



Quality Life Through Research

Federation of American Societies for Experimental Biology

Member Societies

(in chronological order by date joined)

The American Physiological Society

American Society for Biochemistry
and Molecular Biology

American Society for Pharmacology
and Experimental Therapeutics

American Society for Investigative
Pathology

American Society for Nutrition

The American Association of
Immunologists

American Association of Anatomists

The Protein Society

Society for Developmental Biology

American Peptide Society

Association of Biomolecular
Resource Facilities

The American Society for Bone and
Mineral Research

American Society for Clinical
Investigation

Society for the Study of
Reproduction

Teratology Society

The Endocrine Society

The American Society of Human
Genetics

Environmental Mutagen Society

International Society for
Computational Biology

American College of Sports
Medicine

Biomedical Engineering Society

Genetics Society of America

American Federation for Medical
Research

The Histochemical Society

*Representing over 100,000
biological and biomedical
researchers.*

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A-21 Task Force

National Science and Technology Council

Interagency Working Group on Research Business Models

Subcommittee on Social, Behavioral and Economic Sciences of the Committee on
Science

RE: RFI: Input on Reduction of Cost and Burden Associated with Federal Cost
Principles for Educational Institutions (OMB Circular A-21)

SUBMITTED VIA: http://grants.nih.gov/grants/guide/rfi_files/a-21/add.htm

Dear Members of the A-21 Task Force:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide input on the “Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21).” FASEB represents 24 scientific societies and over 100,000 biomedical researchers, and our organization recognizes that compliance and regulatory oversight are essential to the conduct of federally-supported research. Our comments on the RFI, many of which are aligned with those made by the Association of American Universities and the Association of Public and Land-grant Universities, reflect our commitment to promoting accountability and transparency in research while reducing the administrative burden and costs associated with compliance requirements.

In addition to providing specific recommendations as to how the A-21 circular and related regulatory policies could be improved, we urge the Office of Management and Budget (OMB) to adopt the following guiding principles for reducing cost and burden associated with research:

- Establish mechanisms to evaluate the need for both proposed and existing regulations, as well as the impact the implementation of those regulations has, or is expected to have, on the research enterprise.
- Make every effort to harmonize regulations and guidance among federal agencies.
- Develop regulations that are tiered to the level of risk presented by the situation they are intended to address and designed to improve performance rather than simply to satisfy reporting requirements.

Our recommendations for specific changes to the policies regulating federally-funded research are as follows:

Eliminate effort reporting

Researchers have multiple responsibilities in the course of a workday that are inextricably linked, and the separation between these areas of activity can sometimes be arbitrary. Precise allocation of effort is difficult to measure, requires systems that are expensive to install and operate, and does little to ensure that charges are based on actual effort. While FASEB supports the goal of ensuring proper stewardship of federal grant funds, effort reporting requirements do not further this goal and should be eliminated.

Minimize financial reporting requirements

Financial reporting requirements collectively impose a considerable burden on investigators and their institutions. FASEB recommends that OMB identify ways to minimize the number of forms that investigators have to fill out, increase reporting intervals where feasible, and carefully assess the need for and impact of new reporting requirements, including a proposed quarterly reporting requirement for all federal research grants and contracts.

Streamline research training requirements

Researchers are subject to numerous training requirements, including instruction in biosafety, laboratory safety, radiation safety, human subjects protections, and animal care and use. In some cases, investigators must be re-trained or re-certified on an annual basis. While appropriate instruction in each of these areas is important, the time and effort expended to complete all of the training programs is significant; annual re-training adds to this burden while doing little to improve either safety or compliance with the regulations. Moreover, we are concerned that some training programs are poorly designed and may not be meeting their educational end goals. Federal agencies should review their training programs in order to identify topics for which re-training and re-certification could be offered every two years rather than annually, ensure that the programs satisfy their intended educational goals, and identify ways to streamline training requirements.

Human subjects protections regulations

FASEB is committed to the protection of human research participants, and we believe that regulatory oversight is important to ensuring the ethical treatment and care of study subjects. Nonetheless, lack of harmonization among regulations, failure to calibrate regulations to the level of research risk, and institutional practices aimed at mitigating liability rather than protecting participants impose a considerable burden on investigators and their institutions. The following regulatory changes would facilitate biomedical research without compromising the protection of study participants:

- ***Exempt research from the HIPAA Privacy Rule***

A report conducted by the Institute of Medicine concluded that implementation of the Health Insurance Portability and Accountability Act Privacy Rule has created significant obstacles to conducting human subjects research, and these obstacles slow the progress of science critical to developing treatments for human 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 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 so as to 1) allow study participants to authorize the use of their protected health information for future unspecified research as permitted by the Common Rule, 2) relax the data de-identification standards for research, creating a standard that is more closely aligned with the Common Rule, 3) eliminate the distinction between internal and external researchers with regard to conducting activities preparatory to research and require Privacy Board/Institutional Review Board (IRB) approval for *all* of a covered entity's researchers prior to contacting potential subjects regarding study recruitment, and 4) eliminate the accounting for disclosures requirement for disclosures made pursuant to research. These changes would mitigate the negative impact of the Privacy Rule on research without compromising the protection of research participants.

