FASEB

Federation of American Societies for Experimental Biology

Findings of the FASEB Survey on Administrative Burden

June 7, 2013

Disclaimer: This document is a report of the information gathered through FASEB's online survey about the administrative burden of federally funded researchers. The information presented within expresses the opinions of survey respondents, and does not represent an official statement of FASEB or any of its member societies.

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Section I: About the Survey

Introduction

On March 25, 2013, the National Science Foundation (NSF) released a Request for Information (RFI)[1] on behalf of the National Science Board's (NSB) Task Force on Administrative Burdens to seek (1) comment from principal investigators (PIs) with federal research funding on federal agency and institutional requirements that contribute most frequently to their administrative burdens and (2) suggestions for how these burdens could be reduced or eliminated. The RFI is in response to the findings of two Federal Demonstration Partnership Faculty Workload surveys administered in 2005 and 2012 that indicated approximately 42 percent of an awardee's federal research time was devoted to administrative reporting efforts.[2] Responses to the RFI will be used by the NSB Task Force to develop recommendations for reducing the administrative workload of federally-funded researchers to a level that ensures compliance while still allowing time to devote to research activities.

The Federation of American Societies for Experimental Biology (FASEB) represents 26 scientific societies and over 115,000 biological and biomedical researchers. While FASEB recognizes that compliance and regulatory oversight are essential to the conduct of federally-supported research, it also supports efforts to harmonize and streamline reporting of this information. The topic of administrative burden has been a recurring theme in discussions of the FASEB Science Policy Committee and its subcommittees, and the NSF RFI provided an opportunity for FASEB to engage not only its committee members, but also the research community at large. To provide a more comprehensive representation of its society members in its response to the RFI, FASEB developed an online survey tool to solicit feedback on administrative burden.

Method

The FASEB survey on administrative burden was created and administered using SurveyMonkey and consisted of ten questions based on those presented in the NSF RFI. The survey was distributed to FASEB's member societies as well as through the listservs of other professional societies, universities, and research coalitions. Use of the SurveyMonkey platform allowed the survey to be shared through email, e-action alert services, and social media platforms such as Facebook and Twitter. It also provided a simple, structured format through which feedback could be tallied and presented in a concise and easily analyzed format. The survey was launched on April 1, 2013, and was open through May 15, 2013. The survey was completed by 1,324 respondents.

Caveats of RFI Distribution

One of FASEB's goals in distributing the survey was to increase awareness of and responsiveness to the NSF RFI. To test the effectiveness of this method, FASEB's Public Affairs staff analyzed the "click-through" data for an email blast at one institution that included both a link to the FASEB survey and a link to the NSF RFI. Of the 3,684 emails sent over two blasts, 1,292 emails were opened, 154 readers clicked through to the FASEB survey, while only 18 clicked through to the RFI. Although the overall responsiveness in this test was relatively low, it did provide some evidence that an RFI may not be the most effective method to engage and seek feedback from members of the research community.

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[1] Government Printing Office. "Request for Information (RFI): Reducing Investigator's Administrative Workload for Federally Funded Research." Federal Register 78 (61), 19329-30.

[2] Reports and results from Faculty Demonstration Project 2007 and 2012 Faculty Burden Surveys available at http://sites.nationalacademies.org/PGA/fdp/PGA_055749 (Last accessed May 28, 2013).

