standardization of best practices.
- NIH should recalibrate the bar for what is considered JIT so that IRB applications are not prepared for unsuccessful proposals.
- Institutions should dedicate personnel to help with human IRB and animal protocol issues and approval processes.
- Integrate ClinicalTrials.gov and the clinical trials reporting program.
- Institutions should recognize the vital contributions of faculty who serve on compliance boards and committees through performance evaluations and towards promotion or tenure.



## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

In total, 29 percent of submissions to the RFI addressed effort reporting. Eight percent of these respondents stated that effort reporting was either not burdensome or was reasonable in light of receiving federal funding. However, most respondents described effort reporting negatively, with some using terms such as “trivial,” “meaningless,” or “nonsensical.” These respondents felt that effort reporting neither contributes to research nor ensures that investigators spend their time appropriately.

Many respondents indicated that they fulfill time-consuming effort reporting requirements themselves. In particular, respondents cited the challenges of determining exactly how much time each week was spent on a particular project by each contributor. Respondents noted that most researchers work on multiple projects simultaneously. A major research university “conservatively estimates that an annual effort review of all sponsored projects consumes in aggregate 2,200 hours of PI time and 2,850 hours of research administration time” and that “periodic progress reports, site visits, publications, and project renewals are sufficient for the necessary and ongoing Federal agency assessment and oversight of federally-funded projects, and correspondingly for researcher and institutional accountability in conducting these projects.”

*Effort reporting is also a huge time sink. We are already carefully documenting faculty effort on projects in order to charge their salaries appropriately; requiring additional certification is redundant.*

*A policy that inhibits voluntary extra work is wrong. A policy that engenders widespread fraud is wrong (no one works 100 percent on one thing for any extended length of time if the person is involved in multiple research projects, and no one can predict exactly what percent of effort will be spent in a given month on each project).*

### b. OMB Proposed Guidance

In an effort to reform Federal policies relating to grants and cooperative agreements, OMB published *Proposed OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards*,<sup>7</sup> which was open for comment until June 2, 2013. To gauge the effect on PI administrative burden of specific proposed changes, the NSB RFI asked respondents to provide their opinions on OMB-proposed reforms to effort reporting, such as using automated employee payroll reports.

Sixteen individual responses, one institutional response, and one aggregated response approved of the effort reporting changes, noting that it might “greatly lessen” their administrative burden and present a “great improvement” over current practice. Twelve individuals provided generally negative responses. These comments varied, suggesting that effort reporting should be completely removed as a requirement, that the proposed changes are too vague and would complicate the process, that payroll systems vary too greatly at institutions and are often so confusing that burden would increase, and that the proposed changes would not reduce workload.

## II. AGGREGATED RESPONSES

Roundtable participants suggested that effort reporting was “a bookkeeping exercise,” not an internal control, and “not meaningful in any way” and suggested that it be eliminated. The CSHL response expressed disappointment “that the opportunity to significantly reform the current burdensome requirements and practices of effort reporting were not appropriately addressed” and “encouraged that further reforms in this area be developed with input from researchers and administrators.”

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<sup>7</sup> Available via [www.regulations.gov](http://www.regulations.gov), Docket ID OMB-2013-0001



## Recommendations

- OMB should eliminate effort reporting.
- Allow use of existing payroll systems to provide automated information required for effort reporting.
- Limit effort reporting to distinguishing between research, clinical services, and administrative time.
- Harmonize effort reporting and tracking systems used across the Federal government.
- Single-audit auditors should be explicitly prohibited from auditing effort reporting to higher standards than called for in the OMB circular.
- The final grant report summary should be a grouping of each effort report for which funding was provided. Year four should not require a new effort report unless new information needs to be added.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Twenty-five percent of the total responses identified the IACUC process as burdensome. Six percent said that it did not impose a significant or unreasonable burden. Among other concerns, respondents frequently cited writing initial protocols (36 percent), the review process, incorporating required training, and getting protocol revisions approved.

Comments echoed concerns expressed for human subjects research, including:

- Escalating regulations;
- Length of review and approval processes, which can take several months for even minor modifications;
- A focus on liability rather than animal safety;
- IACUCs that exceed the Federal requirements;
- Protocol approvals that do not match grant length;
- Poor or non-existent institutional software for submission;
- IACUCs that evaluate scientific content;
- Agencies that review IACUC protocols;
- Prescriptive agency guidance;
- Lengthy and excessive training requirements that can prevent students from working with animals; and
- Insufficient administrative support.

As with human subjects most IACUC-related administrative work is reportedly performed by PIs or their research staff. Regarding the IACUC burden, the American Physiological Society (APS) noted that a major reason why burdensome requirements are imposed by agencies and institutions is risk intolerance and suggested that “the problem of risk tolerance will have to be addressed before meaningful progress can be made toward actually reducing administrative burden.”

Specific to animal subjects research, respondents noted that the multiple inspections required per year are disruptive, that the Federal requirement to project animal use for all years of a grant runs counter to the unpredictability of the scientific process, that the required literature search is of limited or no value, and that accrediting agencies increase the burden without improving animal care.

### b. Federal Requirements and Initial Protocols

Respondents noted that Federal and institutional requirements for animal research have grown tremendously in recent years and should be scaled back. This growth is reflected in the length of proposals. Respondents indicated that IACUC protocols require excessive experimental details that are not relevant to the evaluation of the animal procedures being proposed and do not improve animal safety.

*The amount of time required to comply with OLAW's [NIH Office of Laboratory Animal Welfare] expectations for vertebrate animal (mouse and rat) protections keeps escalating exponentially, with no obvious benefit to science or to the animals' welfare. There is often no common sense to the new regulations and no way to undo them once imposed.*

*The NIH should revamp animal care compliance regulations to reflect a minimum required for safe animal use, with attention to the time burden imposed by regulations that are too strict. The needs of the PI should be held above those of anti-vivisection groups such as PETA [People for the Ethical Treatment of Animals].*

*The IACUC folder on my office PC is the single largest folder and that includes the folders that contain my data.*

*The primary animal protocols are ridiculously long. When I started about 15 years ago, the form was ~ 2-3 pages. My last animal renewal was 30-40 pages for the exact same protocol.*

### c. IACUC Review and Revision Processes

Review (34 percent) and revision (19 percent) processes were cited as the next two most significant burdens in this category. Respondents cited the initial and three-year reviews as being problematic, saying that reviews often focused on details that were perceived as being marginal to improving animal welfare, did not take into account the evolving nature of scientific inquiry, or evaluated the science of a proposal for peer-reviewed and funded grants. It was noted that Designated Member Review, a form of expedited review that is approved by the USDA and NIH OLAW, is underused. Furthermore, compliance with multiple requests for revisions was similarly described as particularly burdensome to PIs.

Respondents noted that the PHS requirement for re-review of animal-use protocols every three years was arbitrary and burdensome and recommended that the protocol match the grant length. It was suggested that many institutions require that protocols be completely rewritten at year three and that this is not required or necessary as protocols are continually amended.

Several respondents concurred with comments from the AAI, which suggested that the Federal requirement that all experiments be predetermined and statistically justified concerning exact animal numbers forces researchers to project animal numbers years into the future and then to continually file amendments subject to reapproval for each minor modification as investigators obtain new data or capitalize on the newest findings in the field. Further, one response noted that “both PHS Policy and AWA [Animal Welfare Act] regulations require amendments to protocols to follow the review process that is required for full protocols (2.31.d and IV.C.2)” and suggested that “OLAW could amend its guidance documents on review of modifications and/or amendments to permit more rapid turnaround for the scientists.”

*These protocols often take up to four months to get through the approval process even when the techniques have already been approved on previous protocols, and they have to be renewed each year.*

*Every year, I have to renew the IACUC certification, even though there is absolutely no change in the experimental design, which is a waste of time. What is worse, the IACUC takes this opportunity to make meaningless revisions and changes to the protocol that they had approved just a year ago and where there was no change in experiment or available agents.*

*It is impractical and absurd to think that we will submit a revision to our protocol every time we come up with a new idea or redirect our animal work, and it is equally absurd to ask us to predict this sort of thing in advance.*

### d. Training

Burdens arising from IACUC-related training were raised in 21 percent of individual and institutional responses. In describing training requirements, several respondents noted that they were often required to complete training that did not directly relate to their work. While others acknowledged the value of good training, responses also expressed concern that existing training, documentation, and tracking requirements were excessive, that they may preclude student participation in animal research, and that the lack of standardization for training increases the burden.

### e. Other Burdens

A number of respondents indicated that the USDA’s mandated use of the literature search for alternatives to potentially painful or distressful procedures to animals is of limited value. A major research university noted that PIs are experts in animal models and their alternatives and that in its experience, the literature search has “never resulted in a bona fide alternative” and that failure to adequately perform this search is one of the top 10 citations by the USDA each year. One respondent suggested that this requirement could be incorporated into the list of assurance statements that PIs typically affirm or through an undefined process that may be determined at the IACUC level.

*External oversight agencies seem compelled to find infractions that are trivial or meaningless, often that violate common sense, or have no clear link to any stated regulation or any apparent effect on animal welfare.*

*However, the regular inspections with incredible detail available for the inspectors are burdensome, and I don't see how they contribute to animal welfare or the quality of the experiments. I am also worried about double oversight, with the FDA jumping in the mix. My perception is that the inspectors' goal is not to see if things are okay, but to identify as many problems as possible. We have come out okay in all the inspections, but I feel very uncertain about what is coming regulation-wise.*

Finally, some respondents indicated that that Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation has increased administrative burden. These respondents view this accreditation as an unnecessary extra measure that does not actually prevent malfeasance or protect animal welfare. The AAALAC accreditation process requires institutions to go through additional site inspections.

*Reducing the excessive AAALAC level of regulation. This [accrediting] agency was supposed to be optional; however, due to animal welfare pressure, all universities are feeling compelled to force their animal programs to this level of regulatory excess. In my opinion, the level of animal care is not improved with the added level of regulation.*

In aggregate, RFI responses that address animal subjects research indicate that some of the most important problems and recommendations, such as redundant reviews and overlapping inspections, highlighted in the 1999 report “NIH Initiative to Reduce Regulatory Burden” still stand today.<sup>8</sup>

## II. AGGREGATED RESPONSES

In addition to the responses submitted by individuals and institutions, three aggregated responses commented on IACUC-related burden. The FASEB response noted that Laboratory Animal Care and Use/ IACUC were ranked as the second highest burden among surveyed PIs. It also posited that many of the burdens identified by respondents are the result of institutional requirements.

A research university survey response noted that “investigators saw preparing protocols as slightly more burdensome than annual reviews, rewrites, completing revisions, and satisfying training and other IRB/ IACUC requirements,” and that they “also find training requirements and reviews for low-risk projects to be especially burdensome and believe that local institutional requirements go beyond the Federal requirements.” The majority of PIs indicated that they are completing this work themselves.

