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Federation of American Societies for Experimental Biology

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### **FASEB COMMENTS ON OHRP REQUEST FOR INFORMATION ON IRB ACCOUNTABILITY**

*Bethesda, MD* – The Federation of American Societies for Experimental Biology (FASEB) has issued comments on the Office for Human Research Protections (OHRP’s) advanced notice of proposed rulemaking regarding holding institutional review boards (IRBs), and the institutions or organizations operating them (IORGs), directly accountable for meeting regulations for the protection of human subjects. “Our community is committed to ensuring the protection of human research participants, and we believe that an effective IRB system is critical to achieving this goal,” stated FASEB President Richard Marchase, Ph.D.

In its letter to OHRP, FASEB stated that shifting the locus of responsibility from institutions engaged in human subjects research to IRBs or IORGs would diminish research institutions’ concerns about regulatory liability, facilitate collaborative review arrangements, and reduce barriers to conducting multi-center human research projects. Where it is appropriate for either IRBs or institutions to meet certain regulatory requirements, FASEB recommended that both parties be required to specify which responsibilities they will each assume. FASEB noted that the IRB process could be further improved by eliminating the requirement that institutions designate specific IRBs on their Federalwide Assurances and replacing it with a commitment by institutions to rely only on registered IRBs. “These regulatory changes,” stated Marchase, “will increase the efficiency of the IRB process and the pace of clinical research without compromising the effectiveness of the review system or the safety of research participants.”

To read the full FASEB statement, [click here](#).

*FASEB is composed of 22 societies with more than 90,000 members, making it the largest coalition of biomedical research associations in the United States. FASEB enhances the ability of biomedical and life scientists to improve—through their research—the health, well-being and productivity of all people. Our mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences through service to its member societies and collaborative advocacy.*