



January 11, 2006

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Capt. Michael Carome, M.D.
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Associate Director for Regulator Affairs
Office for Human Research Protections (OHRP)
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

By Email to: ohrp@osophs.dhhs.gov

RE: October 1, 2005 Draft Guidance on Reporting and Reviewing Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others

Dear Dr. Carome:

The Association of American Medical Colleges (AAMC) is pleased to submit these comments in response to the OHRP list serve email of October 14, 2005 requesting comments on its proposed guidance about HHS regulations for the protection of human subjects (45 CFR part 46). Specifically, the guidance addresses the review and reporting of (a) adverse events, and (b) unanticipated problems involving risks to subjects or others. The AAMC is a non-profit organization representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies. Our member institutions perform more than half of the extramural research sponsored by NIH, and biomedical and other health sciences research involving human subjects takes place at all of them. Most of our institutions have obtained or are in the process of seeking accreditation of their human research protection programs from the Association for the Accreditation of Human Research Protection Programs.

The AAMC fully supports the OHRP effort to provide clear guidance in this area in order to strengthen human subjects protections while also obviating wasteful redundancies, unnecessary reporting, and growing frustration of both IRB members and investigators. The AAMC commends the OHRP on the clarity of the guidance, and regards the examples provided as especially helpful. However, we have one large concern to bring to your attention.

The guidance includes a note on page 2 that states:

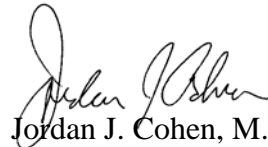
“For some HHS-conducted or -supported research, the Food and Drug Administration (FDA) and the HHS agency conducting or supporting the research (e.g., the National Institutes of Health [NIH]) may have separate regulatory and policy requirements regarding the reporting of unanticipated problems and adverse events. Anyone needing guidance on the reporting requirements of FDA or other HHS agencies should contact these agencies directly.”

Capt. Michael Carome, M.D.
Office for Human Research Protections
January 11, 2006
Page two

The AAMC believes strongly that an urgent need exists to harmonize the regulatory and policy requirements of the various HHS and other federal agencies for the reporting of unanticipated problems and adverse events; the same is true for human research protection regulations more broadly. Discordant guidance from different agencies puts institutions in an untenable position and creates confusion and anxiety where none should exist. For AAMC members, the need is especially pressing for requirements promulgated by the NIH and FDA. Six years ago, then-Secretary Shalala issued a strong call for harmonization of the human subjects protection regulations of NIH and FDA. Although we are given to understand that both agencies are making efforts to harmonize and are preparing suitable guidance, disappointingly little has been accomplished to date. In the strongest terms, we endorse trans-agency harmonization to the maximum possible extent, and we urge that the overlapping guidance provided by multiple agencies cross-reference each other and explicitly identify areas that are the unique purview of a particular agency.

The AAMC appreciates the opportunity to comment on the proposed guidance. We enthusiastically endorse this effort by OHRP and urge the Office to pursue its objectives boldly. Should you wish to discuss these ideas further, please contact Howard B. Dickler, M.D., Director for Clinical Research, at hdickler@aamc.org or 202-828-0567.

Sincerely,



Jordan J. Cohen, M.D.