Section II: Metrics and Quantitative Analysis of Survey Responses

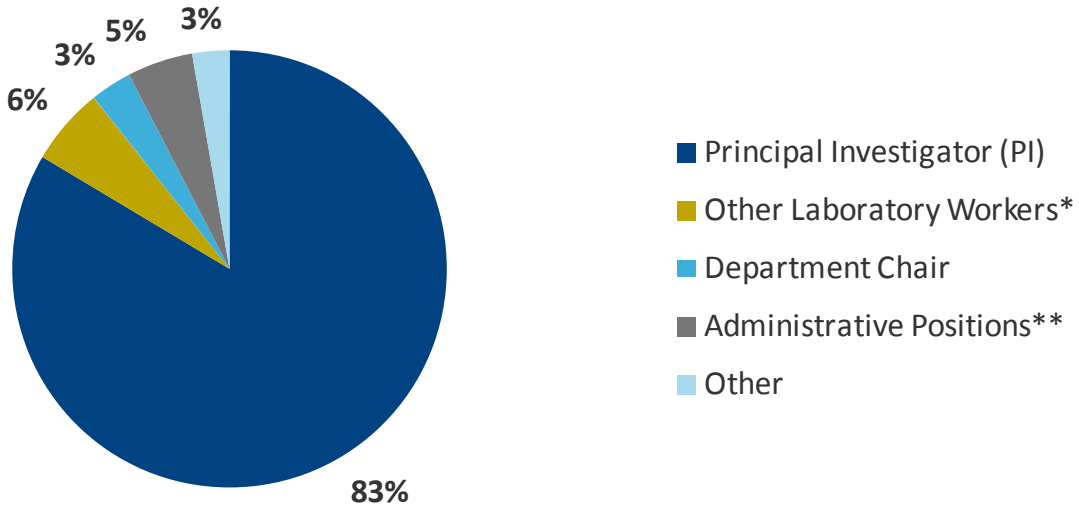
Summary of Survey Findings

A total of 1,324 responses were received from FASEB's survey on administrative burden. All 26 of FASEB's constituent societies were represented in the survey and 756 respondents (59 percent) indicated membership to at least one society. Most respondents identified themselves as PIs who currently have or have had federal research funding from the National Institutes of Health (NIH); however, nearly half have or had received funding from more than one federal agency. The majority of respondents were affiliated with a research institution with a medical school. Among the 15 categories of potential administrative burden listed in the survey, Grant Proposal Preparation and Submission was most frequently identified as the greatest administrative burden by respondents. Ten of the categories were selected by at least 100 respondents as one of their top three administrative burdens.

Demographic Data of Respondents

Of the survey respondents who selected a job title, 83 percent (1,060 out of 1,269) identified themselves as a PI. The additional 17 percent of respondents identified themselves as Other Laboratory Worker, Department Chair, Administrator/Administrative Assistant, or "Other" (see Fig. 1).

Figure 1: Job Title of Respondents



* Includes post-doctoral fellows; staff scientists; graduate students; and laboratory technicians.
**Includes institutional administrators; scientific administrators; and administrative assistants.

Institutional Affiliation of Respondents

Sixty-one percent of survey respondents were primarily affiliated with a Public Research Institution with a Medical School. Respondents also chose Private Research Institution (18 percent); Non-Profit Institution (15 percent); and Public Research Institution without a Medical School (11 percent) as their affiliation. Eight percent of respondents selected an "Other" affiliation, which included Federal Laboratory; Hospital, or Medical Center; Variations of Public/Private Research; and Non-Categorized[3] (see Table 1).

Table 1: Institutional Affiliation of Respondents

Category *(Respondents could select more than one option)*	**Number of Responses**	**Percent of Responses***
Public Research Institution with a Medical School	769	61%
Private Research Institution	222	18%
Non-profit Institution	186	15%
Public Research Institution without a Medical School	133	11%
Primarily Undergraduate Institution	30	2%
Minority-Serving Institution	23	2%
Public Master's Institution	13	1%
For-profit Institution	11	1%
Private Master's Institution	2	<1%
Other	100	8%
• *Federal Laboratory*	*26*	-
• *Hospital or Medical Center*	*9*	-
• *Variations of Public/Private Research Institutions*	*50*	-
• *Uncategorized*	*15*	-

*Percent rounded to the nearest whole number.

[3] Written-in responses for the "Other" category indicated that a number of respondents considered only state universities and similar state or federally-run institutions to be public research institutions. Further review indicated that respondents who selected Private Research Institution, For-profit Institution, or Non-profit Institution, actually had appointments at a federally-funded research university or medical center. This suggests that these terms may need to be more clearly defined when soliciting feedback from the research community.

Federal Funding Sources

Of the 1,271 survey respondents who answered the federal funding sources question, 79 percent indicated that they currently receive federal funding, while 14 percent indicated having received federal funding in the past. Nearly all respondents who either have or had federal funding (93 percent) identified the federal department or agency that provided their funding; approximately half selected more than one source of federal funding. NIH was selected by 86 percent of the respondents as their source of federal funding. NSF was selected by 27 percent; the Department of Energy was selected by 21 percent; and an "Other" agency was selected by 13 percent of respondents who identified their federal funding source (see Table 2).

