



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

President

Leo Furcht, M.D.
Professor of Cancer Biology
Dept. of Laboratory Medicine and Pathology
University of Minnesota
420 Delaware St. SE
760 Mayo Building
Minneapolis, MN 55455-0392
Tel: (612) 626-0622
Fax: (612) 626-2696
E-mail: furch001@umn.edu

Office of Public Affairs
9650 Rockville Pike
Bethesda, Maryland 20814-3998
Telephone: 301-634-7650
FAX: 301-634-7651
WWW: <http://opa.faseb.org/>

Federation of American Societies for Experimental Biology

----Quality Life Through Research----

February 6, 2007

ENGAGEMENT GUIDANCE COMMENTS

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

Dear Mr. Drew:

On behalf of the Federation of American Societies for Experimental Biology (FASEB) I would like to thank the Office of Human Research Protections (OHRP) for the opportunity to comment on the *Draft Guidance on Engagement of Institutions in Human Subjects Research*. Representing 21 biomedical research societies and over 80,000 investigators in the basic and clinical sciences, FASEB recognizes the importance of protecting human research participants and requiring institutions engaged in human subjects research (HSR) to assure that they are complying with established regulations.

We therefore appreciate OHRP's efforts to clarify the conditions under which institutions are and are not considered to be engaged in HSR. In doing so, the proposed guidance will assist institutions in navigating the complex regulatory landscape in this area. We also applaud OHRP's aim to reduce the compliance burden placed on institutions that are not engaged in HSR.

Together, these modifications will facilitate compliance and prevent institutions that are not engaged in HSR from being unduly burdened. We appreciate OHRP's efforts in this regard and encourage future improvements.

Sincerely,

Leo T. Furcht, M.D.
FASEB President