



Quality Life Through Research

# Federation of American Societies for Experimental Biology

## 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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Attention: Jerry Moore  
NIH Regulations Officer  
Office of Management Assessment  
National Institutes of Health  
6011 Executive Boulevard  
Suite 601, MSC 7669  
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VIA ELECTRONIC SUBMISSION TO: <http://www.regulations.gov>

**Re: “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors” RIN 0925-AA53, NIH-2010-0001**

Dear Mr. Moore:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Department of Health and Human Services (DHHS) Notice of Proposed Rulemaking (NPRM) “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors.” FASEB is composed of 23 societies with more than 100,000 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 the biological and biomedical sciences. Many of the scientists funded by NIH are members of FASEB societies and will be directly affected by changes in the Public Health Service (PHS) financial conflict of interest regulations. Although the members of FASEB societies are employed by institutions, our comments address issues from the perspective of the individual investigator.

FASEB vigorously supports efforts to maintain public trust and ensure scientific integrity. As elaborated in our response to the 2009 “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors” Advanced Notice of Proposed Rulemaking (ANPRM), we have developed three guiding principles with regard to financial conflict of interest (FCOI). Investigators must: 1) conduct research activities objectively, 2) operate with transparency, and 3) be accountable to all stakeholders, especially when relevant relationships with industry exist.

Many of the changes proposed in the NPRM are broadly in line with FASEB's ANPRM recommendations. For example, the inclusion of all extramural investigators funded by NIH, independent of whether or not they engage in human subjects research, will provide clearer and more uniform standards and ultimately facilitate compliance. We also agree that it is primarily the responsibility of institutions to manage FCOI of their employees and appreciate that NIH will not be responsible for shouldering the burden for verifying compliance by individual investigators.

Despite general agreement with the intent of the proposed regulations, FASEB recommends that "Significant Financial Interest," under *Definitions* (42 CFR 50.603, 45 CFR 94.3), be modified as follows:

**“(2) The term *significant financial interest* does not include the following types of financial interests: reasonable and customary reimbursements for expenses incurred; salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution; any ownership interest in the Institution held by an Investigator, if the Institution is a commercial or for-profit organization; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, ~~or~~ an institution of higher education as defined at 20 U.S.C. 1001(a), or a non-profit, member-based professional scientific or engineering society; or income from service on advisory committees or review panels for a federal, state, or local government agency, ~~or~~ an institution of higher education as defined at 20 U.S.C. 1001(a), or a non-profit, member-based professional scientific or engineering society.”**

Voluntary participation in non-profit, member-based, professional scientific and engineering societies, including such activities as peer review, governance, and other volunteer service, is an essential part of scientific life. Such activities allow investigators to engage and interact with one another and support the scientific activities of their disciplines. Unless these activities are excluded from the FCOI regulations, scientists volunteering in their respective professional societies could be identified on institutional websites as having FCOI, resulting in a negative public perception of these relationships and their value to the broader biomedical research enterprise. The FCOI regulations should also exclude the reporting of reasonable and customary reimbursement, which is an essential, legitimate, and regular component of scientific and educational exchange.

FASEB continues to appreciate DHHS' efforts to engage the biomedical research community in this critical issue and is pleased to contribute our thoughts. We share a bedrock commitment to the public good and are committed to working with NIH and PHS to ensure the health of the biomedical research pipeline of discovery and the preservation of scientific integrity and the public trust.

Sincerely,



William T. Talman, MD  
FASEB President