



September 29, 2004

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Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

SUBJECT: Office of Human Research Protections
Institutional Review Boards: Registration Requirements
RIN 0940-AA06

Dear Dr. Stith-Coleman:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to offer brief comments on the notice of proposed rulemaking issued by the Office of Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services, regarding registration requirements for institutional review boards (IRBs) that review human subjects research conducted or supported by HHS and that are designated under a federal-wide assurance of compliance approved by OHRP. The AAMC represents the nation's 125 allopathic medical schools, over 400 major teaching hospitals and health systems, and more than 105,000 faculty through 94 academic and scientific societies.

AAMC strongly supports the concept of IRB registration and the goal of creating a single registration system for OHRP and the FDA, as well as OHRP's proposal [46.602(h)] to include accreditation status in the IRB registration process.

We support the collection of information by OHRP that enables it to meet the requirements of 45 CFR 46.103(b)(3). That information includes, in particular, the contact information of the organization itself and the senior official who is responsible for overseeing IRB activities [proposed sections 46.602(a) and (b)]; the IRB number, registration name, and address [46.602(c)]; the name, gender, degree, title, and contact information of each IRB chair [46.602(d)]; and the IRB roster with name, gender, degree, specialty, and affiliation of IRB members [46.602(e)].

In the information accompanying the proposed registration requirements, OHRP indicates that the volume of research is a useful parameter in connection with its determinations of "how active an IRB is" and of OHRP's assignment of its "quality improvement, educational, and compliance oversight resources based on an IRB's activity level." AAMC believes that these assumptions

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are questionable, that is, research volume per se is not an accurate measure of the workload of an IRB.

For OHRP to obtain more reliable data on actual IRB workloads would necessitate the burdensome collection of voluminous, detailed data. In this context, with respect to 46.602(f), we acknowledge and appreciate that OHRP does not propose that institutions be required to supply specific numbers of active protocols undergoing initial and continuing review each year, and have no objection to the proposal of numerical ranges that can be selected by registrants to describe their activity. However, in light of the importance of OHRP's proposed uses of the information collected, we urge that the information be interpreted carefully and cautiously. We urge similar care and caution in OHRP's proposed utilization of information about full-time positions pursuant to proposed 46.602(g) in determinations of whether or not "provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping duties."

AAMC appreciates the opportunity to comment on the proposed single registration process, which has been called for in several recent congressional bills directed at strengthening the protection of human research subjects. We are grateful for OHRP's proposed economical approach to new data collection and reporting, which respects the sensitivity of the academic research community to the imposition of new unfunded mandates. We trust that OHRP will keep in mind the limitations of the information to be received in using those data to assess the adequacy of university investments in their human research protection programs.

Sincerely,

Jordan C. Cohen, M.D.

cc: David Korn, M.D.
Richard Knapp, Ph.D.