Table 2: Federal Funding Sources

Category *(Respondents could select more than one option)*	**Number of Responses**	**Percent of Responses***
National Institutes of Health (NIH)	1,020	86%
National Science Foundation (NSF)	315	27%
U.S. Department of Defense (DOD)	249	21%
U.S. Department of Veterans Affairs (VA)	98	8%
U.S. Department of Agriculture (USDA)	75	6%
U.S. Department of Energy (DOE)	61	5%
Other	159	13%
• *National Aeronautics and Space Administration (NASA)*	*54*	-
• *Other Federal Agency or Department*	*37*	-
• *Non-Federal*	*35*	-
• *Other agencies within the Department of Health and Human Services (DHHS)*	*26*	-
• *U.S. Environmental Protection Agency (EPA)*	*13*	-
• *Moved to an existing category above*	*8*	-
• *Unable to Classify*	*2*	-

*Percent rounded to the nearest whole number.

Areas of Administrative Burden as Identified by Respondents

The survey asked respondents to select up to three areas of administrative burden and rank them as highest burden, second highest burden, and third highest burden. Grant Proposal Preparation and Submission was ranked as the highest burden by nearly half of the respondents; Laboratory Animal Care and Use/ Institutional Animal Care and Use Committees (IACUC) was ranked second as the highest burden; and Human Subjects Research Protection/Institutional Review Board (IRB) was ranked as the third highest burden (675, 211, and 102, out of 1,324, respectively). Of the 15 categories provided, 10 were ranked as an administrative burden by at least 100 of the respondents. Among the 70 respondents who selected an "Other" administrative burden, several additional areas of burden were identified, including institutional policies, post-award grant management, and low federal funding for scientific research. Correlation of funding source did not result in significantly different responses to burden rank (see Table 3).

Table 3: Areas of Administrative Burden

Area of Burden	Highest Burden*	Second Highest*	Third Highest*	Total Selected*
Grant Proposal Preparation and Submission	675	186	88	949
Laboratory Animal Use and Care / IACUC	211	259	129	599
Training Requirements	42	124	181	347
Human Subject Research Protection / IRB	102	142	98	342
Personnel Management	55	120	131	306
Grant Effort Reporting	50	92	125	267
Laboratory Safety Oversight and Requirements	44	87	128	259
Grant Financial Reporting	33	82	95	210
Conflict of Interest Reporting	17	40	78	135
Administrative Support Funding	30	42	55	127
Management of Sub-contracts	15	39	41	95
Biosecurity/Safety and Select Agents Program	11	34	42	87
Agency Specific and Multi-Agency Funded Projects	17	17	32	66
FDA Requirements for Studying Drugs and Devices	11	16	25	52
Data Sharing	5	13	26	44
Other	-	-	-	70

*Number of individual responses

Section III: Summary Analysis of Survey Comments Received

Survey respondents were asked to provide further detail regarding their top three administrative burdens and suggest ways to decrease them. For the first of the questions requiring comment, 94 percent of respondents provided feedback; six percent chose not to respond. For the second of the questions requiring comment, 57 percent of respondents provided feedback and 43 percent either had no comment or skipped the question. Similar to the administrative burdens ranked highest by respondents, comments most frequently addressed the following areas:

1. Grant Preparation, Submission, Management, and Funding
2. Animal Care Regulations and Oversight
3. Training Requirements
4. Clinical Research and Human Subjects Regulations
5. Cross-Sectional/Overarching Burdens

Among survey respondents, several themes also emerged:

- Importance of collaboration and communication between regulatory bodies, institutions, and investigators in improving compliance
- Desire for evidence-based assessment of existing regulations to ensure that they are effective in achieving intended goals
- Thoughtful collection and reporting of metrics for research and program assessment
- Burdens vary based on institution size, funding, and experience of support staff

The five areas of administrative burden most frequently commented on by respondents are discussed below and include specific examples of burden and suggested recommendations to lessen the burden (as noted by survey respondents).

1. Grant Preparation, Submission, Management, and Funding

More than any other area, survey respondents indicated that the grant process posed the greatest administrative burden. This includes grant proposal and submission, effort reporting and financial reporting, and post-award management. Respondents overwhelmingly described the lack of funding as a considerable burden and barrier to their research pursuits, and suggested increases in federal funding to alleviate many of their burdens. While stagnant federal funding for the sciences is not, in itself, an administrative burden, nor is it easily rectified, the current fiscal environment does appear to exacerbate administrative burdens. This is likely due to a combination of factors that include a need for PIs to submit an increasing number of grants proposals to offset decreased funding opportunities and delayed award decisions by agencies due to budget uncertainty. Below, are specific examples of burdens and recommendations related to federally funded grants as reported by survey respondents.

