Date: June 7, 2013

To: National Science Board Task Force on Administration Burden

From: Judith S. Bond, President, Federation of American Societies for Experimental Biology

Subject: FASEB Responds to the RFI on Reducing Investigator’s Administrative Workload for Federally Funded Research

Comments submitted electronically to: Administrative-Reform@nsf.gov

Dear Members of the National Science Board Task Force on Administrative Burden:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the National Science Board’s (NSB) “Request for Information (RFI): Reducing Investigator’s Administrative Workload for Federally Funded Research.” FASEB is composed of 26 scientific societies, collectively representing over 115,000 biological and biomedical researchers. FASEB recognizes that compliance and regulatory oversight are essential to the conduct of federally-supported research and appreciate NSB’s interest in identifying ways to reduce the excessive administrative burden that negatively affects investigators, institutions, and agencies. FASEB supports solutions that significantly reduce administrative burden while continuing to maintain accountability, integrity and safety in the research enterprise.

To prepare this response, FASEB (1) convened meetings of six of its key subcommittees to discuss the regulatory issues affecting animal research, information technology, training, human subjects research, biosecurity, and other areas and (2) developed and distributed an online survey to gain additional insight from its society members as well as the greater research community. The accompanying report summarizes the survey’s findings in greater detail.

As a result of both the online survey and FASEB subcommittee discussions, three major themes of administrative burden were identified:

- **There is a lack of coordination among federal agencies in the development and implementation of regulations, policies, and guidance documents.** This lack of oversight and coordination results in duplicated efforts of investigators and their institutions as they strive to be in compliance with ever-changing regulations and guidelines.

- **Unclear guidance on federal regulations, policies, and guidelines often causes inconsistent interpretation by agency representatives and can lead to institutional “mission creep.”** Such mission creep often results in far more stringent interpretations of federal regulations by institutions, which causes greater administrative burden than intended by the original policy makers. Vague or ambiguous policies can also lead to “defensive implementation” by the institution to ensure compliance.
Multiple layers of unevenly applied and mismanaged regulatory oversight result in increased overall burden for researchers and their staff. Many of our survey respondents and FASEB subcommittee members indicated that the cumulative total of burdens was much more problematic than any one specific area. This suggests that a systematic, coordinated response across funding agencies is required to substantially reduce administrative burden.

These three themes highlight a need for harmonization and clarification of existing federal policies and guidelines to reduce the overall administrative burden for investigators. Therefore, FASEB recommends federal agencies implement the following six recommendations:

1. Coordinate regulations and guidance across all federal agencies to reduce the costs associated with conducting research.
2. 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.
3. Streamline agency-led site visits and review strategies to minimize the potential for additional institution-imposed regulatory burden.
4. Conduct routine evaluations to ensure that all proposed and existing federal regulations are evidenced-based and designed in a manner that minimizes negative impact on the conduct of research.
5. Develop regulations that are concordant with the level of risk presented by the situation in which they are intended to address.
6. Ensure that online reporting and submission systems are user-friendly to decrease the overall time spent on such tasks.

The additional recommendations listed below derive from the specific areas of potential administrative burden outlined in the RFI and address specific changes to the policies regulating federally funded research.

**Effort Reporting**

Precise allocation of effort by investigators on a daily basis is extremely difficult to measure, due to inextricably linked responsibilities and research activities that may be applicable to multiple funded efforts; it also requires a system that is expensive to install and operate. Effort reporting also does little to ensure that charges are based on actual effort since faculty responsibilities are rarely limited to 40-hour work weeks. While FASEB supports the goal of safeguarding proper stewardship of federal grant funds, effort reporting requirements do not support this goal and should be eliminated.

**Financial Reporting Requirements**

Collectively, financial reporting requirements impose considerable burdens on investigators and institutions. FASEB recommends that OMB (1) identify ways to minimize the number of forms that investigators are required to complete; (2) increase reporting intervals where feasible; and (3) assess the need for and the impact of new reporting requirements, including a proposed quarterly reporting requirement for all federal research grants and contracts.

**Reporting Potential Conflicts of Interest**

FASEB supports the harmonization of standards for disclosing potential conflicts of interest (COI) across stakeholder groups. FASEB also recommends a simple and universal electronic COI reporting form to reduce the amount of time currently spent by investigators to complete similar, but not identical, COI disclosures. Adoption of a uniform COI report, as proposed in a recent discussion paper by members of the Institute of Medicine’s (IOM) Best Practices Innovation Collaborative of the Roundtable on Value & Science-Driven Health Care and the Board on Health Sciences Policy, would serve as a significant step towards harmonizing
COI reports, facilitating researcher compliance with reporting requirements, and minimizing the administrative burdens associated with COI disclosure. FASEB also encourages the NSB to revisit the recommendations made in the 2009 (IOM) report, *Conflict of Interest in Medical Research* for additional solutions to reduce administrative burdens.