### Recommendations

- Institutions should use Designated Member Review rather than a full IACUC review for applicable (low-risk) protocols and protocol modification.
- OLAW could amend its guidance documents on review of modifications/ amendments to permit more rapid turnaround.
- Harmonize regulatory requirements for IACUC approval across the funding agencies.
- Agencies should create exempt and expedited review categories similar to human subjects regulations.
- Reduce or consolidate overlapping inspections by agencies and accreditors.
- The NIH should revamp animal care compliance regulations to the minimum required for safe animal use.
- Agencies should avoid regulating through guidance.
- Develop standard operating procedures and a single set of guidelines that can be cited on IACUC protocols.

<sup>8</sup> National Institutes of Health, “NIH Initiative to Reduce Regulatory Burden: VI. Animal Care and Use - Workgroup Report,” (Bethesda, MD, 1999). <http://grants.nih.gov/archive/grants/policy/regulatoryburden/animalcare.htm>

- The USDA should eliminate the required literature search for alternative animal research procedures.
- For approved animal disease models, the protocols for induction of disease, monitoring, and analgesia should be available and easily imported into other protocols.
- Agencies should allow changes to the exact number of animals required for a grant to be approved through a simplified administrative process or rely on reporting of animal use.
- Adopt a streamlined approach in which one IACUC approval satisfies all institutions funded by the same grant.
- Provide standard acceptable protocols and drug dosage ranges for commonly used drugs.
- Reduce IACUC requirements for experimental details that are unrelated to evaluating the health and safety of the animals being used.
- Allow small changes to protocols to be approved through a simplified administrative process.
- The PHS requirement for a re-review of animal-use protocols every three years should be changed to five years to better match grant length.
- Consider a single set of guidelines, perhaps modeled after the Common Rule used in human subjects research.
- Avoid duplication by delineating review responsibilities between scientific review groups and IACUCs for the vertebrate animal section of grants and the animal-use protocol.
- Training requirements should be tailored to an individual's job responsibilities.
- Regulations should state what is required to ensure uniform implementation and reduce confusion caused by ambiguity.
- USDA and OLAW could allay concerns by specifically stating when a practice is not required.
- Agencies should refrain from modifying their regulations without consulting the regulated community.
- "Should" statements should not be reinforced as "must" statements.
- Institutions should provide those who undergo training the documentation that details what subjects they have completed successfully.
- Institutions should consider adopting widely-available standardized modules for training.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Twenty-one percent of respondents addressed personnel management, noting burdens associated with hiring (63 percent), evaluation (19 percent), and visa issues (18 percent). Payroll management and training were also identified as burdensome. Of the total individual and institutional responses on personnel management, 9 percent indicate that they perceived no or acceptable burden.

### b. Hiring

The most frequently cited burden was hiring, with some respondents characterizing their institution's hiring process as "cumbersome" or "time consuming." Human resources tasks such as writing job descriptions, hiring, and layoffs and the associated paperwork may have to be completed by PIs. One PI noted that hiring is very labor intensive due to the requirement that multiple candidates be interviewed and the associated paperwork involved, and another felt that it was due to underdeveloped procedures and staff unfamiliar with the process.

*I recently laid someone off, and it took 2-3 working days of my time.*

*The forms required when hiring students are difficult. In addition, because of different accounting for the school year vs. summer and the summer that is part of one fiscal year and the summer that is part of another physical year, it can take the processing of three forms to hire a graduate student each year, even though it is the same student continuing work on the grant.*

*Everything about hiring has become much more complicated. This includes getting the person on payroll to getting them certified by all of the various oversight committees and offices on campus. It is often six months to a year from the time a person is offered the job until he/she is able to begin working on a project. Much of this time is paid for off of the grant.*

### c. Visa Issues

Visa issues were cited by 19 percent of respondents in this category. The majority of these respondents chose simply to identify it as a burden, but a few expressed frustrations with complicated paperwork and time required for securing visas for foreign-born personnel and students. A joint response from COGR, AAU, and APLU noted that "the issuing of visas and the hiring of international students and staff on certain projects or under certain Federal sponsorship can make the process infinitely more difficult."

*Visa issues take a significant amount of time. The paperwork is complicated, and it takes several visas to figure out how to do it. Even then, the outcome is uncertain, the timing is uncertain, and this then requires development of various contingency plans.*

## II. AGGREGATED RESPONSES

FASEB noted "delays and inefficiencies in the creation of new positions funded by a grant and in transfer of employees from one position to another as grants or research projects change," along with a "lack of sufficient flexibility for PIs to create desired personnel positions due to funding-mechanism-specific rules," makes hiring burdensome. The FASEB survey report notes that performance appraisal mandates have become excessive, involving multi-page documents and repeated rewrites. A university response noted that the respondents to its survey "felt that the procedures for hiring staff working on grant funding were too awkward and time consuming" and that "much of the load fell on the PI." Respondents from another major research university observed that "every personnel action" is "overly reviewed and questioned."

## Recommendations

- Enable projects to hire administrative assistants to support personnel management by returning facilities and administrative monies.
- Simplify the hiring process; giving greater flexibility to hire grant-funded staff.
- Improve institutional personnel management infrastructure.
- Provide bridge funding to protect personnel investment.

## 5. PERCEIVED SOURCE OF BURDEN

### A. SOURCE OF BURDEN

This section discusses responses that identified the perceived source of burden (Federal, institutional, or other), including what level of administrative support is provided to investigators fulfilling requirements associated with federally funded grants.

#### I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

##### a. Overview

Seventy-one percent of the individual and institutional responses answered the source of burden question. Eighty-three percent of those responses indicated the Federal Government, of which 32% of those responses indicated that the grant proposal process was a burden as a result of federal regulations or guidelines, 31% cited financial management, 25% progress reporting, 18% animal research, and 17% general reporting. Comments expressed concerns about lack of standardization across agencies and excessive Federal reporting requirements. Many respondents noted that having to track regular and, at times, small or seemingly insignificant changes to Federal agency requirements is burdensome.

Seventy-seven percent of individual and institutional responses that answered the source of burden question perceived the institution as a source of burden, 47% for financial management, 16% for animal research, and 14% for human research. Thirty-eight percent cited a lack of administrative support. Common themes are the perception that universities are overapplying Federal regulations, failing to provide adequate administrative support in key areas like proposal writing and budget management, and overstepping their bounds in evaluating human and animal research. Thirty-nine percent of responses identified a single burden as originating from both a Federal and institutional source.

*Effort certification which is a Federal requirement but our institution imposes its own requirements. COI is an NIH requirement, but our institution has imposed a very elaborate reporting system for all persons including students who work on grants.*

#### II. AGGREGATED RESPONSES

The FASEB response indicated that respondents perceive Federal burdens to emanate from a lack of standardization among funding agencies and of programs to educate investigators and institutions on regulatory changes and from frequent changes in regulations. For institutional burdens, they noted a lack of support and training for IT systems, budget management, and financial reporting. The CSHL response noted that COI burdens primarily came from Federal sources but that the institutions need to provide increased proposal submission support.

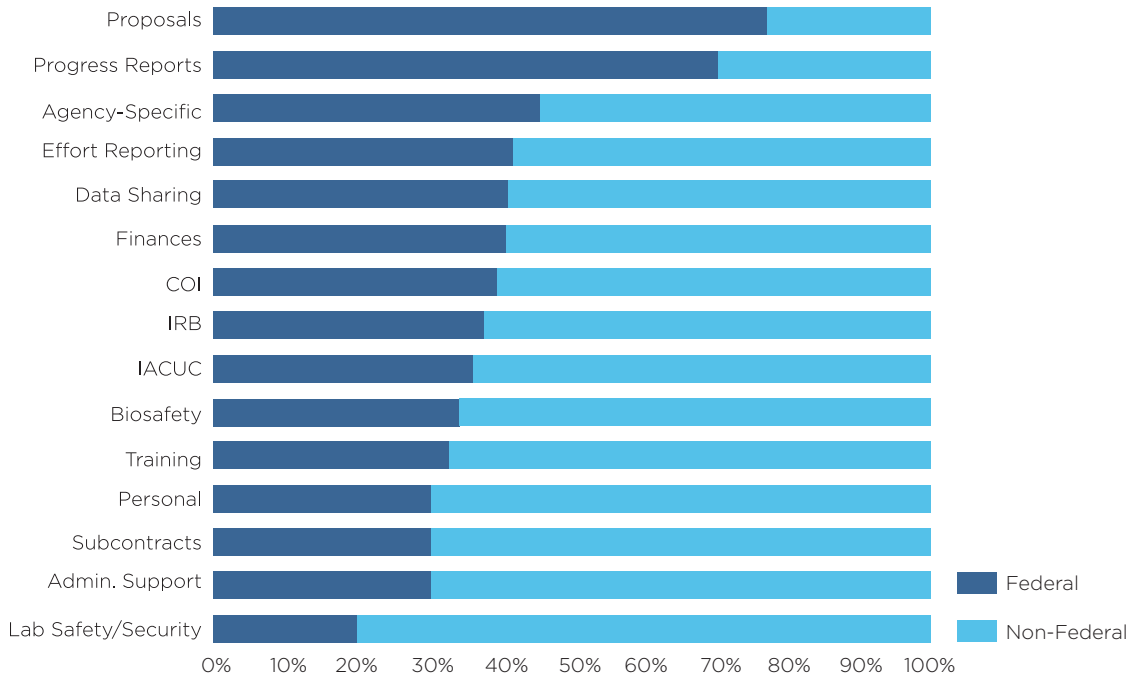
A major research university indicated that PIs believe burdens associated with financial management, effort reporting, and personnel management come primarily from institutional sources, often from inadequate institutional software used to support those functions. In contrast, respondents believe grant progress reporting, responsible conduct of research requirements, and data sharing stem primarily from the Federal government.

Finally, a response from a major research university offered detailed data on the perceived source of burden. Figure 4 shows the attributed source of burden for respondents across different categories. For proposal writing and progress reporting, it shows that investigators generally saw the Federal government as the primary source of burden. In contrast, for the remaining burden areas, an institutional source was seen as the



primary source of burden. These data suggest that institutional variability and institution level could play a significant role, but it likely underestimates the role of Federal requirements.

**Figure 4: Responses to a university survey on sources of burden**



### Recommendations

- Standardize grant proposal, financial management, reporting, and other requirements across the Federal agencies.
- Federal agencies should ensure that institutions do not overapply regulations in fear of audits.
- Federal agencies should detail the projected cost and administrative burden of all proposed new regulations and changes to existing regulations.
- Institutions should increase administrative support and training for key processes (e.g., software for financial reporting and tracking).

