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(FASEB) I would like to thank the Office of Human Research Protections (OHRP) for the opportunity to comment on the Draft Guidance on Engagement of Institutions in Human Subjects Research.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