Burdens Identified by Respondents

- *Grant Preparation*
  - Extremely time consuming, taking anywhere from 25 to 100 percent of a PI's time for several months each year.
  - Each agency has unique formatting and informational requirements, even for basic information such as CVs and conflict of interest reporting.
  - Requirement for institutional regulatory body review and/or pre-approval prior to grant submission.
  - Lack of financial support for a PI's or post-doc's salary during the grant proposal drafting and submission process.
  - Grant proposals require many details that are difficult to accurately predict, such as calculation and justification detailed research budgets.
- *Effort Reporting*
  - Difficult to accurately determine how much time was spent each week on overlapping projects by technical personnel supported by multiple grants.
  - Data from effort reporting may be flawed due to rigid reporting and formatting requirements (i.e., approximations are not allowed and the assumption of a 40 hour workweek is not always applicable to research), creating misinformation that is used to develop policies.
- *Lack of Institutional Administrative Support, Pre- and Post-Award*
  - Lack of administrative support made grant submission and management the highest burden for many responders.
  - Concerns regarding indirect costs and the extent to which they are used to provide pre- and post-award management support.
  - Lack of scientific expertise among support staff results in researchers performing most of the administrative work themselves.
- *Personnel Management*
  - 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. (It is unclear to what extent this is the result of agency policies versus institution policies, or whether this is primarily due to federal, state, or local labor laws.)
  - Having to lay-off trained research assistants and then re-hire and train new research assistants due to short gaps between one grant ending and the next being awarded.

    - Lack of sufficient flexibility for PIs to create desired personnel positions due to funding mechanism-specific rules.
- *Time-to-Award*
    - The time between submission of a grant proposal and receipt of an award makes short- and intermediate-term planning for research projects very difficult.
    - Delays in funding decisions cause PIs to continue submitting more and more "backup" grants.
- *Financial Tracking and Reporting*
    - Issues related to error-prone, overly complex, and difficult-to-navigate billing and financial tracking systems.
    - Lack of institutional expertise with smaller grants or less common funding mechanisms leads to conflicting institutional management and reporting.
    - Difficulty in assigning expenses to individual grants in multi-grant funded laboratories and similar issues with managing segregated funding.
    - Use of different financial categories by Institutions and agencies.
- *Grant Funding Regulations*
    - Inability to charge computers or required hardware and software updates to relevant grants.
    - Expansion of funding mechanism-specific rules for how awards can be spent, creating confusion.
- *Subcontracts, Multi-Institution, and Multi-Agency Funding*
    - Communication issues among researchers and administration across different study sites.
    - Difficulty with project management and oversight creates disincentives to participate in future large-scale collaborations.
    - Monthly invoicing and reimbursements for subcontracts do not always occur in a timely manner.
    - Lengthy finalization process for subcontracts due to institutional and agency requirements as well as state and federal laws.
- *Electronic Submission and Tracking Systems*
    - Institutional and agency systems "opaque" and "confusing."
    - Deploying software prior to full testing and validation is burdensome.
    - Utilization of user-unfriendly electronic forms by both agencies and institutions.

<u>Recommendations Suggested by Respondents</u>

- *Grant Preparation and Submission; Grant Management*
    - Create common forms between agencies.
    - Provide readily available and user-friendly checklists for each stage of pre- and post-award management.
    - Allow select sections (e.g., detailed budgets, data sharing plans, etc.) of a grant proposal to be submitted "just-in-time" once the proposal has received a good peer review and is seriously being considered for funding.
    - Have a secure electronic biosketch/CV database that can be linked to PubMed, eCommons, FastLane, etc.
    - For resubmission, allow forms to be updated rather than completely re-entered.
    - Expand grant writing and management training for both researchers and administrators and provide web-based training guides to communicate agency expectations and goals.
    - When greater than summary information is requested, allow the materials submitted to IRBs, IACUCs, and/or IBCs to be used in place of agency-specific forms.