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Administrative support was addressed by 75 percent of respondents. Opinions of administrative support varied. Some responses cited excellent support for a wide range of topics, while others lamented the lack of support for things like budget preparation, proposal writing, IACUC and IRB protocol writing, financial tracking and management, and post-award support. Other responses noted that they had available administrative support but were displeased with the quality of the staff. In addition, direct charging for administrative support was addressed by 31 percent of respondents.

Many respondents suggested that indirect funding reimbursement was improperly used by institutions and that a greater proportion should be used to support PIs. Others suggested that institutions were not appropriately compensated by the Federal government, leading to reduced support for PIs. Respondents noted that administrative staff were overextended due to Federal requirements, undertrained, and had high turnover rates. Some PIs thought that centralized administrators were out of touch with, and did not prioritize, the needs of the PI. Respondents suggested that administrative staff with scientific knowledge, including grant writers and reviewers, would be beneficial.

*While these are not the direct responsibility of NSF, it would be helpful if NSF and other Federal agencies alert universities that the overhead dollars they collect are expected to actually facilitate sponsored research. Making PIs do everything themselves is not a good solution to university budget constraints.*

*Without any of the indirects coming back to the unit doing the work, the more successful we are, the bigger the hole we dig for ourselves. The current situation is increasingly untenable.*

*I am not sure that advocating more institutional support is the way to go. That builds local institutional bureaucracy and ultimately increases the overhead cost (which is now at about 50 percent). The right thing to do is to simplify the procedures on the Federal level.*

One major research university stated that “the institutional administrative support that is available to faculty has eroded as more and more staff time is consumed by addressing new requirements and as more and more resources are diverted from faculty support to fund new staff to administer systems, programs, reviews, and other duties associated with ever changing reporting, regulatory, and monitoring requirements.”

### b. No Support Provided

Twenty-one percent of the total responses addressing administrative support indicated that they received no administrative support for one or more activities. Of these responses, 69 percent affiliated themselves with public research institutions and 16 percent affiliated themselves with private research institutions. Responses generally indicated a range of burdensome tasks where no administrative support was given but where it would be appreciated, including financial management (19 percent), animal research (13 percent), general reporting requirements (13 percent), and progress reporting (9 percent).

### c. Satisfied with Support

Many respondents (81 percent) commenting on administrative support acknowledged receiving administrative support for at least one activity. Of these responses, 56 percent stated that they were relatively satisfied with available support for one or more burdensome activity. Seventy percent of these responses came from individuals affiliated with public research institutions, and an additional 21 percent of responses came from individuals at private research institutions. Across the major burden categories, respondents were most satisfied with administrative support for financial management (27 percent), human research (11 percent), the proposal process (10 percent), general reporting (6 percent), and animal research (4 percent). In addition, 14 percent of the responses indicated that they are satisfied with their current support but could use additional support.

#### d. Dissatisfied with Support

Forty-six percent of the administrative support responses acknowledged being dissatisfied with some part of the administrative support they received. Sixty-five percent of these responses indicated affiliation with public research institutions, and 16 percent indicated connection to private research institutions. Most responded generally about their administrative support systems, saying that they were dissatisfied because they did not receive enough support (58 percent) or because the quality of the support they received was poor (56 percent), with some responses identifying both problems (14 percent). Across the largest burdens identified, respondents indicated great dissatisfaction with administrative support associated with financial management (26 percent), the proposal process and requirements (11 percent), and personnel management (9 percent).

#### e. Direct Charging Administrative Support

The OMB published *Proposed OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards*, which was open for comment until June 2, 2013.<sup>9</sup> The NSB RFI asked respondents to provide their opinions on the utility of proposed guidance that would allow some charging of administrative support as a direct cost.

Of those who responded to this question, 42 percent approved of clarifying guidelines for direct charging and encouraged the government to allow more direct charging of administrative support. One aggregated response noted that 61 percent of investigators who responded to the question approved of the proposal. A major research university noted that the 1993 prohibition against direct charging resulted in a drop of approximately 50 percent in the number of project-funded support staff.

Twenty percent of individuals provided generally negative responses to the proposal, suggesting that clarified guidance would not reduce administrative burden, would result in less funds for research, is more confusing and too general and that institutions would require PIs to directly charge administrative support.

## II. AGGREGATED RESPONSES

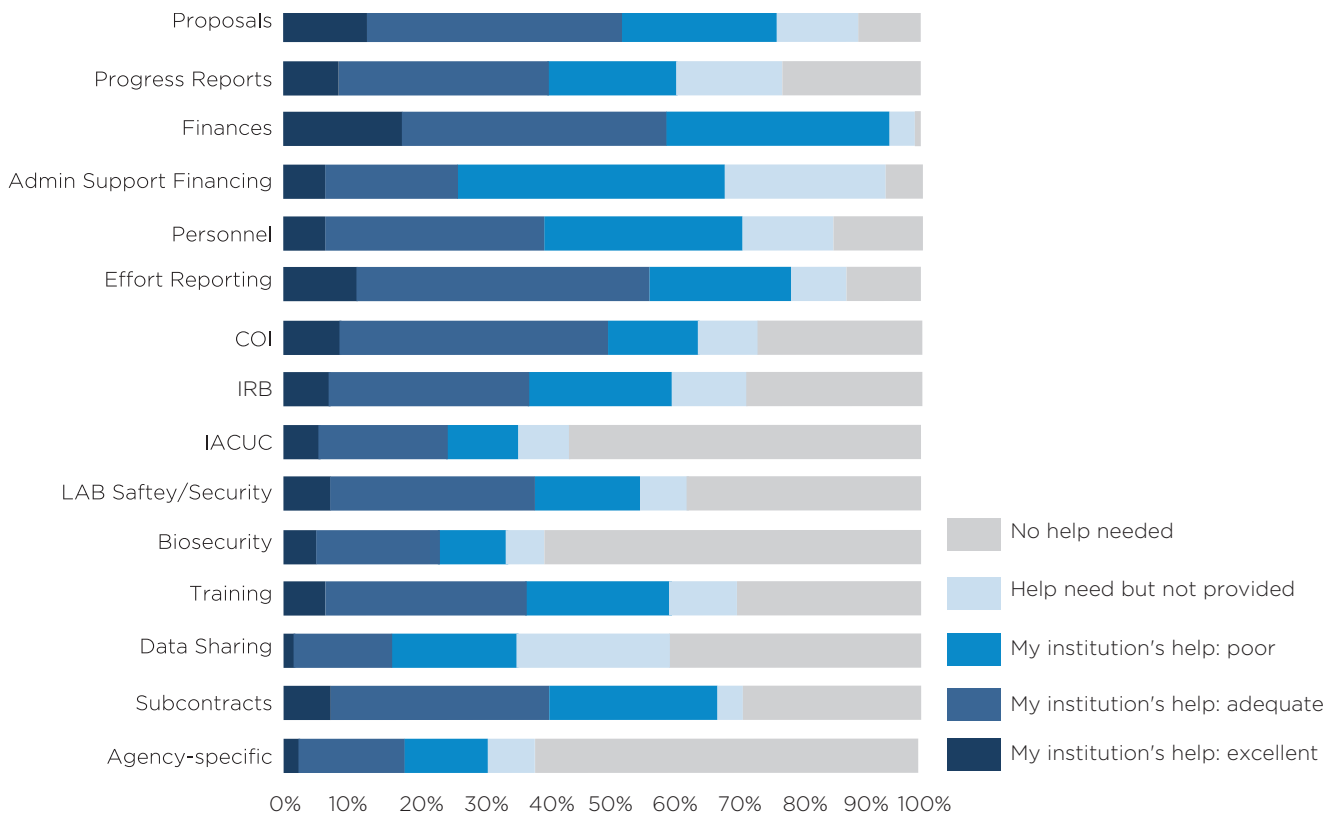
The FASEB response noted that investigators felt that the administrative support for grant proposal writing and preparation and personnel management post-award was lacking. The CSHL response supported direct charging, noting that PIs and their staff usually manage all research reporting activities and coordinate increasing collaborative efforts along with associated research compliance requirements. Roundtable participants described significant disparities in administrative infrastructure for grants between large and small universities, putting PIs at small institutions at a distinct disadvantage.

In areas where investigators at a major research university received support, they were asked about the quality of that support and whether it is sufficient. Figure 5 summarizes their responses. For each burden category, PIs generally reported a range of levels of support, with 20–50 percent of faculty being satisfied with their institution's level of support (excellent or adequate) and 30–60 percent needing additional help. Interestingly, in categories reported as burdensome, like IACUC or biosecurity, some faculty members indicated that no help was needed. It is unclear whether these numbers reflect the faculty's willingness to deal with these issues themselves or whether they perceive their administrative support as unable to assume the burden.

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<sup>9</sup> Available via [www.regulations.gov](http://www.regulations.gov), Docket ID OMB-2013-0001

**Figure 5: PI perceptions of the level, quality, and necessity of administrative support**



### Recommendations

- Allow direct charging of administrative support, particularly for large grants.
- Reduce the number of institution-level administrators.
- Return to a departmentally based, distributed system of support.
- Train specialized staff in specific processes such as grant proposals and management and provide backups in case of absence or turnover.
- Increase administrative support generally.
- Federal grants should provide adequate funds for administrative support under control of the PI. Administrative funds could be made available through overhead reductions imposed by the Federal agency.
- Universities should return a portion of the indirect costs to the investigator for administrative support.
- Administrators should focus on facilitating PI efforts

## 6. AGENCY-SPECIFIC ISSUES

### A. CROSS-AGENCY STANDARDIZATION

#### I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

This section summarizes comments on the lack of standardization between Federal funding agencies and those that specifically address NSF or NIH and their processes.

##### a. Overview

Twenty-four percent of responses suggested that lack of agency standardization creates burdens. Of these, only 13 percent suggested that effective measures had already been taken to reduce differences between agencies. The rest suggested that burdens stem from the lack of standardization in the proposal process and its associated requirements (40 percent), lack of standardization in forms and formatting requirements (25 percent), and technology differences (17 percent) for grant reporting and submission.

Technology is a cross-cutting issue that was mentioned in reference to many of these burdens. Among the responses on technology, the majority focused on usability, system flexibility, and lack of standardization. Most respondents expressed frustration with electronic systems, which many suggested were not user friendly and varied by agency. The use of electronic portals and submission has placed greater burden on PIs because tasks that used to be completed by skilled administrative assistants now require a PI to log in. FDP roundtable participants questioned the need for changing Federal passwords every 60 days and asked if any evidence showed that this requirement enhanced security (particularly since it necessitates writing them down). One major research university noted that “the necessity of learning and utilizing multiple post-award and compliance systems imposes a large and unnecessary administrative burden directly on the nation’s academic researchers, and the need to regularly adapt grantee eRA systems to the changing requirements of numerous different Federal eRA systems and practices results in a huge financial burden to grantee institutions ...”

