January 6, 2015

Office of Clinical Research and Bioethics Policy
Office of Science Policy, National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Submitted electronically via: SingleIRBpolicy@mail.nih.gov

Dear NIH Clinical Research and Bioethics Policy Team,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the National Institutes of Health’s (NIH’s) draft Policy to promote the use of a single Institutional Review Board (IRB) of record for domestic sites of multi-site clinical studies funded by NIH (NOT-OD-15-026). FASEB is composed of 27 scientific societies, collectively representing over 120,000 biological and biomedical researchers. The Federation has long advocated for widespread use of a single IRB of record for multi-site studies, and we applaud NIH for this proposed Policy.

In our response to the 2011 Department of Health and Human Services Advance Notice of Proposed Rulemaking, “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” FASEB agreed that the Department should mandate use of a single IRB of record for all domestic multi-site studies. In these comments, we noted that “[t]his change would facilitate collaborative review arrangements and reduce the obstacles that investigators encounter when embarking on multi-center projects.” This perspective was reiterated in our response to a 2013 Request for Information from the National Science Board on “Reducing Investigator’s Administrative Workload for Federally Funded Research.”

FASEB commends NIH for proposing this Policy that will increase the efficiency of clinical studies. Use of single IRB of record for multi-site studies will decrease administrative burden for clinical research staff and reduce delays in patient recruitment.

Thank you for considering FASEB’s comments. Please do not hesitate to contact me if we can provide you with additional information.

Sincerely,

Joseph R. Haywood, PhD
FASEB President