**Research Training Requirements and Portability of Training Certifications**

Researchers are subject to numerous training requirements and mandatory annual re-certifications, including instruction in biosafety, laboratory safety, radiation safety, human subjects protections, and animal care and use. While FASEB agrees that appropriate instruction in each of these areas is important, the time and effort expended to complete all of the training programs is significant and annual re-training does little to improve either safety or compliance with the regulations. Moreover, FASEB is concerned that some training programs are poorly designed and may not be meeting the intended educational goals. Therefore, federal agencies should (1) review each training mandate to identify which re-training and re-certifications could be offered every two years rather than annually; (2) ensure that each training requirement satisfies its intended educational goals; and (3) identify ways to streamline training requirements. Agencies and institutions could also reduce reporting burdens by adopting a system that recognizes completion of core laboratory training requirements by investigators, and allows transfer of these credits when an investigator moves to a new institution. Portability of training requirements is particularly critical for postdoctoral trainees and early-stage investigators, as these individuals are more likely to change institutions within shorter timeframes and to find the requirements more detrimental to their early careers.

**Human Subjects Protections Regulations**

FASEB is committed to the protection of human research participants and believes that regulatory oversight is necessary to ensure the ethical treatment and care of study participants. However, (1) the lack of harmonization among the 19 departments and agencies that do not participate in the so-called Common Rule on regulations pertaining to protection of human subjects, (2) failure to calibrate regulations to the level of research risk, and (3) misguided institutional practices aimed at mitigating liability rather than protecting participants impose a considerable burden on investigators. Therefore, FASEB recommends the following regulatory changes to facilitate biomedical research without compromising the protection of study participants:

- **Streamline regulations and clarify responsibilities of federal agencies and institutions**
  The administration should identify opportunities to streamline regulations related to Institutional Review Board (IRB) operations. This should include (1) clarifying the delineation of responsibilities between IRBs, institutions, and federal agencies regarding review of the human subjects sections of grant applications, to avoid unnecessary duplication of review and (2) identifying research areas in which guidelines for determining the criteria for protocol review or exemption could be improved.

- **Exempt research from the HIPAA Privacy Rule**
  An IOM report concluded that implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule has created significant obstacles for investigators conducting human subjects research, slowing the progress of science critical to developing treatments for illness and disease. The administration could facilitate research and ensure the protection of study participants by exempting research from the Privacy Rule and strengthening data security and privacy protections through the U.S. Department of Health and Human Services’ (HHS) Common Rule. In the absence of a full exemption, FASEB strongly recommends that the Privacy Rule be modified to increase the number of data elements permitted in the limited data set to create a standard that is more closely aligned with the Common Rule.
Streamline IRB review of multi-site studies
FASEB agrees with the 2011 HHS Advance Notice of Proposed Rule Making, “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators,” which stated that HHS should mandate that all domestic sites in a multi-site study rely upon a single IRB as their IRB of record for the study. This change would facilitate collaborative review arrangements and reduce the obstacles encountered by investigators when embarking on multi-center projects. While the IRB of record could reside at the principal investigator’s institution and assume review responsibilities for the duration of the studies, institutions should also have the option to designate an external IRB. Upon completion of the project’s review by the IRB of record, draft copies of the review and recommendations should be transmitted to each participating site’s IRB. All study sites should be required to use the same consent form. FASEB encourages HHS to work with all agencies that conduct or support human subjects research to develop common policies and consent language, particularly for addressing local issues, to facilitate a single review for multi-site studies.

Laboratory Animal Care and Use
Regulations related to the care and use of animals in research and education are a major source of administrative burden for investigators. The following regulatory changes recommended by FASEB would facilitate biomedical research without compromising the protection of laboratory animals:

- **Clarify responsibilities of federal agencies and institutions**
  The delineation of responsibilities between federal agencies and institutional animal care and use committees (IACUCs), regarding the review of the vertebrate animal section of grants and the animal use protocol, should be clarified to avoid duplication of effort and increase consistency across institutions.

- **Reduce the frequency and burden of protocol review**
  Update the timeframe for conducting complete reviews of animal care and use protocols from every three years to every four years. Extending this requirement will better align the timeframe of protocol approval with the length of a typical grant, eliminating the possibility that in-progress research would be halted for protocol review. In addition, the use of Designated Member Review rather than Full Committee Review for protocol modifications should be promoted to streamline the review process. Finally, federal agencies should be encouraged to clarify that animal use protocols do not need to be completely re-written to satisfy re-review requirements. These changes would greatly decrease the workload for both investigators and IACUCs without negatively affecting animal welfare.

Select Agents and Biosecurity
FASEB supports appropriate oversight of research involving organisms and toxins that pose a threat to the nation’s security and public health. FASEB also recognizes that such research is critically important for protecting Americans from these very same threats. Biosecurity regulation continues to evolve, with frequent modification of existing policies to the creation of new policies, making it challenging to maintain compliance. Therefore, FASEB encourages federal agencies to coordinate and harmonize oversight programs, which could reduce administrative burden for researchers and even improve oversight as agencies would apply their joint expertise to the creation of unified policies.