    - Provide better guidance of what services should be provided through indirect costs.
    - Encourage greater institutional support for PIs for pre- and post-award.
- *Effort Reporting and Financial Tracking and Reporting*
    - Allow greater flexibility for spending plans to account for on-going and mid-project adjustments.
    - Limit effort reporting to distinguishing between research, clinical services, and administrative time.
- *Grant Funding Regulations*
    - When appropriate, standardize rules and requirements across all funding mechanisms and funding agencies and, when not possible, provide summary tables and documents highlighting important differences.
    - Develop funding mechanisms that allow for more long-term, sustained support.
    - Provide bridge funding to protect personnel investment.
- *Subcontracts and Multi-Institution/Multi-Agency Funding*
    - Contracting institutions should provide timely, easy-to-understand financial statements to PIs to facilitate laboratory budgeting.
    - Allow award subcontract funding to go directly to the subcontracting institution.

2. Animal Care Regulations and Oversight

In addition to grants, Laboratory Animal Care and Use/IACUCs was frequently commented on by survey respondents as a considerable administrative burden. However, many of the burdens identified by the respondents could be classified as institutionally imposed. For example, institutional policies that require full IACUC review cause unnecessary burden to investigators, staff, and the committee. Because of the burdens associated with conducting research using animals, several respondents noted that they have elected to forgo the use of animals even though their research would have benefited from it. An overwhelming number of respondents suggested that standard operating procedures could be developed for common/standard experiments and cited on the IACUC protocol to reduce the amount of time that investigators spent developing IACUC proposals, with the added benefit of ensuring procedures were standardized across laboratories. Below, are specific examples of burdens and recommendations related to laboratory animal care and use as reported by survey respondents.

<u>Burdens Identified by Respondents</u>

- IACUC protocol approval time (three years) and the length of a grant (four to five years) are not aligned.
- Protocol review/approval time is too long - research can be delayed by months waiting for minor modifications to animal use protocols.
- IACUC protocol submission software can be extremely time consuming and cumbersome.
- All changes to a protocol – even administrative – are required to have a full IACUC review.
- Issues within a protocol that do not affect animal well-being, such as spelling errors, are potential causes for a rejection of the protocol by the IACUC.
- Animal use protocols can be lengthier than the grant applications they support.
- IACUCs may attempt to evaluate the merit of the science that has already gone through peer review.
- There can be a lack communication between the IACUC and the PI.

- Multiple, uncoordinated inspections per year that disrupt research.
- Interpretation of "should" as "must" in the Guide to the Care and Use of Laboratory Animals.
- Mission creep by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and the U.S. Department of Agriculture.
- Lengthy training requirements that make it difficult for students doing short rotations to work with animals.
- Lack of support to help navigate regulatory requirements.
- Additional staff hired to maintain regulatory compliance.

Recommendations Suggested by Respondents

- Encourage IACUCs to use Designated Member Review instead of Full Committee Review for protocol amendments that do not significantly affect animal welfare.
- Delineate responsibilities between scientific review groups and IACUCs regarding the review of the vertebrate animal section of grants and the animal use protocol to avoid duplication of effort.
- Develop Standard Operating Procedures for common experimental procedures that can be cited within an IACUC application.
- 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.
- Create exempt and expedited review categories similar to human subjects regulations.
- Hire compliance liaisons to assist the PI with the writing and submission of the IACUC proposal.

3. Training Requirements

While survey respondents agreed on the importance of training in safe laboratory practices and proper implementation of studies incorporating human subjects or laboratory animals, many comments indicated several areas in which administrative burdens related to training had become burdensome. Overall, survey respondents expressed frustration with the number and frequency of mandatory training courses and its effect on their ability to conduct actual research. It was suggested numerous times among respondents that transferable training requirements across departments and agencies would greatly reduce redundancy and enable them to focus their efforts on conducting federally funded research and the training of other researchers. Below, are specific examples of burdens and recommendations related to training requirements as reported by survey respondents.

Burdens Identified by Respondents

- Lack of uniform training requirements across federal agencies trickles down to multiple overlapping training requirements for different schools/colleges/departments within a single academic institution.
- Varied quality of training materials.
- Frequency of training renewals/refreshers varies and changes often.
- Training requirements for areas of research irrelevant to the type of research conducted by an investigator.
- Inadequate tracking of completed certifications can result in false accusations of non-compliance and lead to additional time spent collecting verification of training.

Recommendations Suggested by Respondents

- 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.
- Centralize tracking for completion of basic training modules that is readily accessible by individual investigators, institutional staff, and agency administrators.
- Decrease the frequency for renewal of basic laboratory safety renewals.
- Offer shorter "refresher" modules for new regulations rather than making investigators repeat entire training courses.

