



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.*

## President

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Irene Stith-Coleman, PhD

Office for Human Research Protections

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

**Re: HHS-OPHS-2010-0023**

VIA ELECTRONIC SUBMISSION TO: <http://www.regulations.gov>

Dear Dr. Stith-Coleman:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), I am writing in regard to the Office for Human Research Protection's (OHRP's) Draft Revision of the Federalwide Assurance (FWA) notice. FASEB applauds OHRP's efforts to simplify and shorten the FWA and the Terms of Assurance, and we generally agree with the proposed changes. We would, however, like to recommend a modification to the proposed revisions related to the designation of specific institutional review board (IRBs).

As we stated in our June 5, 2009 letter to OHRP regarding IRB accountability, FASEB agrees with the Secretary's Advisory Committee on Human Research Protections that institutions should not be required to designate specific IRBs on their FWAs so long as they make a commitment to rely only on registered IRBs. This change would facilitate collaborative review arrangements insofar as institutions would not be required to modify their FWAs each time they enter an arrangement with a new IRB, a process that can be burdensome for institutions, IRBs, and the regulators who review and approve FWA changes.

Consistent with our comments, we support OHRP's proposal to require institutions to assure that they will rely only on registered IRBs. We are concerned, however, that they would still be required to designate specific IRBs on their FWAs. OHRP proposes to replace the current requirement that institutions designate all IRBs on which they rely with a requirement to designate only internal IRBs. If an institution does not have an internal IRB, it would have to designate the external IRB that reviews the largest percentage of the research to which its FWA applies. This modification would certainly improve upon the current FWA in that it would give institutions the flexibility to use IRBs that they have not designated. Nonetheless, it is not clear to us what purpose designating specific IRBs serves, particularly if institutions do not have to use the ones

that they designate. This requirement may lead to uncertainty as to whether the use of non-designated IRBs is permissible. It would also mean that institutions that rely on multiple external IRBs would have to monitor the number of reviews each of those IRBs conducts to ensure that the IRB conducting the greatest percentage of reviews is the one listed on its FWA. These monitoring and reporting mandates would neither facilitate regulatory compliance nor serve the protection of human research participants. We, therefore, reiterate our recommendation that institutions not be required to designate specific IRBs on their FWAs so long as they assure that they will rely only on registered IRBs.

On behalf of FASEB's 23 scientific societies and the 100,000 biomedical researchers they represent, I thank you for considering these comments.

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