August 3, 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

Dear Dr. Menikoff:

On behalf of the Association for American Universities (AAU) and Association of Public and Land-grant Universities (APLU), please accept this request for an extension of the deadline for submission of comments in response to the Department of Health and Human Services (HHS) Advanced Notice of Proposed Rulemaking (ANPRM) titled, “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.” We request an extension of at least an additional 30 days.

AAU and APLU together represent most of the major public and private universities in the United States, all of whom are engaged in research impacted by the proposed revisions in human subjects research regulations contained in the ANPRM. We greatly appreciate the opportunity to provide feedback on the proposed changes to the Common Rule, and applaud HHS for its efforts to enhance protections for research subjects while reducing regulatory burden. However, we are concerned that the 60-day comment period provided is insufficient to provide substantive input on the extensive and detailed questions and proposals outlined in the ANPRM. In order to ensure a thoughtful and thorough response, the research community needs adequate time to consult with our investigators and other stakeholders, many of whom use the summer/non-academic year months to conduct research and are, as a consequence, less available.

Therefore, we respectfully request that you extend the comment period by at least 30 days. Thank you for consideration of this request.

Sincerely,

[Signature]
Dr. Hunter R. Rawlings III
President
Association of American Universities

[Signature]
Peter McPherson
President
Association of Public and Land-grant Universities