*Different reporting and invoicing systems are used by each agency. For example, the SF425s for NIH are submitted in eRA Commons, but other agencies may have their own systems that we need to gain access to for submitting the SF425. For SF270s cost reimbursables, some sponsors require us to submit via mail, or via their own systems (i.e. Payweb or Wide Area Workflow). Submission methods are varied—each agency seems to have a different system. One example is HUD [United States Department of Housing and Urban Development], which requires us to submit information by telephone, including the caller’s SSN [Social Security Number]!*

*The shift to practically everything being online also means that practically everything is now done individually by PIs.*

## II. AGGREGATED RESPONSES

All six of the group responses included comments on agency standardization, noting how its absence creates burdens for PIs.

Respondents from a major research university suggested that the Federal government use one online system that contains information about investigators, including C&P support. FASEB noted three major themes of administrative burden, all related to a need for harmonization:

- Lack of coordination among Federal agencies in the development and implementation of regulations, policies, and guidance documents, resulting in duplicative efforts of investigators and their institutions;
- Unclear guidance on Federal regulations, policies, and guidelines, resulting in inconsistent agency interpretation, institutional mission creep, and “defensive implementation” to ensure compliance; and
- Multiple layers of unevenly applied and mismanaged regulatory oversight that results in increased overall burden for researchers and their staff.

### Recommendations

- Coordinate regulations and guidance across all Federal agencies.
- Forms and formatting, including grant proposals, should be standardized across Federal agencies.
- Federal regulations, policies, and procedures should be performance-based, specifying goals but allowing institutions flexibility in meeting them.
- All Federal funding agencies should, in a timely manner, establish common eRA mission statements and standardize and consolidate their post-award systems.
- The same software interface should be used across agencies.
- A consistent policy for auditing would be helpful. Inspectors should use the same criteria and should not be able to reinterpret regulations.
- All regulatory proposals should be submitted to a single Federal panel to ensure that requirements are the same at every institution and training certifications are transferrable; the panel should include representatives from institutions that will be directly impacted by the regulations.
- Conduct routine evaluations to ensure that all proposed and existing Federal regulations are evidence-based and designed in a manner that minimizes negative impacts on the conduct of research.
- Evaluate how existing Federal regulations and guidelines are interpreted and implemented by research institutions and related entities to identify inconsistencies and develop ways to minimize variance through training or clarification of policies.
- Develop regulations that are concordant with the level of risk they intend to mitigate.
- Streamline agency-led site visits and review strategies to minimize the potential for additional institution-imposed burden.
- Standard biographical and institutional information should be available electronically in a secure database accessible by Federal granting agencies.
- Use a single system for all Federal grant processes.
- Ensure that online reporting and submission systems are user friendly.
- Create harmonized policies and practices for data sharing, privacy, security, and preservation.
- Support the creation of broadly accessible IT infrastructure (i.e., do not limit support of IT infrastructure development to PIs funded by one agency).
- Create one CV format that fits all agencies.
- Allow administrative assistants to use Research.gov.
- Have a “data dictionary” for all Federal agencies to follow so that varying interpretations of data fields would be less likely.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Forty-four percent of respondents noted that they received NSF funding and described at least one associated burden. These included NSF-specific requirements related to the grant proposal process, financial management, and progress reporting. However, it is notable that a slight majority of these respondents (58 percent) also believed that at least some aspects of NSF's grant funding process did not impose serious or unreasonable burden.

### b. Proposal Process and Progress Reports

Seventy-six percent of NSF responses discussed the NSF grant proposal process, of which 80 percent of these responses referenced one or more associated burdens. A number of respondents stated a preference for FastLane over Grants.gov and did not seem to be aware that NSF accepts submissions from both systems.

NSF progress reporting was specifically mentioned in 54 percent of the NSF responses, with 80 percent of these responses terming it burdensome. Those citing little or no burden mostly contended that NSF's annual reports, though time consuming, were not unreasonable, were often useful to the PI and important to the progress of the grant overall, and were better than other funding agencies like DOE, DOD, and the U.S. Agency for International Development (USAID). Other respondents suggested setting limits on progress reports. One indicated that annual reports for large grants like Materials Research Science and Engineering Centers (MRSECs) were "an unbelievable amount of work" and that they did not believe they were used by the agency. Another indicated that the program requirements of the NSF Industry and University Cooperative Research Program (I/UCRC) are highly burdensome.

While some respondents indicated that they did not believe that the agency uses information from annual reports, one conveyed the perspective that NSF uses the information to evaluate performance, design programs, and inform Congress about outcomes. One respondent stated "the long-term time horizons in many research areas renders the now nearly year-to-year accounting and proposing extremely inefficient" and that "the lower amount grants on shorter intervals delimits grand challenge, transformational research that NSF ostensibly wants to support, but cannot support, given these constraining trends."

A number of respondents commented on the "new" NSF progress report and use of Research.gov, clearly referring to the RPPR. One respondent noted that Research.gov was more frustrating to use, and several noted that questions were repetitive. Others suggested that the reports were much more complex and burdensome and that entering small bits of text in multiple windows was painful. Respondents suggested returning to the practice of submitting the report in a single document. One response noted that none of the information previously entered on FastLane has moved over to Research.gov and that it has to be reentered.

Respondents suggested that outreach and broader impact requirements are broadly misinterpreted by NSF personnel and reviewers, that having a separate section for broader impacts leads to redundancy, and that it is difficult to have to justify this relevance at the level of individual projects, which are often designed to "open new frontiers of knowledge" and therefore "have an uncertain future." It was suggested that broader impacts should be scaled back to what they were about 10 years ago and that not every NSF proposal should be required to include Broader Impacts: "Surely, there is merit in focusing on Intellectual Merit for technical proposals." One respondent said that NSF's focus on outreach and broader education is misplaced and not productive: "This is the National SCIENCE Foundation and not the outreach foundation."

### c. Financial Management

Seventy-three percent of the respondents discussed NSF requirements for financial management, all of them citing one or more burdens and only 10 percent stating that some aspect of financial management did not pose a serious additional burden. One respondent noted that NSF has become very difficult and obstructive regarding budget line items. Many noted that NSF has always required a detailed budget and suggested that NSF adopt the NIH modular budget model.

#### **d. Administrative Requirements for Large Grants and Centers**

One respondent noted that the “relentless administrative load that is required of NSF Science of Learning Centers has been overwhelming and ultimately disruptive to academic productivity” and estimated that upwards of 65 percent of the time and resources of the Centers have been spent complying with administrative requirements. It was also noted that annual visits and monthly phone calls were required where similar NIH-funded initiatives, it was suggested, required only one visit every 5–10 years. Similar comments were made regarding recently implemented annual review for the Cornell High Energy Synchrotron Source (CHESS) program.

One respondent noted that “by far and away the greatest amount of administrative work is associated with the ever-changing reporting requirements for NSF MREFC programs” and offered a number of specific recommendations. Another noted “compliance demands from the Cost Analysis and Audit Resolution (CAAR) Branch within NSF,” without providing specifics as to what is not in compliance.

#### **e. Other**

Respondents stated that redundant NSF proposal reviews from multiple programs, program requests for additional information with little notice, and last-minute changes to reporting or formatting guidelines increased their administrative workload. Other comments indicated that some PIs were relatively satisfied with NSF requirements. Several pointed out that the requirements did not pose significant burdens, and others mentioned that NSF compared favorably to other agencies. Respondents did suggest that NSF increase the duration and size of awards.

A major research university noted an “increase in regulatory burden imposed on investigators performing field studies involving wild animals and receiving NSF funding, which does not appear to be based on regulation.” One investigator suggested that the preliminary proposal process instituted by the NSF Division of Environmental Biology (DEB), which invites a percentage of highly rated preliminary proposals to submit a full proposal and has moved to an annual funding cycle, has “greatly complicated and delayed the funding process,” and is “slowing the pace of science.”

## **II. AGGREGATED RESPONSES**

Four of the six aggregated responses indicated that some PIs received funding from NSF. A university survey response noted that several PIs found “no NSF-specific requirements that added to their administrative workload,” while others cited the ambiguity of and excessive emphasis on the broader impacts criterion and data management requirements. It also stated that numerous questions about the impacts to institutional infrastructure and so forth in the final report are cumbersome. These responses also described a need for increased standardization between NSF and other agencies.

The CSHL response reported that PIs they interviewed recommended that the NSF Higher Education R&D (HERD) survey be reevaluated because the current long form survey requires 50 hours to complete. The response indicated that this represents a high level of effort and burden for institutions and investigators. A Stanford roundtable participant suggested that the NSF Management Information System (MIS) is burdensome, taking hundreds of hours to prepare data that are not (and perhaps cannot be) used. Another noted that on an NSF collaborative grant the PIs cannot move funding across institutions. A roundtable participant at Georgia Tech noted that NSF used external evaluators who independently required the same materials provided in NSF progress reports. This requirement was cited as a particular burden on smaller institutions that lack administrative support. Participants at the FDP roundtable discussion expressed concern about NSF adding more requirements at the proposal stage, including data management plans, post-doc mentoring plans, and more information on broader impacts.



## Recommendations

- Reduce expectations for the length of annual and final progress reports.
- Simplify reporting and allow investigators to submit reports as single documents.
- Standardize the proposal structure with other major funding agencies like NIH.
- Clarify requirements for the Broader Impacts criterion and integrate these requirements into the research description rather than isolating them in a separate section.
- “Broader impacts” should be consolidated with “intellectual merit” to make a common total merit standard.
- NSF should provide a clear definition of necessary minimums for outreach and education required to meet the Broader Impacts criterion.
- Simplify budget requirements and/or use modular budgets in grants proposals.
- Reduce the number of questions on annual reports (currently 40 per award).
- Provide guidance or templates for first-year reports.
- Reduce the scope of questions on final reports to include the important information such as the number of presentations given, manuscripts published, and students and post-docs trained.
- Develop a NSF policy that eliminates IRB review for program evaluations.
- Use Researcher ID or Open Researcher and Contributor ID (ORCID) to query publications and determine COI.
- Integrative Graduate Education and Research Traineeship (IGERT) and Research Experience for Undergraduates (REU) should have funds for direct administrative support.
- NSF could lead an effort to identify inconsistencies and guideline shortfalls in data sharing across organizations and agencies.
- Streamline the format for IGERT annual reports.
- Do not require the co-author list at the preliminary proposal stage; instead, only require it when a full proposal has been invited.
- The NSF HERD survey and the questions contained within it should be reevaluated. Survey managers should consider ways to reduce the time required to complete the survey.
- The data management plans should have fewer open-ended descriptions. Provide some data management plan template options, giving the PI the choice of which is the best fit.

## I. INDIVIDUAL AND INSTITUTIONAL RESPONSE DETAILS

### a. Overview

Thirty percent of individuals and institutions indicated that they receive funding from NIH. NIH-specific comments focused on perceived overly stringent reporting requirements, the lack of outcomes associated with new regulatory actions, and challenges resulting from the lack of standardization between NIH and other agencies. A number of comments also mentioned NIH positively, saying that other agencies should adopt the NIH modular budgets.