4. Clinical Research and Human Subjects Regulations

Many respondents expressed frustration regarding the volume of administrative effort associated with conducting research studies involving human subjects. Overall, comments exposed an adversarial relationship between researchers and IRBs, which appears to stems from poor communication. While respondents showed a general appreciation of the role of IRB oversight of research involving humans, several commenters stated that IRBs have become increasingly risk averse, and have implemented additional regulatory barriers that can severely impede the conduct of research studies. Specifically, survey respondents cited extensive documentation and length of IRB review as key pain-points associated with conducting human subjects research. Adoption of more collaborative attitude, use of standardized electronic forms, and overall clearer guidance regarding IRB requirements were all suggested as means of reducing the administrative burdens associated with human subjects research. Below, are specific examples of burdens and recommendations related to clinical research and human subjects regulations as well as potential solutions to these burdens, as reported by survey respondents.

Burdens Identified by Respondents

- The length of time to obtain IRB approval is compounded by multiple rounds of protocol revision and review.
- Multi-site IRB reviews for multi-site studies frequently results in research being delayed and increased administrative burden.
- The application of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to research is confusing and frustrating.
- Protocol revisions often result from an IRB's lack of understanding of non-clinical research.
- Increasing complexity of paperwork associated with IRBs deters investigators from pursuing human subjects research.

Recommendations Suggested by Respondents

- Create standardized informed consent templates and other IRB forms that can be shared across all institutions engaged in human subjects research.
- Adopt a standard process for low-risk IRB review that would be acceptable to all federal agencies.
- Support automated linkage of local IRB approvals to federal agency databases to make applications and approvals immediately available to funding agencies.
- Encourage more open lines of communication between IRB and investigator during protocol review and revision process.
- Develop clearer guidance as to what constitutes exempt research.
- Clarify guidelines regarding use of a centralized IRB for multi-site studies.

5. Cross-Sectional/Overarching Burdens

In addition to the four administrative burdens previously listed, several other burdens that could be generally applied to multiple categories were noted by respondents. Most frequently, comments identified burdens associated with personnel management and administration, excessive conflict of interest (COI) reporting, and inconsistent data sharing policies.

Many survey respondents expressed a general concern regarding the amount of paperwork and regulatory oversight required to conduct laboratory research. For example, one PI commented that he or she no longer felt confident recommending medical research as a rewarding career path for incoming scientists due to the increasing level of bureaucracy. Another respondent projected that increasing administrative burdens, combined with a decreasing federal budget for research, will result in the U.S. being less competitive in science, technology, and innovation.

Several others commented that multiple levels of IRB and IACUC regulations discourage scientists from conducting animal or human research. Survey respondents also noted that some institutional regulatory bodies review components of research projects beyond their regulatory scope. However, it was also noted that the burdens placed on investigators by institutional regulatory bodies are in response to federal regulations. Therefore, agencies should standardize and streamline procedures to simplify institutional implementation.

One common perception of regulatory oversight among responders was that regulations "punished all" for the "mistakes of a few." Similarly, many respondents expressed a concern that federal regulation and oversight has reached the point at which documentation (in the form of electronic and hard copy forms, certifications, and tracking) has supplanted substance. Respondents found that the focusing on lists of requirements and rules distracted regulators from the underlying values and goals of the regulations. Finally, respondents indicated discord between tracking regulatory requirements on the U.S. fiscal year versus calendar year. Below, are specific areas of these burdens and potential solutions to these burdens, as reported by survey respondents.

<u>Burdens identified by Respondents</u>

- *Regulatory Issues*
    - More full-time staff is needed to handle regulatory requirements that did not exist five years ago.
    - Excessive federal and duplicative state regulations have necessitated local institutional administrative oversight in the form of dedicated Compliance offices.
    - Institutions often over-comply to avoid sanctions, creating unnecessary burdens.
    - There is an inordinate and disproportionate emphasis on the storage of chemicals and on lab safety protocols when compared with industrial standards.
    - Excessive paperwork is required for laboratory and radiation safety and biosafety inspections.
    - Many terms used in connection with safety regulations are inadequately defined, putting investigators in situations in which the correct response or action is unclear
    - Some institutions make the investigator responsible for maintaining compliance with all regulations.
    - Frequent changes in NIH guidelines.
    - Frequent and intrusive safety inspections that often do not actually affect lab safety.

