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January 6, 2016

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

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

SUBJECT: HHS-OPHS-2015-0008, Federal Policy for the Protection of Human Subjects, Notice of Proposed Rulemaking (NPRM)

Dr. Menikoff:

The Association of Independent Research Institutes (AIRI) is a national association of more than 70 non-profit independent research institutes conducting peer-reviewed basic, translational, and applied research in the biomedical and behavioral sciences. AIRI members are unique in that our small size, research-only missions, and flexibility provide an environment particularly conducive to creativity and innovation. Many AIRI members engage in research using human subjects, and AIRI is pleased to submit these comments on the Notice of Proposed Rulemaking (NPRM).

AIRI appreciates efforts by the Department of Health and Human Services Office for Human Research Protections to incorporate elements suggested in our October 2011 letter commenting on the Advance Notice of Proposed Rulemaking (ANPRM). However, we have concerns with the NPRM that largely echo comments submitted by the Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Association of American Medical Colleges (AAMC), and the Council on Governmental Relations (COGR).

Given our relative small size and staff, AIRI member institutes are acutely affected by increased administrative burden. Hence, AIRI is greatly concerned that the NPRM's proposed requirements would increase burden and not necessarily increase protections for human subjects. Overall, AIRI concurs with the sentiment expressed by AAMC that "proposals to...mandate a single institutional review board (IRB) review for cooperative research, and extend the Common Rule to all clinical trials at federally funded institutions have significant foreseeable burdens with insufficient evidence as to their benefits to human subjects or institutions."

Single IRB of Record

As noted in our October 2011 comments, AIRI supports a single IRB of record for multi-site studies, but does not see an advantage in mandating it. AIRI agrees with recommendations made by AAU, APLU, and AAMC that implementation of a single IRB of record for multi-site trials be phased in gradually to allow for flexibility and exceptions when appropriate. AIRI also agrees with AAMC that HHS should postpone the mandate until it can be informed by recently-funded NIH research on the principles and characteristics of central IRBs.

Rushing to implement a single IRB of record for multi-site studies could be very costly and not result in significant cost savings assumed in the NPRM.

Extension of Common Rule to All Clinical Trials

As noted in our October 2011 comment letter, AIRI believes the extension of federal regulations to an institution's entire research portfolio would not provide greater protections to human subjects, but rather, would increase costs and burden for institutions and potentially delay research. Further, the proposed extension would not reach organizations and institutions currently operating outside the regulations as the proposed change only would apply to institutions that receive federal funding. Overall, AIRI is in agreement with our university colleagues that the extension of the Common Rule to all trials would not result in an appreciable benefit for human subjects and would increase administrative burden and compliance costs.

In conclusion, AIRI appreciates the opportunity to comment and recognizes HHS for its efforts to propose changes that increase protections for human subjects while not imposing significant administrative burden. We hope the Department takes into consideration AIRI's comments and those of our fellow organizations when revising the NPRM.

Sincerely,

A handwritten signature in black ink that reads "Cary E. Thomas". The signature is written in a cursive, flowing style.

Cary E. Thomas
President
Association of Independent Research Institutes