### b. Proposal preparation and progress reports

Respondents suggested that the new, “shorter” NIH grant proposal format “has gone a long way toward reducing the workload” but that the instructions for grant proposals were excessive. Respondents also mentioned that the different institutes at NIH have different policies, that the NIH IDeA Networks of Biomedical Research Excellence (INBRE) have excessive reporting requirements, that P01 protocols experience delays, and that funding rates under 10 percent at most NIH institutes require more grants and resubmissions. Respondents noted that having to document “other” support for individuals not paid on the grant and provide a personal statement for biosketches that are tailored to each proposal is burdensome. Roundtable participants suggested that peer reviewers will look at the researcher’s publications, not the reasons they think they can do the work.

Several respondents suggested that completing tables for training grants is burdensome, and one noted the instructions are ambiguous. One respondent suggested that completing competing renewals for T32 training grants is burdensome and that the level of burden will increase if NIH requires T32 renewals to adhere to NIH open-access policies for publications. The AAU/APLU/COGR response indicated that the T32 training grant is “so onerous that it’s become a disincentive to participation” and indicated that they were “not confident the additional data collected is put to any useful purpose.”

*The NIH has a 280-page instruction booklet to fill out a 12-page scientific grant.*

*The NIH biosketch format is idiosyncratic and redundant with my regular CV. I like the NSF two-page biosketch description.*

### c. Other

Respondents suggested that COI reporting requirements have become increasingly onerous with conflicting NIH rules, institutional requirements, and state rules. Similarly, respondents stated that the NIH COI forms are “painful for people who are highly interdisciplinary and take several days to create.” One respondent stated that the “new” Federal COI requirements “have resulted in—literally—weeks of additional workload for faculty, legal compliance offices, general counsel, [and] sponsored programs” and suggested that it was not clear who is considered a PHS PI. Another individual suggested that the broad definition of investigator “tends to include most members of the research team including students, who have little potential for significant financial interests.”

Several investigators mentioned that NIH has a practice of cutting final budgets after detailed preparations. Many respondents suggested that all Federal agencies should consider the modular budget format that NIH uses and that the cap should be increased.

*Financial aspects are now the greatest administrative burden. This has become much worse in the past two years because of NIH funding cuts. After careful and lean budgeting, we are routinely getting major cuts (25 or 30 percent) and then flat funding for items like salaries that are not flat for many reasons, including union contracts. Keeping a research group viable has become much more difficult.*

## II. AGGREGATED RESPONSES

Three of the six aggregated responses included comments on NIH requirements. The FASEB response noted that most of its 1,324 respondents received NIH funding, and, of those responding to the question on sources of burden, 86 percent identified NIH as a source of burden. Specific comments highlighted frequent changes to NIH guidelines, intrusive laboratory safety inspections, a lack of standardization for data submission requirements across NIH Institutes and Centers, and that the eRA Commons website is difficult to use and requires a new password every three months.

TES response applauded NIH's use of JIT procedures for grant proposals and awards and suggested that "Federal agencies apply these procedures more broadly to reduce administrative burden associated with grant preparation."

Finally, a university response noted that roughly half of its respondents identified NIH as a funder. Some individual responses recommended that NIH limit audits, increase the use of modular budgets, use similar forms as the other funding agencies, and eliminate the requirement to provide a personal statement in the biosketch. Some comments also mentioned that the NIH online submission system was preferable to those of other agencies.

### Recommendations

- NIH should harmonize policies across Institutes.
- Review agency requirements and assess whether these requirements meet their intended goal while weighing the costs and benefits of the requirement.
- Streamline the NIH grant proposal process and align forms and requirements with those of other funding agencies.
- NIH should raise the modular budget to \$350K or \$400K to reflect recent dramatic increases in salary/benefit costs.
- Projects funded and budgeted under modular guidelines should be funded without modification by NIH upon notification of award.
- Each unit of NIH funding (\$250K) should come with 10 percent funding for an administrator under the direct control of the investigator.
- All appointments for all trainees should align with the budget period of the award.
- NIH should follow the OHRP Federal regulations that do not require IRB review of grants for exempt research.
- The definition of "investigator" should be limited to the individual responsible for planning the funded research and making purchasing decisions (e.g., the PI).
- Dual agency funding should be streamlined, and financial awards and reporting should be aligned between NIH and other funding agencies.
- NIH should consider eliminating the proposal summary.
- The NIH biosketch should not include a personal statement specific to each grant.
- Replace vertebrate animal statements with the previous one-page statement of use.
- Eliminate the NIH requirement to download research publications into the NIH system.
- Training grants should be more straightforward and easier to manage.

## 7. COMMENTS ON ADDITIONAL BURDENS

### A. SUBCONTRACTS

This section provides details on burdens mentioned less frequently by RFI respondents.

Eighteen percent of responses commented on burdens associated with subcontracting, only six percent of which indicated that they did not perceive significant additional burdens. Responses indicated that subrecipient monitoring, the need for multiple approvals, related management and paperwork (e.g., checking and processing invoices), and budget management were “time consuming,” “complicated,” and a “huge administrative burden.” One respondent indicated that his/her institution required the completion of a 12-page questionnaire related to export control regulations for “ANY potential subcontract” regardless of whether controlled technology is involved. Another respondent indicated that the NSF collaborative research proposal is far preferable to overseeing a subcontract. The FASEB survey report noted the “lengthy finalization process for subcontracts due to institutional and agency requirements as well as state and Federal laws.”

*Subcontracts are to be avoided at all costs if one wants to have even a second to be involved in actual research.*

*There is currently no efficient means for processing subcontracts . Each subcontract must go through numerous people and institutions for approval, creating a lag in payment. Furthermore, most subcontracts are paid retroactively, requiring the setup of a “zero-dollar” budget in which the institution pays for services upfront, invoices for the work, and is then paid at a later date. This creates difficulty determining effort levels and developing financial projections.*

#### Recommendations

- The OMB should eliminate subrecipient monitoring requirements for entities subject to A-133 audits.
- Auditing should be focused on monitoring high-risk recipients.
- Agencies should issue multiple awards to support collaborations rather than single prime awards with multiple subawardees.
- Allow award subcontract funding to go directly to the subcontracting institution.
- Reduce duplication of institutional and Federal requirements for subcontracting.
- Simplify and standardize the processes for setting up and paying subcontracts, potentially through greater use of automation.

COI was addressed by 16 percent of individual and institutional responses, of which six percent suggested that COI reporting did not represent a substantial burden. The remaining responses indicated that COI reporting was excessively time consuming and onerous.

AAI noted that its members “have found that the interpretation by some institutions of the new conflict of interest rules has resulted in excessive reporting requirements and time-consuming paperwork” and recommended that “funding agencies reassess what information must be reported to prevent COIs and develop clear guidance for institutions.” This was echoed by individual respondents who noted the redundancy of COI paperwork, that COI requirements for collaborators delay grant preparation and hinder collaborations, and that frequent changes to COI reporting requirements and systems makes maintaining compliance challenging.

One response noted that “these regulations have resulted in the addition of significant staff and development of computer programs to track and report potential significant financial COIs” and that “the number of “problems” identified by these expenditures are limited.” Another indicated that “the majority of university administrators interpret these policies and reporting requirements as de facto prohibitions of entrepreneurial activities by faculty and students.” Regarding varying COI requirements, one respondent stated the following:

*Some ask about the last 12 months, some ask about 2012, and some ask for the last three years. Some only want to hear about amounts over \$5000, some want to hear about \$1, and some are concerned with the “total” of all outside interests in the last year. Some want to know exact amounts and some don’t. Some concern relationships with manufacturers of drugs or devices used on patients, some with any company related to healthcare, some only with activities directly related to the activity at hand, and some require everything so that they can decide what’s related and what isn’t. Some want to hear about research funding paid to the institution rather than personally. Some ask for percent owned of the total shares of the company and some ask for a dollar value for shares.*

The aggregated responses from FASEB and CSHL emphasized the need for standardization in COI reporting and the advantage of providing updates only when conditions have changed significantly for a PI. Participants at the Tufts University roundtable were emphatic in recommending that NSF not adopt NIH’s COI rules and advocated a risk-based approach that would target major income sources instead of listing every honorarium or speaking fee.

### Recommendations

- Streamline COI training and harmonize COI reporting within and across agencies.
- Agencies should adopt a simple and universal electronic COI reporting form.
- Agencies should require COI reporting annually, or if significant changes occur, rather than for every grant and every submission. If required for every grant, it should be required only when the proposal has been recommended for funding.
- COI reporting should be standardized and only required if grant funding exceeds a set value.
- COI reporting should not be the responsibility of the institution. Individual PIs should provide certification.
- Agencies should provide COI forms pre-populated with relevant grant information.
- Agencies should adjust COI policies to encourage entrepreneurship among faculty and students and encourage university administrators to support entrepreneurial activities.

Sixteen percent of respondents mentioned various training requirements as creating an additional burden. The most frequently mentioned included training requirements related to human and animal research; COI, responsible conduct of research, and general ethical procedures; regulatory compliance, personnel management and administrative work; and hazard or general laboratory safety. One respondent noted that institutions have adopted broad training requirements, while regulations requiring training are minimal. Respondents also commented on the frequency of “refresher” courses and other training requirements related to IT and student training. One response noted that PIs with funding from more than one agency must complete training sessions on the same topic by multiple agencies. Aggregated responses from FASEB and a major public research university echoed those described above. The AAU/APLU/COGR response noted that “broad-based requirements for training or, in the language of some regulations, ‘communicating’ or ‘informing’ the entire research staff of the regulation or policy at increasingly frequent intervals create an often unnecessary and burdensome training requirement.”

*Annual refresher courses, which are often required, are unnecessary since changes from year to year in a specific area are either non-existent or minimal at best.*

### Recommendations

- Create an online comprehensive training resource to provide a uniform core curriculum for basic laboratory safety, human subjects protections, and care and use of laboratory animals.
- For completion of basic training modules, provide centralized tracking that is readily accessible by individual investigators, institutional staff, and agency administrators.
- Offer shorter “refresher” modules for new regulations rather than making investigators repeat entire training courses.
- Develop standardized training across agencies so that completion of a course satisfies the requirements of all agencies.
- Agencies/institutions should reduce training burden by ensuring that investigators are only required to take training courses that apply to their research;
- Limit training to new investigators.
- Reduce the number of annual refresher courses.
- Limit supporting documentation required for training.