- *Personnel Management/Administration Oversight*
    - Institutional-level administrative personnel can increase administrative burdens rather than reduce them for investigators.
    - Lack of expertise in laboratory operations among HR personnel.
    - Minimal administrative support provided by institutions.
    - Performance appraisal mandates have become excessive with multi-page documents and repeated rewrites.
    - Tracking personnel provides little value for the effort required.
    - Lack of personnel management training for PIs.
    - Institutional managers have difficulty communicating and maintaining proper records for each department, which are often linked to inadequate software and computers issues as well as inadequate number of qualified administrators.
    - Some institutions lack a well-organized system for processing requested information.
    - Inefficient institutional purchasing systems and inadequate support.
- *COI Reporting*
    - COI reporting for every grant application is excessive and very time consuming.
    - COI requirements for collaborators delay grant preparation and hinder collaborations.
    - Redundancy of COI paperwork for the institution and the government.
    - Frequent changes to COI reporting requirements and reporting systems, makes maintaining compliance very challenging.
- *Data Sharing*
    - The Electronic Research Administration Commons website is difficult to use and requires a new password every three months.
    - Gaining access to data from a Data Access Committee is time-consuming and often requires a one to three month waiting period.
    - Differing data submission requirements among NIH Institutes and Centers.

<u>Recommendations Suggested by Respondents</u>

- *Regulatory Issues*
    - All regulatory proposals should be submitted to a single federal panel to ensure that all requirements are the same at every institution and training certifications are transferrable; such a review panel should include representatives from institutions that will be directly impacted by the regulations.
    - All regulations should be subject to a regular re-assessment process.
    - Reduce the frequency of lab safety inspections for institutions that remain in good standing.
    - Clearly demarcate laboratory categories and implement levels of safety oversight commensurate with each category.
    - Compliance officers should provide examples of successfully completed forms required by the institution.
    - Federal agencies should develop and implement online tutorials or local workshops to help investigators navigate the federal regulatory process.
    - Reduce restrictions on PIs who do not work with sensitive information.
- *Personnel Management/Administration Oversight*
    - Institutions should provide PIs and other personnel with classes or training opportunities on laboratory budget management and financial reporting.
    - Trainees who plan to operate a lab should be required to take a course in personnel management.

    - Require institutional support of information technology systems.
- *COI Reporting*
    - COI reporting should be standardized.
    - Require COI reporting only if grant funding exceeds a set value.
    - COI reporting should not be the responsibility of the institution; individual PIs should certify themselves.
    - Provide COI forms pre-populated with relevant grant information.

Section IV: Acknowledgments

FASEB would like to thank the NSB Task Force on Administrative Burdens for extending the RFI response deadline, which allowed additional time to collect survey responses and prepare this report. FASEB also thanks the leadership and staff of its 26 constituent societies for sharing the survey with their members and colleagues. Similarly, FASEB acknowledges the efforts of its Science Policy Committee and its subcommittees for oversight of the survey effort.

Section V: Appendix

FASEB Survey on the Administrative Burden of Federally-Funded Researchers

The Federation of American Societies for Experimental Biology (FASEB) is preparing a response to the National Science Board's Task Force on Administrative Burdens' request for information (RFI) and would like to include/highlight perspectives from the scientific community regarding areas that result in the greatest amount of administrative burden.

The survey will ask you to identify up to three areas where you experience the greatest administrative burden in your daily operations. Your input will be compiled and used as examples in FASEB's response. If you would like to provide additional feedback, we encourage you to submit a response to the RFI. The Federal Register Notice with additional details for individual submissions can be found here: http://www.gpo.gov/fdsys/pkg/FR-2013-03-29/pdf/2013-07331.pdf

***1. Of the following, which three areas represents the greatest area of administrative burden for you?**

	Highest Burden	Second Highest	Third Highest
Grant Effort Reporting	◯	◯	◯
Grant Financial Reporting	◯	◯	◯
Administrative Support Funding	◯	◯	◯
Personnel Management	◯	◯	◯
Conflict of Interest Reporting	◯	◯	◯
Laboratory Safety Oversight and Requirements	◯	◯	◯
Biosecurity/safety and Select Agents Program	◯	◯	◯
Training Requirements	◯	◯	◯
Management of Sub-contracts	◯	◯	◯
Grant Proposal Preparation and Submission	◯	◯	◯
Human Subject Research Protection / Institutional Review Boards (IRB)	◯	◯	◯
Laboratory Animal Use and Care / Institutional Animal Care and Use Committees (IACUC)	◯	◯	◯
Data Sharing	◯	◯	◯
Agency Specific Requirements and Multi-Agency Funded Projects	◯	◯	◯
Food and Drug Administration (FDA) Requirements for Studying Drugs and Devices	◯	◯	◯