- **Limit reactive biosecurity policies to research that poses the greatest risk**
  It is difficult to determine what risks should be the focus of policies that respond to emerging biosecurity and biosafety issues until additional information is obtained through research. Thus, hastily-created, reactive policies may fail to substantially increase safety, while simultaneously increasing burden for low-risk research. FASEB recommends that agencies addressing emerging
biosecurity issues follow the example of HHS and the National Institutes of Health’s (NIH) development of a framework to fund research on H5N1 highly pathogenic avian influenza. HHS and NIH held an international workshop to consult with the research community and the public when developing this framework. The resulting framework is specifically targeted to research that poses the greatest public health risks and creates minimal administrative burden for researchers, institutions, and funding agencies. FASEB also encourages agencies to subsequently evaluate these policies as we gain a greater understanding of the emerging threats and related research risks, and then, when appropriate, modify or eliminate outdated policies to avoid “legacy” burdens.

- **Eliminate requirements to quantify biological agents present in a research setting**
  FASEB appreciates the importance of maintaining an accurate list of the select agents present in research facilities. However, the inventory requirements pertaining to infectious select agents are at odds with the biology of microorganisms. Keeping a record of the number of vials, or how much of each agent is removed from vials, has little meaning when dealing with organisms that can not only rapidly replicate but can be transferred with no discernible loss in volume or mass. While keeping a detailed inventory may make sense for chemicals, radioactive materials, or even the toxins on the select agent list, the inventory requirement is inappropriate for living organisms and results in an inefficient use of valuable laboratory personnel time and resources. This regulation should be modified to eliminate the requirement to quantify infectious agent stocks.

- **Harmonize laboratory inspections by multiple agencies of jurisdiction**
  Many laboratories that work with select agents report being subjected to duplicative inspections by several federal and local authorities that typically take multiple days and involve large teams of inspectors. While FASEB appreciates the need to have thorough inspections of select agent facilities to ensure security plans are being properly implemented, these inspections should be effectively coordinated at the federal level.

**Research Information Technology (IT) and “Big Data”**
While there are general expectations by federal agencies in the area of research IT, there is a dearth of specific guidance leading to mission creep by institutions. For further insight into addressing administrative burdens associated with “Big Data,” FASEB recommends that the NSB consult with staff of the NIH’s Big Data to Knowledge (BD2K) Initiative. In addition, the National Science Foundation (NSF) has historically been a major supporter of IT research and could lead an effort to identify inconsistencies and guideline shortfalls across organizations and agencies.

- **Create harmonized policies and practices for data sharing, privacy, security, and preservation**
  While some federal agencies have articulated the need for policies related to data sharing, privacy, security, and preservation (such as NSF’s requirement of a data management plan for grant proposals), currently there is very little specific guidance, leading to widely divergent institutional policies. Policies need to specify which practices constitute “good behavior” among investigators and institutions, such as describing acceptable data security practices, rather than just describing values and outcomes associated with good behavior. There are a number of potential barriers to effective data sharing, and greater guidance is needed on issues such as the sharing of genomic information and the legal implications of the Patent and Trademark Law Amendments Act of 1980, also known as the Bayh-Dole Act.

- **Support the creation of broadly-accessible IT infrastructures**
  Historically, federal agencies have preferentially supported IT infrastructure development when the end users were primarily investigators funded by the same agency. This fragmentary approach is an impediment to the efficient deployment of institutional infrastructure and is counterproductive. Utility
of federally-funded IT infrastructure is further eroded by requirements to track use of computers and other low to moderate cost devices, an activity that can be more costly than the equipment itself. IT infrastructure funding should favor broad use throughout the scientific community.

**Hazardous Chemicals**

The Chemical Facilities and Anti-Terrorism Standards categorize policies, procedures, and reporting requirements for academic research institutions in the same class as industrial chemical manufacturers. Not only do these regulations impose a considerable burden on research institutions, but they are also unnecessary because industrial settings differ so dramatically from academic settings. Academic laboratories are not engaged in the large-scale production of chemicals and only use hazardous chemicals in relatively small quantities. Therefore, FASEB recommends separate policies and procedures be developed for research institutions and stratifying regulations according to the risk posed by the chemicals involved.

FASEB commends your efforts to confront the growing problem of regulatory burden. Excess regulation is wasteful of scarce resources and reduces productivity. It is also slowing our progress in many critical fields of inquiry. Much needed relief to the nation’s researchers can be achieved through greater coordination among federal agencies, clearer guidance, and consolidated oversight.

Thank you for considering FASEB’s comments. Please do not hesitate to contact me if we can provide you with additional information.

Sincerely,

Judith S. Bond, PhD
FASEB President