Sixteen percent of responses commented on burdens associated with laboratory safety and security requirements. Thirty-nine percent of these responses identified security as burdensome, citing complex regulations and “restrictions on the use of Select Agents and Toxins under the Chemical Facilities Anti-Terrorism Standards [CFATS] as problematic. Thirty percent cited biosafety as burdensome, listing similar issues, along with inspections and training. Twelve percent of individual responses cited occupational safety as problematic, citing inspections and oversight. AAI noted that shipping some biological reagents requires a permit from the USDA which can take months to obtain. One respondent noted that increasing safety requirements may prevent students from participating in research. The three aggregated responses from FASEB and two major research universities cited all of the issues noted above and added the additional category of radiation safety.

*There is an explosion of requirements in terms of laboratory safety certification. This has happened within a span of the last 2–3 years. It has gotten so bad that it takes one talented postdoc at least two weeks of intensive work just to comply with the paperwork for laboratory safety. Everyone in the laboratory has to spend at least a day’s worth of work to ensure compliance on paper. This is an absurd waste of tax payers’ money.*

### Recommendations

- Coordinate training for biosafety and laboratory safety among the Federal government, state government, and grantee institutions so that one course addresses all applicable requirements.
- Agencies should review all safety rules to foster streamlining, avoid duplication, and expedite processes that can cause harmful delays.
- The Federal government should exempt research institutions from CFATS and develop separate policies for research institutions and stratify regulations according to risk.
- Harmonize laboratory inspections by multiple agencies of jurisdiction.
- Reduce the frequency of laboratory safety inspections for institutions that remain in good standing.
- Streamline the select agent program and remove pathogens from risk that have been used safely for research and cannot be easily used to harm human health or the environment.
- Agencies should limit biosecurity policies to research that poses the greatest risk.
- Agencies should eliminate requirements to quantify biological agents (which can rapidly replicate and be transferred with no discernible loss in volume or mass) present in a research setting.

## 8. CONCLUSION

Several cross-cutting themes emerged from the RFI responses. Respondents indicated that growth in Federal requirements, lack of standardization across Federal agencies, increasing use of non-standard electronic systems, and a lack of sufficient or high-quality administrative support has resulted in PIs spending a greater proportion of their research time on administrative tasks. Regarding new regulations aimed at reducing fraud, waste, and abuse, many respondents expressed the view noted by FASEB survey respondents that regulations “punish all” for the “mistakes of a few” and suggested that these regulations fail to meet their intended goals. Respondents also suggested that unclear guidance and “aggressive” audits lead to greater institutional burden as institutions overcomply to avoid sanctions.

Respondents noted that postdocs, graduate students, and laboratory staff spend research time addressing institutional and funding agency requirements and that IRB/ IACUC, general training, and safety requirements can prevent students from conducting independent research or laboratory work generally. Most PIs and institutions suggested that new requirements are not improving how science is conducted or improving safety and that the current situation is untenable.

To reduce burdens, respondents recommended the harmonization of agency guidelines; standardization of agency forms, requirements, and methods of submission; and standard language and templates for forms and procedures. Similarly, respondents recommended reducing initial grant proposal requirements, progress reports, financial reports, and other requirements to the minimum needed.

The responses to the RFI provide valuable insight into the administrative workload that PIs and institutional administrators incur while applying for and executing Federal grants. With responses from faculty members, administrators, and institution officials, the collective insight not only substantiates information from previous work, but also provides new information and recommendations that can guide the Task Force as it seeks to address the administrative burden incurred by Federal grantees.



# APPENDIX D

RESPONSE FROM THE  
NATIONAL INSTITUTES  
OF HEALTH (NIH) OFFICE  
OF LABORATORY ANIMAL  
WELFARE (OLAW)

# BACKGROUND

Federal laws, regulations, policy, and guidance determine the oversight of animals used in federally funded biomedical and behavioral research. The authority of NIH to oversee Public Health Service (PHS) funded animal activities derives from the [Health Research Extension Act of 1985 Public Law 99-158 “Animals in Research”](#) (HREA) which states that the “Secretary [of the U.S. Department of Health and Human Services] acting through the Director of NIH, shall establish guidelines for the...proper care of animals to be used in biomedical and behavioral research.”

The agencies of the United States Government adhere to the [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#) (U.S. Government Principles). The Principles address: (1) animal transportation, (2) relevance of research using animals, (3) use of appropriate species in minimum numbers and alternatives to animals, (4) avoidance of pain and distress, (5) use of sedation, analgesia, and anesthesia, (6) euthanasia, (7) living conditions of animals and veterinary care, (8) personnel training, and (9) exceptions.

[The Public Health Service Policy on Humane Care and Use of Laboratory Animals \(Policy\)](#) implements and supplements the U.S. Government Principles. The Policy is applicable “to all PHS-conducted or supported activities involving animals.” The Policy was implemented in 1985 and has remained unchanged to date except for provisions added in 2002: “just-in-time” review to reduce regulatory burden and a provision to allow IACUC members names to be coded. OLAW, acting on behalf of the NIH Director, is responsible for the general administration and coordination of this Policy.

*The [Guide for the Care and Use of Laboratory Animals](#)* (Guide) is an operations manual of best practices for the humane care and use of research animal subjects published by the Institute for Laboratory Animal Research (ILAR) of the National Research Council of the National Academy of Sciences. The PHS Policy requires that PHS Assured institutions (institutions that receive funding from PHS for the conduct of animal activities) base their programs of animal care and use on the Guide and that they comply with the applicable regulations issued by the U.S. Department of Agriculture (USDA) under the [Animal Welfare Act](#) (AWA).

# RFI COMMENTS AND RECOMMENDATIONS

## **Comment:**

OLAW and the USDA Animal and Plant Health Inspection Service (APHIS) should clarify the expectation of IACUC “review and approval of animal facility Standard Operating Procedures (SOPs)” (see 2012 Lab Animal 41:02). “If twice a year as most have interpreted this statement, this places a significant burden on the committee members without demonstrable benefit to the animals.” “An expectation of regular review, however, is not unreasonable and most places are reviewing SOPs on the same three year cycle used to review all other animal use activities.”

## **OLAW Response:**

OLAW expects IACUCs to review SOPs at appropriate intervals (at least once every three years) to ensure they are up-to-date and accurate, as described in OLAW FAQ [D14](#). Benefit to the animals accrues by review of procedures involving animals. SOPs that describe animal program operations (e.g., cage wash operations, water acidifier operations, cleaning procedures) affect the living conditions of animals and the safety of animals and personnel and therefore contribute to a well-run animal care and use program.

## **Comment:**

Reconsider the requirement for the use of pharmaceutical grade substances in all cases unless justified and approved by the IACUC.

## **OLAW Response:**

In FAQ [F4](#), OLAW defines a pharmaceutical grade substance as “a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the [United States Pharmacopeia-National Formulary \(USP-NF\)](#), or [British Pharmacopeia \(BP\)](#). According to guidance from the FDA, “pharmaceutical secondary standards” are acceptable for use in clinical animal studies if obtained from a reputable source and comply with compendia standards.”

OLAW has had a consistent policy on the use of non-pharmaceutical-grade substances consistent with that of the USDA since their issuance of Animal Care Policy 3, Veterinary Care in 1997. OLAW addresses the issue of use of non-pharmaceutical-grade substances in FAQ [F4](#): May investigators use non-pharmaceutical-grade compounds in animals? OLAW and USDA agree that pharmaceutical-grade substances, when available, must be used to avoid toxicity or side effects that may threaten the health and welfare of vertebrate animals and/or interfere with the interpretation of research results. However, it is frequently necessary to use investigational compounds, veterinarian- or pharmacy-compounded drugs, and/or Schedule I controlled substances to meet scientific and research goals.

The IACUC may implement institutional policies to review and approve the use of such non-pharmaceutical-grade substances. For example, the IACUC may establish acceptable scientific criteria for use of these agents within the institution, rather than on a case-by-case basis. Investigators and IACUCs should consider relevant animal welfare and scientific issues including safety, efficacy, availability of pharmaceutical-grade compounds, and the inadvertent introduction of new variables. Cost savings alone are not an adequate justification for the use of non-pharmaceutical-grade substances in animals.

## **Comment:**

Eliminate annual reports to the IACUC. Protocols are continually amended. Annual review often invites extensive revisions to protocols that are already approved and have not changed.

### OLAW Response:

OLAW does not require annual reports of protocols to the IACUC. The PHS Policy (IV.C.5.) requires “continuing review of each previously approved, ongoing activity covered by this policy at appropriate intervals, as determined by the IACUC, including a complete review in accordance with IV.C.1-4. at least once every three years.” An institution’s IACUC must review ongoing animal activities every three years to remain in compliance with the PHS Policy, a requirement for continued PHS funding. This is a minimum standard; the IACUC may choose to require more frequent monitoring.

### Comment:

Reduce or consolidate overlapping inspections by agencies and accreditors.

### OLAW Response:

OLAW and USDA cooperate in resolving noncompliant situations by conducting joint OLAW site visits/ USDA inspections. OLAW allows institutions to use the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit or the pre-visit preparation activities to meet the requirements for an IACUC semiannual program evaluation and report. OLAW also accepts AAALAC accreditation in lieu of submission of an institutions’ semiannual program review and facility inspection report during initial negotiation or renewal of the PHS Assurance.

### Comment:

Encourage IACUCs to use Designated Member Review (DMR) instead of Full Committee Review (FCR) for protocol amendments that do not significantly affect animal welfare.

### OLAW Response:

IACUCs may review proposed animal experiments by either of the two valid review methods recognized by the PHS Policy, FCR or DMR. IACUCs and institutions are free to use either method for protocol review. More information is provided by OLAW FAQ D3: What are the possible methods of IACUC approval?

### Comment:

Respondents suggested the requirement to detail the exact number of animals required over the course of a research project be eliminated, that IACUCs rely on reporting of animal use, that an estimate be allowed, and that agencies allow changes to the number of animals to be approved through a simplified administrative process.

### OLAW Response:

OLAW addresses the issue of animal numbers in FAQ F2: Is the IACUC responsible for tracking animal usage? Although the PHS Policy does not explicitly require a mechanism to track animal usage by investigators, it does require that proposals specify a rationale for the **approximate** number of animals to be used and be limited to the appropriate number necessary to obtain valid results

The IACUC may approve a range of animal numbers, rather than a specific animal number, if the range is appropriately justified. An increase of up to 10% of the initially approved number of rats, mice, and fish approved is permitted without additional IACUC approval. In all situations except rats, mice, and fish, individual animals should be accounted for. Any change in animal number or range of animal number that has been previously approved should be approved by the IACUC.

### Comment:

Allow small changes to protocols to be approved through a simplified administrative process. - “both PHS Policy and AWA Regulations require amendments to protocols to follow the review process that is required for full protocols (2.31.d and IV.C.2).” “OLAW could amend its guidance documents on review of modifications/amendments to permit more rapid turnaround.”