Other (please specify)

***2. In the space below, please provide brief examples of these administrative burdens in your day-to-day operations and describe any solutions you might have to reduce these burdens.**

3. The 2012 Federal Demonstration Partnership (FDP) Faculty Burden Survey indicated that some of the major categories identified by faculty as requiring substantial time for faculty to address were IACUC, IRB, Finances, and Personnel. Do you have any additional comments on specific examples of these burdens and suggestions to reduce them?

4. Name (optional; comments will not be attributed to individuals)

5. Email (optional; we will only contact you if we require additional clarification of written responses)

6. Which best describes your institution (select as many as apply)?

- [ ] Public Research Institution with a Medical School
- [ ] Public Research Institution without a Medical School
- [ ] Private Research Institution
- [ ] Public Master's Institution
- [ ] Private Master's Institution
- [ ] Primarily Undergraduate Institution
- [ ] Minority-Serving Institution
- [ ] Non-profit Institution
- [ ] For-profit Institution
- [ ] Other (please specify)

7. What job title best describes your current position?

- ◯ Principal Investigator (PI)
- ◯ Post-Doctoral Fellow
- ◯ Scientific Administrator
- ◯ Administrative Assistant
- ◯ Graduate Student
- ◯ Staff Scientist
- ◯ Laboratory Technician
- ◯ Laboratory Manager
- ◯ Department Chair
- ◯ Institutional Administrator
- ◯ Other

8. Do you currently have or have ever you received U.S. federal research funding, either as a the principal investigator of a grant or as a researcher supported by a grant?

- ◯ Yes, currently
- ◯ Yes, in the past but not currently
- ◯ No

9. From which federal departments and agencies have you received research funding? Please select all that apply.

- [ ] The National Science Foundation (NSF)
- [ ] The National Institutes of Health (NIH)
- [ ] The Department of Energy (DoE)
- [ ] The Department of Defense (DoD)
- [ ] The U.S. Department of Veterans Affairs (VA)
- [ ] The U.S. Department of Agriculture (USDA)
- [ ] Other (please specify)

10. Are you a member of a FASEB constituent society? Please select all that apply.

- [ ] American Association of Anatomists (AAA)
- [ ] The American Association of Immunologists (AAI)
- [ ] American College of Sports Medicine (ACSM)
- [ ] American Federation for Medical Research (AFMR)
- [ ] American Peptide Society (APEPS)
- [ ] The American Physiological Society (APS)
- [ ] American Society for Biochemistry and Molecular Biology (ASBMB)
- [ ] The American Society for Bone and Mineral Research (ASBMR)
- [ ] The American Society for Clinical Investigation (ASCI)
- [ ] The American Society of Human Genetics (ASHG)
- [ ] American Society for Investigative Pathology (ASIP)
- [ ] American Society for Nutrition (ASN)
- [ ] American Society for Pharmacology and Experimental Therapeutics (ASPET)
- [ ] Association of Biomolecular Resource Facilities (ABRF)
- [ ] Biomedical Engineering Society (BMES)
- [ ] The Endocrine Society (TES)
- [ ] Environmental Mutagenesis and Genomics Society (EMGS)
- [ ] Genetics Society of America (GSA)
- [ ] The Histochemical Society (HCS)
- [ ] International Society for Computational Biology (ISCB)
- [ ] The Protein Society (PS)
- [ ] Society for Developmental Biology (SDB)
- [ ] Society for Glycobiology (SFG)
- [ ] Society for Pediatric Research (SPR)
- [ ] Society for the Study of Reproduction (SSR)
- [ ] The Teratology Society (TS)

Thank you for participating in this survey. FASEB staff will review your responses and contact you if they require any additional clarification. If you have any additional questions or concerns, please contact us at regulatoryburden@faseb.org

Again, if you are interested, we would encourage you to also reply directly to the National Science Board RFI, which can be found here:http://www.gpo.gov/fdsys/pkg/FR-2013-03-29

FASEB

Federation of American Societies for Experimental Biology

FASEB is composed of 26 societies with more than 115,000 members, making it the largest coalition of biomedical research associations in the United States. Our mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences through service to our member societies and collaborative advocacy.