



Quality Life Through Research

Member Societies

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

Representing over 100,000 biological and biomedical researchers.

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Federation of American Societies for Experimental Biology

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Department of Health and Human Services
Office of Documents and Regulations Management
200 Independence Avenue, SW, Suite 639G
Washington, DC 20201

To Whom It May Concern:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), thank you for the opportunity to provide input on the Department of Health and Human Services (HHS) "Preliminary Plan for Retrospective Review of Existing Regulations." FASEB represents 23 scientific societies with a collective membership of 100,000 biomedical researchers, and we are particularly interested in HHS regulations that impact the research enterprise.

Scientists, and the institutions in which they work, are subject to a wide range of regulations intended to address serious and valid concerns. While we have no doubt about the importance of regulatory oversight, compliance with a myriad of regulations requires a considerable administrative effort, the cumulative burden of which is having a deleterious effect on scientific productivity. Scientists responding to a 2007 survey conducted by the Federal Demonstration Partnership (FDP) estimated that 42% of the time they spent on federally funded research was devoted to administrative and regulatory activities. Based on these data, the FDP estimated that a total of \$97 million in salary support for principal investigators and co-investigators was spent on administering these grants rather than on research. These findings underscore the importance of periodically reviewing existing regulations to determine whether they should be modified, streamlined, expanded, or repealed. FASEB thanks HHS for undertaking this important endeavor and for soliciting feedback from the regulated community.

We have listed below the broad regulatory domains as well as specific regulations that we would like HHS to examine in the course of its review.

General principles

- HHS should establish mechanisms to evaluate the need for both proposed and existing regulations, as well as the impact the implementation of those regulations have, or are expected to have, on the research enterprise.
- HHS should make every effort to harmonize regulations and guidance within HHS and among federal agencies.

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 hard to discern. 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.

Research training

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. FASEB encourages HHS to review its 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

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. HHS 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 HHS Common Rule.

In the absence of a full exemption, FASEB strongly recommends that HHS modify the Privacy Rule as follows: 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.

Institutional review board processes. HHS should identify opportunities to streamline regulations related to IRB operations. This should include 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 identifying research areas in which guidelines for determining the criteria for protocol review and exemption from review could be improved.

Regulatory accountability. The Office of Human Research Protections (OHRP) should hold IRBs and the institutions or organizations (IORGs) operating them 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.

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.

Delineation of responsibilities. HHS should clarify 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 to avoid duplication of effort.

Protocol review. HHS should eliminate the requirement that animal care and use protocols be reviewed 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.

Advising on animal care and use. HHS should 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.

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

Sincerely,

A handwritten signature in black ink, appearing to read "William T. Talman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

William T. Talman, MD
FASEB President