### **OLAW Response:**

PHS Assured institutions may make minor changes to a previously approved animal activity through an administrative process. These changes include but are not limited to:

- change in strain;
- correction of typographical errors;
- correction of grammar;
- contact information updates;
- change in personnel other than the PI; and
- change from one approved housing or performance site to another approved site.

Significant changes to an animal activity must be reviewed and approved by the IACUC through designated member review or full committee review. The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis. More information about what is considered a significant change is provided in NOT-OD-03-046 and OLAW FAQ D9: What is considered a significant change to a project that would require IACUC review?

### **Comment:**

Respondents suggested that the PHS requirement for a re-review of animal use protocols every 3 years was arbitrary and burdensome and should be changed to five years to better match grant length. It was noted that many institutions require a complete re-write every three years. Respondents suggested the Board “encourage federal agencies to clarify that animal care and use protocols do not need to be completely re-written to satisfy the requirements for annual and/or triennial re-review.”

### **OLAW Response:**

PHS Policy (IV.C.5.) requires a complete review of animal activities at least once every three years. Investigators are not able to describe their proposed animal experiments in the detail required for adequate IACUC review and approval for the entire five years of a grant. Protocols are frequently amended during the three years approval duration to accommodate changes in experimental design.

The PHS Policy (IV.C.5.) requires that the IACUC conduct continuing review of each previously approved, ongoing activity covered by this [PHS] Policy at appropriate intervals, as determined by the IACUC, including a complete review in accordance with IV.C. 1-4. at least once every three years. The Policy requires that a complete review be conducted; it does not require that the protocol be rewritten. IACUCs may review the initial protocol and all modifications. Many IACUCs determine that a rewritten protocol facilitates better understanding of the animal activities currently being conducted. This understanding enables a more efficient, effective review by the IACUC and promotes compliance with the protocol by the research team. Performing work not described in a protocol is the most frequently occurring noncompliance reported to OLAW. IACUCs, in requiring protocols to be rewritten at three year intervals, are following a best practice intended to promote compliance with the PHS Policy. As most protocols are prepared using a computer, the cut and paste function makes development of a complete up-to-date protocol a less onerous task than in earlier times.

### **Comment:**

The NIH should revamp animal care compliance regulations to the minimum required for the safety of animals.

### **OLAW Response:**

OLAW’s guidance reflects the minimum standards required for humane animal care and use. Acceptance of PHS funds to conduct animal activities obligates the institution and researcher to conduct their research in compliance with the PHS Policy (IV.A.). Animal welfare is the concern of many U.S. citizens. OLAW guidance represents the welfare of the animals in the service of biomedical research, not the wishes of activist organizations or researchers, on behalf of the NIH Director, the U.S. Government and the citizens of the United States.

The purpose of OLAW's guidance is to facilitate compliant implementation of the PHS Policy (V.A.3.), as required by NIH Grants Policy Statement (Part II, Subpart A 4.11 [Animal Welfare Requirements](#)), in PHS funded animal activities. OLAW's guidance is based on OLAW's experience with the subject matter and draws on best practices followed by the biomedical community regarding the use of research animals. Unless OLAW guidance cites specific statutory or regulatory language, an institution may use an alternative approach if the approach satisfies the requirement of the PHS Policy.

OLAW develops procedures to reduce regulatory burden, e.g., [NOT-OD-11-053](#), Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates. OLAW coordinates guidance with USDA and FDA under a [Memorandum of Understanding](#) (MOU).

Changes in OLAW's guidance are related to advances in biomedical research and technology, and changes in ethical standards required by law and public perception. OLAW is required by the PHS Policy (V.A.3.) to advise "awardee institutions concerning the implementation of this [PHS] Policy."

OLAW's new guidance and changes to existing guidance are made to:

- provide humane care of animals used in research and a safe environment for program personnel involved in PHS funded animal care and use programs; and,
- reduce animal pain and distress, especially to incorporate advances in research methods and technology.

OLAW issues guidance as needed to:

- clarify the meaning or language of policy, guidance or regulation, as deemed necessary by OLAW or in response to requests from the research community;
- reduce regulatory burden, especially to harmonize with other federal regulations and guidance; and
- ensure compliance with federal laws, regulations, guidance, and Congressional and Executive directives.

OLAW reviews, revises, updates, and modifies guidance on a continual basis. OLAW welcomes comments on any of its policy guidance. Comments may be submitted to OLAW by email at: [olaw@od.nih.gov](mailto:olaw@od.nih.gov) (please insert the title of the specific guidance document in the subject field), or by mail to:

Division of Policy and Education  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

All relevant comments will be considered in OLAW decisions on timing and content of revisions to guidance documents, or development of new guidance documents. In 2009, OLAW added a topic index as an online resource to OLAW guidance by subject matter. It provides browsing and search capability to OLAW Frequently Asked Questions, Commentaries and Articles written by OLAW staff, plus policy Notices published in the NIH Guide for Grants and Contracts. The [Topic Index](#) can be found on the OLAW homepage under Guidance.

### **Comment:**

Avoid duplication by delineating review responsibilities between scientific review groups and IACUCs for the vertebrate animal section of grants and the animal use protocol. Scientific review panels should not re-review animal use protocols that have already been reviewed and approved by the applicant's IACUC.

### OLAW Response:

In order to receive a grant award, review of proposed activities by a Scientific Review Group (SRG) is required by the NIH Grants Policy Statement (Part I., 2.4 The Peer Review Process) and federal law (sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006). If the proposed research includes the use of animal subjects, review of the Vertebrate Animal Section (VAS) and proposed animal experiments is conducted by the SRG. This review is required to compete for an award. After determination of an award, but before release of funds, IACUC approval to determine that the animal activity is in compliance with the PHS Policy and the institution's Assurance is required by the PHS Policy (IV.B.6.). Compliance with PHS Policy is a term and condition of the NIH Grants Policy Statement (Part II, Subpart A 4.1.1 [Animal Welfare Requirements](#)) to obtain PHS funds.

### Comment:

What is the relationship between OLAW and AAALAC?

### OLAW Response:

About forty percent of PHS Assured institutions are AAALAC accredited; about sixty percent are not. AAALAC accreditation is optional and voluntary and does not affect the institutions ability to hold a PHS Assurance.

The PHS Policy (IV.A.2.) states, each institution must assure that its program and facilities are in one of the following categories: **Category 1- Accredited by AAALAC.** All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS. **Category 2 - Evaluated by the Institution.** All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1 and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy. **The most recent semiannual report of the IACUC evaluation shall be submitted to OLAW with the Assurance.**

OLAW does not discriminate between Category 1 and Category 2 institutions. Non-accredited institutions supply OLAW with the most recent copy of their semiannual report with the institution's Assurance. Accredited institutions assure OLAW of their accreditation status instead of supplying the most recent semiannual report. Either of these activities allows OLAW to assess if the institution's program is being operated in compliance with PHS standards according to the institution's Assurance.

The OLAW Division of Assurances assesses compliance with the Guide through negotiation of Assurances. OLAW Division of Compliance Oversight assesses compliance with the Guide through noncompliance reporting. Site visits are conducted by the Divisions to augment these methods of assessment, as required by the PHS Policy (V.A.6.)

### Comment:

"Should" statements (in the Guide) should not be reinforced as "must" statements. "OLAW's FAQ C.7 provides the following guidance: 'Reporting requirements for should statements in the Guide vary. Should statements often involve performance standards. Well-established performance standards are not departures from the Guide and need not be reported in the semiannual report to the IO. Deviation from a "should" statement with IACUC approval is a departure from the Guide and must be reported in the semiannual report to the IO. Deviation from a "should" statement without IACUC approval is a noncompliance that must be reported to OLAW through the IO.' In effect, should statements are must statements."

### OLAW Response:

"Should" statements of the Guide are best practices in animal care and use practiced by the biomedical research community. Deviation from a "should" statement that is not described as an exception in the Guide or as a result of a performance standard must be reported to the IO via the semiannual program and facility inspection report as required by the PHS Policy (IV.B.1.-3.). Since the adoption of the PHS Policy in 1985, the

PHS has required that Assured institutions base their programs of animal care and use on the Guide, which is an operations manual of best practices for the conduct of animal care and use programs.

**Comment:**

Consider a single set of guidelines, perhaps modeled after the Common Rule used in human subject research. “The USDA/ APHIS has its Animal Care Resources Guide Policies and Annual Report of Research (APHIS Form 7023). OLAW has its guidance documents, commentary, FAQs, and Annual Report. AAALAC has its Position Papers, FAQs and Annual Report. Each governing body has different licensing fees and inspection/audit schedules. Each body also has different reporting requirements for issues involving animal welfare that may present themselves during the course of animal care, research, testing, or the IACUC review and approval process. In addition, there may be funding agency reporting requirements that differ by agency. Is it time to take a holistic view of the regulations, policies, and guidelines affecting our use of animals in research, testing and training?”

**OLAW Response:**

The U.S. government is organized with various agencies responsible for oversight of different functions. These agencies operate under various mandates, regulations and guidelines, with overlapping areas of authority. NIH operates by authority of the [Health Research Extension Act of 1985](#); the FDA operates according to the [FDA Rules and Regulations](#); and the USDA enforces the Animal Welfare Act and Regulations. NIH and FDA, organizations within the [Department of Health and Human Services](#) and the USDA cooperate to harmonize oversight of research animal subjects as described earlier in this document.

**Comment:**

Agencies should create exempt and expedited review categories similar to regulations for human subjects.

**OLAW Response:**

The PHS Policy requires review and approval of animal activities by IACUCs at PHS Assured institutions. Compliance with the PHS Policy is a term and condition of NIH Grants Policy and is required for the institution to obtain PHS funding to conduct animal activities. Institutions may conduct review of proposed animal activities by either “designated member” or “full committee” review. Designated member review can result in a more rapid turnaround and approval of protocols.

**Comment:**

Harmonize regulatory requirements for IACUC approval across the funding agencies.

**OLAW Response:**

PHS funding components include FDA, CDC, and the Institutes and Centers (IC) of the NIH. All IACUCs are required to comply with the standards of the PHS Policy for PHS funded animal activities and to operate their animal programs in compliance with their PHS Assurance. The PHS Policy permits flexibility in operation of animal care and use programs as long as the program meets the standards of the PHS Policy. If the institution specifies standards that exceed the PHS Policy in its Assurance, the institution is then expected to meet the higher standards as described.

OLAW has had a [Memorandum of Understanding](#) (MOU) continually for more than twenty years with USDA and FDA. The MOU sets forth a framework for reciprocal cooperation which assists each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals.

In Section III. Shared Concerns, the MOU commits to a “mutually shared perspective on acceptable standards of laboratory animal care that presents a consistent Federal approach and fosters compliance by regulated entities.” In Section IV. Substance of Agreement, “The cooperating agencies agree to consult and coordinate with each other on regulatory or policy proposals and significant policy interpretations involving animal care and use under consideration by each agency.”



