December 5, 2014

Jerry Menikoff, MD, JD
Office for Human Research Protections
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

RE: Docket ID HHS-OPHS-2014-0005

Submitted electronically via http://www.regulations.gov

Dear Dr. Menikoff,

The Federation of American Societies for Experimental Biology (FASEB) welcomes the opportunity to comment on the Office for Human Research Protections’s (OHRP’s) Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care. FASEB appreciates OHRP’s efforts to address informed consent issues specific to the conduct of comparative effectiveness research and to clarify concerns that were raised subsequent to OHRP’s investigation into the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT) clinical trial.

The draft Guidance adequately describes the issues that investigators should consider when conducting research that evaluates standards of care and the question and answer format makes the guidance easy to follow. Clarity of the document – particularly the section defining “risks of research” – could be enhanced, however, by incorporating more examples of research study risks in clinical studies comparing standards of care, similar to what is provided in OHRP’s Guidance on Engagement of Institutions in Human Subjects Research. Even with these clarifications, FASEB is concerned that the draft Guidance assumes fundamental differences between research that assesses differences between standard practices of medical care and that which assesses novel treatments for which risks are unknown, similar to the points articulated by the editors of the New England Journal of Medicine1. Assuming that the risks and benefits of the treatments being compared are equal, standards of care research does not expose study participants to risks beyond those to which they would be exposed through medical practice. Therefore, clear

examples of what constitutes activities that would be considered research risks in this context would help to decrease the likelihood of the Guidance being over-interpreted by the individual Institutional Review Boards that oversee the review of study protocols and informed consent materials and would minimize the risk of unnecessary increases in administrative burdens for investigators conducting the research.

On behalf of FASEB’s 27 member societies and the more than 120,000 biological and biomedical researchers they represent, I thank you for the opportunity to provide input on this draft Guidance. While we appreciate OHRP’s efforts to provide ample protections to human subjects, we urge you to re-evaluate the intent and impact of the proposed Guidance. As currently written, the Guidance has the potential to increase informed consent expectations for research activities evaluating standard and tested medical practice to those expected for research evaluating novel treatments. FASEB is concerned about the potentially negative impacts on patient participation in clinical research\textsuperscript{2}. Please do not hesitate to contact me if we can provide you with any additional information.

Sincerely,

Joseph R. Haywood, PhD
FASEB President