



# Federation of American Societies for Experimental Biology

— 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  
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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  
Society for Gynecologic Investigation  
Environmental Mutagen Society  
International Society for  
Computational Biology  
American College of Sports Medicine

September 3, 2008

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BY ELECTRONIC MAIL TO: [humansubjectstraining@hhs.gov](mailto:humansubjectstraining@hhs.gov)

### **Re: Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs**

Dear Dr. Carome:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide feedback on the Office of Human Research Protections' (OHRP) *Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs*. As an organization representing 21 scientific societies and over 80,000 biomedical researchers, FASEB recognizes the profound importance of protecting human research participants. We affirm that all individuals involved in the conduct, review, or oversight of human subjects research must be knowledgeable of, and in compliance with, human subjects protections requirements. We also believe that institutions should be required to implement human subjects protections training and education programs for investigators, designated institutional officials, human protections administrators, institutional review board (IRB) members and staff, and others involved in this type of research.

OHRP should not, however, impose additional human subjects protections training and education requirements on principal investigators and other key study personnel funded by the National Institutes of Health (NIH). These individuals are already obligated to complete such training as a condition of grant funding and/or IRB approval, and institutions have developed a variety of excellent programs to enable them to do so. New training requirements would add to the many administrative burdens already shouldered by investigators while doing little to improve the protection of research participants. We note also that training is a requirement for NIH-funded individual investigators whereas it is only recommended for IRB members and other personnel.

In our view, research participants would be better served if OHRP focused its efforts on improving compliance with existing human subjects regulations. To that end, OHRP should continue to require IRBs to conduct periodic reviews of human subjects research performed at their institutions and report incidences of

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#### *President*

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noncompliance to OHRP. In addition, FASEB encourages OHRP to reaffirm its recommendation that institutions conduct internal audits of their human subjects protections practices to ensure they are in compliance with all applicable regulations. This internal oversight would not only encourage individuals involved in human research to adhere to regulations, but it would help OHRP to align training and education requirements with the needs of institutions and their personnel.

OHRP could also enhance the protection of research participants by ensuring that all institutions have the ability to develop effective human subjects protections training and education programs. We recognize that it may be a challenge for institutions lacking in resources or a history of involvement in human research to develop training programs on their own. These institutions would benefit from the ability to use or build upon the excellent programs that have been created by other organizations. To that end, we recommend that OHRP highlight programs that could serve as models for the type of training necessary to safeguard research participants. OHRP could accomplish this by collaborating with the Regulatory Working Group of the Clinical and Translational Science Award consortium, which is working to identify and disseminate best practices related to clinical research regulation compliance, including human subjects training.

Human subjects training needs differ depending on the nature of an individual's involvement in research (e.g., principal investigator compared to IRB chairperson) as well as the type of research in which they are involved (e.g., patient-oriented research compared to human tissue research). It is not necessary or advisable, therefore, to impose identical training requirements on all individuals engaged in clinical research. Any new training and education policies implemented by OHRP should be flexible enough to accommodate the diverse training needs of the clinical research community.

Thank you for the opportunity to respond to this request for information. Please do not hesitate to contact me if FASEB can be of further assistance to you.

Sincerely,

A handwritten signature in cursive script that reads "Richard B. Marchase".

Richard B. Marchase, Ph.D.  
FASEB President