In practice, USDA and OLAW coordinate all guidance regarding laboratory animal welfare released by OLAW. This includes [FAQs](#) as described in the following statement in the introduction to the FAQs: The USDA Animal and Plant Health Inspection Service (APHIS), Animal Care has reviewed and concurs with the guidance provided in these FAQs where applicable.

The three agencies meet semiannually to discuss shared issues of concern and new regulatory initiatives, and to coordinate ongoing collaborative activities. In addition, the OLAW Division of Compliance Oversight is in regular contact with the Eastern and Western Regional Offices of Animal Care, APHIS, USDA. The two agencies work closely to coordinate joint responses including educational outreach activities and site visits when concerns involving PHS-funded activities at USDA-registered research facilities are raised. OLAW's interactions with FDA are less frequent because FDA's inspections for compliance with the Good Laboratory Practice Regulations (GLPR) have less direct involvement with animal welfare issues. Ongoing since 2012, OLAW and USDA representatives have been actively participating in the FDA's working group tasked with modifications to the GLPR to ensure its consistency with each agency's directives concerning animal welfare and to minimize burden.

#### **Comment:**

Consider whether IACUCs should be required to use similar guidelines (best practices), perhaps via a standard federally developed template that is consistent for all research facilities.

#### **OLAW Response:**

PHS oversight is based on a system of self-evaluation. IACUCs oversee this system which relies heavily on professional judgment and performance standards at the local institution. Self-evaluation enables the individuals at an institution – IACUC members, veterinarians, scientists, animal program staff and administrators – to draw upon their education and experience to determine compliant best practices for their animal care and use program.

IACUCs are responsible for compliance with the PHS Policy, a requirement for an institution to conduct PHS funded animal activities ([IV.B.](#)). Federally funded animal activities are conducted at a diverse array of institutions: public and private, large and small, for profit and nonprofit, academic, research and business organizations. A flexible system of self-evaluation enables organizations to tailor their programs to their academic expertise, program size, core competencies, and other facets of their business or research model.

A standard federal template for animal program operations at research institutions would not empower outstanding biomedical research, as the more flexible self-evaluation system, currently in practice, has done. OLAW does provide [sample documents](#), as required by the PHS Policy ([IV.A.](#)). Although institutions are not required to use these documents, they may use them as examples or templates. The sample documents are provided in a format that can be modified by the institution, as desired.

OLAW supports [best practice training workshops](#) targeted at IACUCs and those involved in animal programs at PHS Assured institutions, including yearly IACUC Administrators Association (IAA) Best Practice Meetings, IACUC 101, IACUC 201+, IACUC 301, Scientists Center for Animal Welfare (SCAW) Conference and IACUC Training Workshops, the Public Responsibility in Medicine and Research (PRIM&R) IACUC Conference, and the American Association of Laboratory Animal Science (AALAS) National Meeting. In addition, OLAW supports numerous intermittent workshops including those conducted by the American Society for Laboratory Animal Practitioners (ASLAP), Institute for Laboratory Animal Research (ILAR), and States United for Biomedical Research (SUBR). OLAW has participated in updates to numerous best practice resources including the IACUC Handbook (CRC Press) and the IACUC Guidebook (a joint NIH and ARENA publication). OLAW conducts a quarterly [webinar series](#) to advise the community of policy updates and best practices. OLAW maintains a listing of current workshops and resources on the [OLAW website](#).

#### **Comment:**

Provide standard acceptable protocols and drug dosage ranges for commonly used drugs.

### OLAW Response:

IACUCs develop protocol forms appropriate to the business practices at their PHS Assured institution to facilitate review of animal activities as required by PHS Policy (IV.C.).

### Comment:

USDA and OLAW could allay concerns by specifically stating when a practice is not required.

### OLAW Response:

OLAW includes examples of practices that are not required in its guidance. For example, [NOT-OD-05-034](#) provides examples of both reportable situations and situations that are normally not required to be reported. In its guidance on [reporting departures from the Guide](#), OLAW provides examples of deviations that are not required to be reported to OLAW. In [FAQ D9](#), OLAW identifies changes to a project that may be made administratively without IACUC review.

Institutions are encouraged to seek guidance as to the requirement for specific practices within their animal care and use programs. OLAW can be reached by telephone at 301-496-7163, by email at [olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov) or in person at one of the many community outreach events attended by OLAW personnel. (For a current listing of events, see the OLAW website [Workshops and Conferences](#) section.) Unless OLAW guidance cites specific statutory or regulatory language, an institution may use an alternative approach if the approach satisfies the requirement of the PHS Policy. [Performance standards](#), supported by OLAW and the Guide, provide increasing flexibility to PHS Assured institutions in the operation of humane animal care and use programs.

### Comment:

Return to more performance-based approaches, giving institutions and their review board's greater latitude in assessing risk and ensuring appropriate protections without the added burden of extraneous documentation and approvals.

### OLAW Response:

OLAW and the *Guide* have supported the use of performance standards from 1985 to the present. The following text was published by OLAW on December 2, 2011 in its [Performance Standards](#) guidance.

"The 8th Edition of the *Guide* further develops the concept and advocates the use of outcome-based performance standards that were a basis of the 7th Edition of the *Guide*. Performance standards are **the most important component of the infrastructure of PHS oversight of animal programs at Assured institutions**. IACUCs are able to meet their responsibility to ensure humane animal care and use while advancing quality scientific research through the use of performance standards in their oversight of institutional animal programs. OLAW encourages the cooperative application of diverse expertise to develop outcome-based performance standards that enhance the quality of animal care and use programs. OLAW expects Assured institutions to apply appropriate professional judgment and experience to the challenges inherent in developing policies and procedures to maintain a quality program that provides humane care to vertebrate animals."

"Performance standard means a standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher, and the IACUC. The performance approach requires professional input, sound judgment, and a team approach to achieve specific goals... Performance standards can be advantageous because they accommodate the consideration of many variables...so that implementation can be best tailored to meet the recommendations in the Guide.' (See [Guide](#) pages 6-7.)"

Implementation of the *Guide* is expected to have a minimal impact on institutions that are currently using policies and procedures based on well-developed performance standards. These policies and procedures may not need to be revised as part of the institution's implementation of the 8th Edition of the *Guide*.

The following OLAW FAQs provide information about application of performance standards in PHS Assured animal care and use programs:

- FAQ [G10](#): What is OLAW’s position on performance standards?
- FAQ [F16](#): May performance standards determine housing issues?
- FAQ [F17](#): May performance standards determine environmental enrichment issues?
- FAQ [F18](#): Can performance standards be used in determining rabbit housing practices?

On April 19, 2012, OLAW offered additional guidance through a webinar on “Performance Standards.” (see [http://grants.nih.gov/grants/olaw/educational\\_resources.htm](http://grants.nih.gov/grants/olaw/educational_resources.htm) and [http://grants.nih.gov/grants/olaw/120419\\_seminar\\_transcript.pdf](http://grants.nih.gov/grants/olaw/120419_seminar_transcript.pdf))

**Comment:**

Agencies should refrain from modifying their regulations without consulting the regulated community.

**OLAW Response:**

OLAW solicits [public comment](#) on changes to significant guidance, including a 90 day [public comment](#) period on the adoption of the 8th Edition of the Guide; a 90 day public comment period on the provisions of the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition; and a 60 day [public comment](#) period on the implementation of the revised International Guiding Principles for Biomedical Research Involving Animals.

**Comment:**

Adopt a streamlined approach in which one IACUC approval satisfies all institutions funded by the same grant.

**OLAW Response:**

OLAW addresses dual review in FAQ [D8](#): **When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity?**

If both the awardee institution and the performance site institution have Domestic Assurances, they may exercise discretion in determining which IACUC reviews animal activities and under which institutional program the research will be performed. **There is no requirement for dual review;** IACUCs may choose which IACUC will review protocols for the animal activities being conducted. It is recommended that if an IACUC defers protocol review to another IACUC, documentation of the review should be maintained by both committees. Additionally, the IACUC conducting the review should notify the other IACUC of significant questions or issues raised during a semiannual program inspection of a facility housing a research activity for which that IACUC bears some oversight responsibility.

**Comment:**

Training requirements should be tailored to an individual’s job responsibilities.

**OLAW Response:**

OLAW does not specify nor dictate the training provided by institutions beyond the requirements of the U.S. Government Principles, PHS Policy, and the Guide. It is the institution’s responsibility to determine the method, subject matter, duration and frequency of training of personnel, including students. Some noncompliance and/or reportable incidents at an institution may be due to inadequate training. OLAW offers guidance about institutional training programs in FAQ [G1](#): What kind of training is necessary to comply with PHS Policy, and how frequently should it be provided?

Discussion of appropriate training is found throughout the five chapters of the Guide. At a minimum, the PHS Policy and the Guide ([page 15](#)) require institutions to:

- ensure that individuals who use or provide care for animals are trained and qualified in the appropriate species-specific housing methods, husbandry procedures, and handling techniques;
- ensure that research staff members performing experimental manipulation, including anesthesia and surgery, are qualified through training or experience to accomplish such procedures humanely and in a scientifically acceptable fashion;
- provide training or instruction in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress;
- ensure that professional staff whose work involves hazardous biological, chemical, or physical agents have training or experience to assess potential dangers and select and oversee the implementation of appropriate safeguards; and
- ensure compliance with any initial and continuing education regarding state requirements for the licensing of veterinarians, veterinary or animal health technicians.

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<sup>1</sup> The [U.S. Government Principles](#) direct that, "...housing, care, and feeding...must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied" (VII) and that, "Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals" (VIII).

<sup>2</sup> The [Health Research Extension](#) Act of 1985 requires that, "scientists, animal technicians, and other personnel involved with animal care, treatment, and use...have available to them instruction or training in the humane practice of animal maintenance and experimentation..." (Sec. 495.(c) (1) (B)).

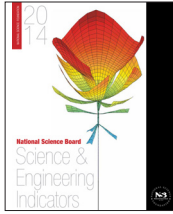
<sup>3</sup> The PHS Policy requires that institutions seeking an Assurance provide "a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number or animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment or use" (IV.A.1.g.); that medical care for animals will be provided by "qualified" veterinarians (IV.C.1.e.) and that, "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures" (IV.C.1.f.)."



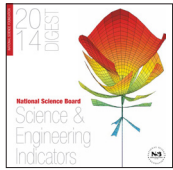
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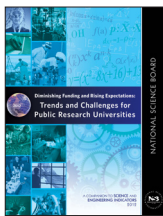
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(NSB-12-45)



Research and Development, Innovation, and the Science  
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A Companion to Science and Engineering Indicators 2012  
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### RECOMMENDED CITATION:

National Science Board. 2014. Reducing Investigators' Administrative Workload for Federally Funded Research. Arlington, VA: National Science Foundation (NSB-14-18).

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