Mr. Glen Drew,
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 you for the opportunity to comment on the Office of Human Research Protections’ (OHRP) proposed changes to the Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure. Comprised of 21 scientific societies and 80,000 biomedical researchers, FASEB recognizes the obligation to protect the health and well being of human research participants. We are grateful, therefore, for OHRP’s efforts both to safeguard individuals who participate in research studies and to facilitate the progress of science when minimal risk to those participants is involved.

FASEB greatly appreciates OHRP’s proposal to clarify and expand the types of research that may be reviewed by institutional review boards through an expedited review procedure. In particular, we support modifying expedited review category five to clarify that this category includes research involving materials that were previously collected for either non-research or research purposes. Likewise, FASEB supports OHRP’s proposal to include research on affective states and interpersonal characteristics, as well as research employing methods commonly used in social, behavioral, epidemiologic, health services, and educational research in expedited review category seven.

These modifications will accelerate the review of minimal-risk clinical research proposals while ensuring that the safety of human research participants remains a top priority. Thank you once again for giving FASEB the opportunity to comment on these changes.

Sincerely,

Robert E. Palazzo
FASEB President