



*Integrating
the Life Sciences
from Molecule to
Organism*

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The American Physiological Society

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October 24, 2011

Jerry Menikoff, M.D., J.D.

Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

Re: HHS-OPHS-2011-0005

Dear Dr. Menikoff,

The American Physiological Society (APS) appreciates the opportunity to comment on the advanced notice of proposed rulemaking (ANPRM) on Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Researchers. Volunteer participants play a critical role in basic, translational and clinical research, and the scientific community has a responsibility to protect the health, safety and privacy of research participants. We endorse the Department of Health and Human Services' goal of enhancing protections for research subjects while at the same time being mindful of reducing regulatory burden for researchers and implementing regulations that are clear and unambiguous.

The APS is a professional society dedicated to fostering research and education as well as the dissemination of scientific knowledge concerning how the organs and systems of the body work. Many of our members engage in research using human subjects. The Society was founded in 1887 and now has nearly 10,000 member physiologists who conduct research at colleges, universities, medical schools, and other public and private research institutions across the U.S. As a member of the Federation of American Societies for Experimental Biology (FASEB) we endorse their comments, submitted separately.

The APS will restrict our comments to the recommended changes to the exempt/excused category of research studies and consent for the use of biospecimens.

Exempt research studies involving surveys

The ANPRM proposes that "research conducted with competent adults, that involve educational tests, surveys, focus groups, interviews, and similar procedures would qualify for the new Excused category, regardless of the nature of the information being collected, and regardless of whether data is recorded in such a manner that subjects can be identified." The studies would also be subject to the new standard data security and information protection standards. The APS supports the shift of this category of research from exempt to excused. Doing so will reduce administrative

burden and save both time and resources. With regard to the new data security and information protection standards, we agree that this is an important aspect of protecting human subjects involved in research. We urge you to calibrate the level of data security required to the identifiability of the data being collected.

Consent for biospecimen use

The ANPRM proposes that “written general consent would be required for the research use of such biospecimens.” Deidentified biospecimens represent an important resource to the research community and the APS does not support new consent requirements. Biospecimens that have been appropriately deidentified according to standard rules for deidentification should not represent a threat to patient privacy and confidentiality.

As the Department of Health and Human Services considers and implements new regulations, the APS urges the Department to carefully consider possible unintended consequences of new regulations, and to remain open to revisiting the regulations at reasonable intervals to ensure that the goals of the regulations are being met.

Thank you for considering our comments.

Sincerely,

A handwritten signature in black ink that reads "Joey P. Granger". The signature is written in a cursive, flowing style.

Joey P. Granger, Ph.D.
President
American Physiological Society