

September 26, 2008

BY ELECTRONIC MAIL: humansubjectstraining@hhs.gov

Captain Michael A. Carome, M.D.
U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Human Subjects Protection Training and Education Programs, Request for Information and Comments

Dear Dr. Carome:

The Council on Governmental Relations (COGR), the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) appreciate the efforts of the Office for Human Research Protections (OHRP) to engage the public in a dialog and welcome this opportunity to comment on the notice entitled: "Request for Information [RFI] and Comments on the Implementation of Human Subjects Protection Training and Education Programs."

COGR is an association of more than 175 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies and practices on the performance of research and other sponsored activities conducted at its member institutions.

The Association of American Universities comprises 60 leading U.S. research universities, which together perform 60 percent of federally funded university-based research.

AAMC is a not-for-profit association representing all 129 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs' medical centers; and 94 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians.

We share OHRP's view of the importance of training and educational programs for the individuals involved in the conduct, review or oversight of human subject research and we have pursued a variety of mechanisms to ensure that this training and education occurs at our

institutions. However, we do not believe that a change in the regulations mandating training is necessary or appropriate at this time.

The background information provided in the RFI as a rationale for proposing such a change is useful and interesting from a historical perspective. Nonetheless, we do not believe it reflects the evolution of educational programs at our institutions. Since the HHS Office of Inspector General (OIG) 1998 Report "Institutional Review Boards: A Time for Reform," the community has instituted mechanisms and approaches to education and training. Institutions have developed programmatic initiatives including seminars and workshops delivered in a variety of settings and approaches to train investigators, Institutional Review Board (IRB) members and administrative staff as well as research participants to ensure the protection of human subjects. In addition to these unique, local opportunities, institutions have invested in the development of their professional staff and their human participant protection programs as a whole.

For example, as of June 2008, 129 organizations, representing 550 entities have earned voluntary accreditation of their human subjects protection programs through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Since 1999, over one thousand individuals have been certified under the Public Responsibility in Medicine and Research's (PRIM&R) Certified IRB Professional (CIP®) program. Finally, as of August 2008, more than 900 institutions have participated in the training programs provided by the Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Research Subjects. These processes and programs materially supplement those that our institutions routinely offer to ensure that those involved in human subjects research meet applicable federal and state requirements.

Assurance through FWA

We support the existing approach of a recommendation from OHRP through the terms of the Federalwide Assurance (FWA) regarding education. The FWA is the instrument used for assuring that the institution meets the requirements regarding human subject protections and OHRP's endorsement of training as one measure or mechanism for meeting the terms of the assurance is appropriate. We strongly oppose any additional regulations on the issue of human subject protection training and education.

We do not believe that noncompliance is, necessarily, a reflection of a lack of training. Compliance is a result of a variety of factors including comprehensive training and the development of a culture of compliance within an institution achieved by providing adequate support to investigators, maintaining effective oversight and, finally, holding individuals accountable for their performance. All of these elements that lead to compliance are appropriately managed at the individual institution level, not imposed through regulatory imperative. Therefore, we believe that the existing framework is fully adequate in its reliance on the FWA's strong recommendations for training and education. We are unaware of any study

assessing whether institutions have or have not “routinely implemented OHRP’s recommendations” and until such a study is completed and analyzed, the role of training as a contributing factor to non-compliance is purely speculative and cannot serve as a basis for additional regulations.

Scope and Content of Training

It is extremely difficult if not impossible to meaningfully prescribe through regulation either content, frequency, or adequacy of training. We agree that individuals involved in the conduct, review or oversight of human subject research should know and understand their responsibilities within the process. We believe that individuals should receive initial training appropriate to their roles prior to any involvement in the conduct, review or oversight of human subject research. However, due to broad variability in job categories and the responsibilities of involved individuals, any prescriptive requirements would be impractical and unworkable. Institutions are best able to determine the content and extent of relevant training according to an individual’s role in the research process. Continuing or ongoing appropriate training and educational activities should be offered to individuals as roles and circumstances, including regulations, change, but we strongly oppose arbitrarily prescribed or recommended intervals for training programs.

Increased Documentation

New regulations calling for written documentation on training completion or procedures for implementing training programs or monitoring the training of individuals involved in human subject research are unnecessary and add significant bureaucratic and unfunded record-keeping requirements without enhancing the protection of subjects and should not be implemented.

Cost of Compliance

The costs related to compliance with the Federal regulations governing human subjects research have increased exponentially since 1995. In a survey COGR conducted in 2001, member institutions reported average increases in the cost for their human subjects protections programs of 176% between 1995 and 2000. The time commitment by faculty and staff to meeting the requirements grew substantially as well with average commitment in hours rising 141% from 1995 to 2000. With the introduction of the National Institutes of Health training requirement in 2000, we asked the participating institutions to provide actual and/or estimates of costs to meet this requirement. Institutions estimated expenditures on average of \$255,000 in the next fiscal year to meet the then-new NIH requirement. These costs are not recovered by the institutions through their Facilities & Administrative (F&A) cost recovery (indirect costs) because of the cap of 26% imposed by the Office of Management and Budget in 1995.

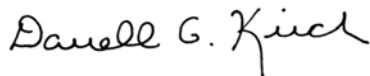
A change in the regulations would, without question, result in substantial additional costs to our institutions. The cost of implementation of any new regulations would be in addition to these already considerable expenses that our institutions incur in conducting human subject protection training. The institutions would face these additional, unfunded costs at a time when, due to the stagnant NIH budget as well as economy in general, institutions are struggling to raise funds necessary to sustain teaching and research.

OHRP Contribution

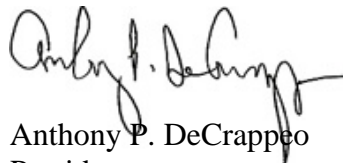
Some institutions would welcome OHRP collecting and making available to all institutions links to educational programs that have been developed by individual institutions and academic societies. A number of major research institutions and societies have extensive, well-developed, multi-module training programs allowing flexibility and scalability of training requirements. Furthermore, to promote institutional educational efforts, the OHRP could expand mechanisms to fund the development of training tools and modules at the national levels.

We appreciate the opportunity to comment on the OHRP notice entitled: "Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs." Please feel free to contact us should you have any questions about our comments or if we can be of further assistance.

Sincerely,



Darrell G. Kirch, M.D.
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Medical Colleges (AAMC)



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Robert M. Berdahl, Ph.D.
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