

AAU Association of American Universities
AAMC Association of American Medical Colleges

July 30, 2009

Standards Revision
AAHRPP
2301 M Street, NW, Suite 500
Washington, DC 20037

Reference: Comment on the Proposed Revised Accreditation Standards and Accreditation Period

Dear AAHRPP:

The Association of American Universities (AAU) is the association of 60 leading U.S. public and private research universities whose member institutions perform roughly 60 percent of federally funded university-based research, and award more than half of all Ph.D. degrees earned in our country.

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 131 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 nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

The AAU and AAMC appreciate the opportunity to comment on the Proposed Revised Accreditation Standards of the Association for Accreditation of Human Research Programs (AAHRPP). The Associations especially appreciate AAHRPP's effort, in response to those who have gone through or are going through the accreditation process, to produce a set of Proposed Revised Standards that is far more streamlined, far more logically organized, and much less internally duplicative than the current Standards. We believe most of the changes will be helpful to those institutions that are accredited and to those seeking accreditation. That said, we urge AAHRPP to consider substantive revisions regarding a few of its Proposed Revised Standards. We also request an opportunity to review our comments—and others we have heard from our constituents—with the AAHRPP Board and you, in the near future and as appropriate.

Each of the Proposed Revised Standard or Element is quoted, followed by the AAU's and AAMC's comments, below.

Standard I.4.C. The Organization or Researchers involve community members in the design and implementation of research and the dissemination of results, when appropriate.

The Associations support the involvement, as appropriate, of community members in community-based research. But not all research is community based, and community involvement is not appropriately part of every protocol. Exactly how community members should be involved in design, implementation, and dissemination of research is also unclear. The Associations suggest that community involvement, while highly appropriate and desirable in some kinds of research, should not be addressed in a separate Standard, but rather should be incorporated into an Element under Standard III-1. At a minimum, the Associations support moving the phrase in this Standard, "when appropriate", to modify the verb "involve" so that the Standard would read in part "The Organization or Researchers involve, when appropriate, community members...."

Standard I-6: The Organization has and follows written policies and procedures to ensure that research is conducted so that financial and other interests are identified and managed, minimized, or eliminated.

The Associations strongly object to the revisions in the wording of the new Standard I-6, for the reasons provided under our comments, below, to each of this Standard's three Elements, and urges AAHRPP to revise the wording of the Standard as well as its Elements.

Element I.6.A. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate financial interests of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program, and to separate competing Organizational interests from ethics review functions.

The AAMC has recommended since 2002 that institutions adopt institutional conflict of interest policies, and renewed that recommendation, with the Association of American Universities, in 2008. However, both Standard I-6 and Element I.6.A. are too broad, too vague, and have no referent that would enable the establishment of outer limits of institutional responsibilities. There are three major problems with both the Standard and the Element.

The first problem involves a major conceptual difficulty, that is, the substitution in the new version of the Standard and Element of the phrase "financial interests" for the phrase financial "conflicts of interest". This substitution of "financial interests" represents a serious departure from accepted norms. The issue of concern centers on those financial interests that could inappropriately affect the research in question as explained below, and these interests are routinely referred to by regulation and by the regulated community as financial conflicts of interest, NOT financial interests generally. We urge AAHRPP to abandon this inappropriate phrasing.

The focus of applicable regulation, the Associations' and other national organizations' recommendations, institutional policies, and, we believe, accreditation standards should be financial conflicts of interest. To reliably identify financial conflicts of interest, an institution must start by examining a subcategory of financial interests, that is, those that are reasonably related to the research project in question (and in this case, human subject research project). Current regulation places the responsibility of making this relatedness determination on the Investigator in the case of individual financial conflicts of interest, but the Associations have recommended that institutions assume this responsibility. Wherever the responsibility lies, the fact that it is necessary to consider all financial interests before one can determine what subset relates to the research in question does not mean that all financial interests are thus subject to management, reduction, or elimination, nor does it mean that the focus of the standard should shift from financial conflicts of interest to all financial interests.

According to regulation, which is the only external referent that institutions have with respect to this area, the last step in an inquiry is to determine whether or not, in the words of existing PHS regulation of individual financial conflicts of interest for example, the interest "could directly and significantly affect the design, conduct, or reporting of the PHS-funded research". Only if the answer to the last inquiry is affirmative has a financial "conflict of interest" been identified and thus subject to management, minimization, or elimination. The question does not arise unless and until a financial interest is identified as a financial conflict of interest, and the reasoning is no different when the focus shifts from individual to institutional conflicts of interest.

The second problem with the Standard and the Element is the extension of both to “financial and other interests” as those that should be identified and managed, minimized, or eliminated. The Associations strongly disagree with this extension and urge AAHRPP to eliminate it. Institutions should NOT be occupied in a process described as the identification, management, reduction, or elimination of non-financial interests. In this regard, please see our comments to Element I.6.C., below.