- ***Streamline regulations and clarify responsibilities of federal agencies and institutions***
The administration should identify opportunities to streamline regulations related to IRB operations. This should include 1) clarifying the delineation of responsibilities between IRBs, institutions, and federal agencies with respect to 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 and exemption from review could be improved.
- ***Hold IRBs, not institutions, accountable for regulatory compliance***
IRBs and the institutions or organizations (IORGs) operating them should be held directly accountable for compliance with human subjects protections regulations. The current system, in which OHRP enforces compliance with 45 CFR part 46 through institutions, has made institutions reluctant to use external IRBs for fear that they will be liable if those IRBs fail to comply with the regulations. Holding IRBs and IORGs directly accountable for meeting certain human subjects protection requirements would diminish institutions' concerns about regulatory liability, thereby facilitating collaborative review arrangements and reducing barriers to conducting multi-center human research projects. As long as the regulations are clear with regard to the specific responsibilities of both IRBs and institutions, this change will not compromise the effectiveness of the IRB system or the safety of research participants.

Laboratory animal care and use

Regulations related to the care and use of animals used in research and education are a major source of administrative burden for biomedical researchers. The following regulatory changes 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) with respect to the review of the vertebrate animal section of grants and the animal use protocol should be clarified so as to avoid duplication of effort.
- ***Reduce the frequency of protocol review***
Eliminate the requirement for a complete re-review of animal care and use protocols every three years and replace it with a requirement to match the period of the animal protocol to the length of the grant. This would remove the disconnect between protocol approval times and grant length and greatly decrease the workload by both investigators and IACUCs.
- ***Establish an advisory committee on animal care and use***
Consider establishing an advisory committee to coordinate the formulation and interpretation of policies and guidelines between federal agencies involved in oversight of animal care and use and accrediting organizations. Topics on which this committee could advise may include: harmonization of regulations among agencies with responsibility for oversight of animal care and use; opportunities to reduce redundancy in reviews and inspections; the adequacy of, and ways to improve, the training provided to site visitors, inspectors, and accreditors; the development of a common reporting format for the yearly reports required by regulatory and accrediting organizations.

Select agents

- ***Stratify the select agent list***
The administration should stratify the select agent list to allow for a spectrum of security controls relative to the risk posed by the agent. The current system treats all agents on the list as if they pose equal risk to public health and safety, despite differences in their pathogenicity and ability to be used as bioterrorism agents. It may make sense to have stricter security measures (i.e., greater personnel reliability measures, increased

physical security, etc.) for extremely high risk agents not found in nature, such as smallpox, while allowing greater access to less pathogenic and ubiquitous agents.

- ***Eliminate requirements to quantify biological agents present in a research setting***

FASEB appreciates the importance of having an accurate list of, and some details on, 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 count 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 is a waste of valuable laboratory personnel time and resources. This regulation should be modified so as to not require quantification of infectious agents.

- ***Harmonize laboratory inspections by multiple agencies of jurisdiction***

Many laboratories working with select agents report being subject to duplicative inspections by a number of federal and local authorities. These inspections typically take multiple days and involve large teams of inspectors. While we appreciate the need to have thorough inspections of select agent facilities to ensure security plans are being properly implemented, these inspections should be harmonized at least at the federal level.

Facilitate reporting of potential conflicts of interest

FASEB supports the development and adoption of clearer and more uniform standards for reporting and managing potential conflicts of interest across stakeholder groups. We urge the administration to develop and make available to all investigators a simple, electronic, universal reporting form to help to ensure compliance with reporting requirements while minimizing regulatory burden.

Establish separate policies and procedures for universities with regard to hazardous chemicals

The Chemical Facilities and Anti-Terrorism Standards categorizes academic research institutions in the same class as industrial chemical manufacturers with regard to the policies, procedures, and reporting requirements aimed at securing chemical facilities. The regulations impose a considerable burden on research universities, yet they are unnecessary because academic research settings differ dramatically from industrial settings. Unlike in industry, laboratories are not engaged in the large scale production of chemicals, and they use hazardous chemicals in relatively small quantities. Separate policies and procedures should, therefore, be developed for universities, and regulations should be stratified according to the risk posed by the chemicals.

Thank you for considering our comments, and please do not hesitate to contact me if FASEB can provide you with additional information.

Sincerely,



Joseph C. LaManna, PhD
FASEB President