The third problem with Element I.6.A. relates to describing the required policies as those that “separate competing Organizational interests from ethics review functions.” The Associations have long recommended that our member institutions adopt and implement institutional conflict of interest policies, and we support, as is more fully stated in our comments to Element II.1.B., an accreditation Element that requires institutions to adopt and implement such policies. If AAHRPP believes that an accreditation standard should be created for institutional conflicts of interest policies insofar as human subject research is concerned, AAHRPP should refer to it by the name that is used both in the regulatory and academic research community, institutional conflicts of interest, rather than referring to such policies as those that “separate competing Organizational interests from ethics review functions.” The message is otherwise highly confusing.

Moreover, it is inappropriate to select one technique (separation of function) that may be used in the management of institutional financial conflicts of interest or in the prevention of some (but certainly not all) institutional financial conflicts of interest as the surrogate name for an institutional conflicts of interest policy. The phrase, “separate competing Organizational interests from ethics review functions”, should be deleted and a revised Element II.1.B. should be inserted that references the necessity for policies on institutional financial conflicts of interest in human subjects research, if that is the intent of this Element. If it is not, then this Element should be clarified and re-proposed for comment.

Element I.6.B. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate individual financial interests of Researchers and Research Staff. The Organization works with the IRB or EC in ensuring that financial interests are managed, minimized, or eliminated, when appropriate.

This Element presents the same concerns regarding the change of the phrase financial “conflicts of interest” (used appropriately in the comparable current Element) to “financial interests”. The phrase is misaligned with its apparent purpose, meaningless in terms of management, reduction, or elimination, and confusing in its apparent extension of accreditation purview into areas for which there are no external definitions or referents. Moreover, the appropriate focus on “conflicts of interest” rather than on “financial interests” is retained in Element II.1.C. and should be retained in this Element I.6.B. as well. Again, AAHRPP should abandon the “financial interests” wording.

Element I.6.C. The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate interests – other than financial – of Researchers and Research Staff that could bias research. The Organization works with the IRB or EC in ensuring that the interests are managed, minimized or eliminated, when appropriate.

This entirely new Element is unworkable, and the Associations are strongly opposed to any attempt to extend accreditation standards into “other than financial” interests. There is no definition of what such interests would comprise (with the exception of the matter already addressed in Element II.1.C). For example, are unstated motives the target, for example, professional ambition? How would one reliably identify it, or manage it?

What about reputational interests? What about desire for promotion or for publication of results? There is no reliable way for either the institution or the researcher to define such interests, identify them and then do as the Element requires. This Element has no content that is in any way amenable to community-wide definition or measurement. It should be eliminated in its entirety.

Element II.1.B. The Organization has and follows written policies and procedures to separate competing business interests from ethics review functions.

The Associations strongly support the adoption and implementation of institutional conflicts of interest policies. However any Element referring to such policies (and we assume this Element focuses on institutional conflicts of interest policies) should be couched in the language that is already established in both the regulatory community and the research community – institutional conflicts of interest. Moreover, the appearance of this item under Standard II and Element II.1.B. is confusing and suggestive of an extension of authority to the human research protection program that is inappropriate and unwise. In addition, because one of AAHRPP’s stated purposes in these proposed revisions is the elimination of duplication, this matter is adequately addressed already in revised Element I.6.A.

Element II.1.C. The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of protocols or research plans in which they have a conflict of interest, except to provide information requested by the IRB or EC.

It is noteworthy that this Element retains the phrase “conflict of interest” rather than substitutes the meaningless “financial interests”, which substitution is found in Standard I-6 and Elements I.6.A.-C. We urge AAHRPP to retain this “conflicts of interest” phrasing throughout, with the modifier “financial”.

Element III.1.B. Researchers and Research Staff identify and make transparent financial and other interests that might affect relationships with research participants or the outcome of the research and, with the Organization, identify and manage, minimize, or eliminate such interests.

Researchers and research staff should be required to follow institutional policy regarding the identification and “making transparent” of conflicts of interest rather than impose on researchers and their research staff the responsibility to “identify and make transparent financial and other interests that might affect relations with research parties or the outcome of research....” As stated in our response to Element I.6.A., both the reference to “financial interests” and to “and other interests” miss the mark by, respectively, failing to focus on those financial interests that may be problematic (financial conflicts of interest) and by attempting to cast a net so

wide that neither the Organization, nor the Researcher, nor AAHRPP can ever know whether or not there is compliance with this Element.

Element III.1.E. Researchers and Research Staff minimize risk and maximize potential benefits when designing research.

The insertion of the phrase “and maximize potential benefit” into Element III.1.E. is confusing in its implication that every study must have direct benefit to subjects. It is also confusing in its reference to benefit in connection with research design, when the applicable OHRP standard speaks in terms of risks being “reasonable in relation to anticipated benefits, if any”.

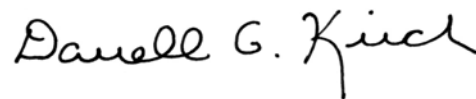
Finally, we strongly support extending the accreditation period to five years.

We appreciate the opportunity afforded by AAHRPP to the community to comment on its Proposed Revised Standards, and we appreciate your consideration of our comments.

Sincerely,



Robert M. Berdahl, Ph.D.
President
Association of American Universities



Darrell G. Kirch, M.D.
President and CEO
Association of American Medical Colleges