



July 30, 2009

Standards Revision
AAHRPP
2301 M Street, N.W., Suite 500
Washington, DC 20037

By E-mail: revision@aahrpp.org

RE: "Proposed Revised Accreditation Standards" Request for Comments

On behalf of the PRIM&R (Public Responsibility in Medicine and Research) Board, we applaud AAHRPP's considerable and ongoing efforts to strengthen protections for human subjects in research and appreciate the opportunity to submit comments on the proposed revised accreditation standards.

As you know, PRIM&R is the original founding member of AAHRPP. As you also know, we are an international, non-profit organization dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by providing educational programming and professional development services to the full array of individuals and organizations involved in biomedical, social science, behavioral, and educational research. Via a variety of conferences, regional programs, onsite courses, and webinars, PRIM&R offers those working in these and related fields access to balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research.

PRIM&R's vibrant membership community, which numbers almost 3500 individuals, includes professionals working with human subject protections, animal care and use, institutional biosafety programs, RECs, and ESCROs. Our members are administrators, researchers, research staff, institutional officials, government representatives, subject advocates, ethicists, policy makers, pharmaceutical and biotechnology personnel, and attorneys. We offer them unparalleled access to educational and professional development opportunities, including credentialing programs, two outstanding e-publications, mentoring, networking, and a wide variety of member-only web-based resources.

PRIM&R appreciates AAHRPP's significant contributions to our shared mission of advancing ethical research and protecting human subjects. In that spirit, we urge that any revisions made to the accreditation standards enhance the ethical conduct of research and the protection of research subjects.

As institutional budgets shrink, there needs to be a recognition that time spent on certain aspects of the accreditation process may take away from time that might otherwise be spent on the primary task of actually protecting human subjects. We therefore urge

AAHRPP to refrain from creating unnecessary administrative burdens and requirements that would hinder or prevent those charged with the work of the HRPP from carrying out their extensive shared responsibilities. In general, we ask AAHRPP to examine its current and proposed standards with a focus on determining their effectiveness in enhancing ethical research and protecting human subjects so as to maintain the primacy of those objectives.

While several of the proposed revisions involve clarifications and elimination of redundancies, some changes are more substantive. PRIM&R would like to comment on the following sections:

Domain I: Organization

Standard I-4: The Organization responds to the concerns of research participants
Addition of **Element I.4.C:** The Organization or Researchers involve community members in the design and implementation of the research and the dissemination of results, when appropriate. **New element.**

PRIM&R understandably supports the concept that researchers and research institutions should be responsive and sensitive to the concerns of research participants and their communities, consistent with the Belmont Report's principles of justice and respect for persons. Responsiveness to the priorities and concerns of local communities also promotes cooperation and helps prevent the exploitation of minority populations and other vulnerable groups.

PRIM&R is concerned, however, about adding an accreditation element that requires the involvement of individuals outside of the current provisions of the research and review process "when appropriate." Federal regulations address goals of diversity and representation in the review and design of research. For example, the regulations:

- Require the IRB to include in its membership a diverse group of individuals with both scientific expertise and sensitivity to community attitudes. 45 CFR 46.107(a)
- Encourage IRBs and ECs to consult with experts outside the committee when necessary to more fully inform their decisions, and
- Require researchers to provide information on the study design and implementation. 45 CFR 46.111(a)(1).

We are not aware of any data that demonstrate that "community" members' input into the "design and implementation" of research projects have an impact on the protection of human subjects. In terms of the design of research, researchers who are trained in scientific methods and basic science, are in the best position to propose and find approaches to answering specific research questions with the oversight of IRBs and ECs. Moreover, the *design* of research involves technical matters that are not common knowledge for the general population. At times, of course, individual researchers may find it useful or even essential to consult with community members. This, though, should be decided by the researchers and IRBs or ECs on a case-by-case basis.

In addition, the proposed language, "as appropriate," is vague and, in our opinion, does not define *when* community involvement would be useful. Furthermore, we do not believe that an accrediting body can or should determine on a case by case basis when community input is "appropriate."

Another problem with this proposed requirement is that there is no generally accepted definition of the term “community,” no universally agreed up means of determining who can or cannot represent a community, and no established process for involving community members.

Given these problems and the vagueness of the proposed element, we suggest that AAHRPP not adopt this requirement, as it would be difficult, if not impossible, to implement and evaluate and as it would not, in our opinion, demonstrably further the goal of ethical research.

Domain I: Organization

Addition of **Standard I-3:** The Organization’s transnational research activities are consistent with the principles set out in its Human Research Protection Program and meet the same levels of protection of research participants as research conducted in the Organization’s principal location while complying with local laws and cultural context.

New standard.

Needless to say, PRIM&R strongly supports any effort to provide the maximal level of protection to all research subjects, *wherever* they are located. However, PRIM&R is concerned about the application of this new element because may be the case that local laws or, particularly, local customs, require different levels of “protection” depending on how that term is interpreted.

For example, if written consent by a research subject was required in the U.S. for a particular project, what would be required if that research was conducted in a culture where written documents were not the norm, or were even suspect? Would a verbal consent process afford the same “protection” in AAHRPP’s view?

Similarly, it might be the case that a substance that would not be used in the U.S., because it presents an unreasonable risk in the U.S. context might be appropriate and favorably considered in other parts of the world. For example, there has been recent discussion of using DDT to kill malarial mosquitoes in those areas where malaria is epidemic, even though DDT would not be used in the U.S. Does this amount to unequal “protection?”

If the standard required that the same “principles” apply to transnational research with consideration for local customs, practices, and laws, this would be more clear than also requiring the same “protections.” Such standards would permit justifiable variations in the application of the principle and, indeed, may even require greater “protections” in some transnational research in resource-scarce countries.

Domain I: Organization

Addition of **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. **New standard.**

Addition of **Element I.6.C:** The Organization has and follows written policies and procedures to identify and manage, minimize, or eliminate interest—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. **New element.**

As with so many other organizations, PRIM&R strongly supports efforts to eliminate, minimize or manage financial conflicts of interest. However, there is little or no consensus on what constitutes a non-financial conflict of interest. This has been a topic discussed at many of our conferences, and it is fair to say that it is a matter of great contention.

Not every personal or academic interest necessarily compromises the integrity of the researcher in the design and conduct of scientific studies. A researcher's interest in publishing research and achieving tenure is sometimes described as a "non-financial conflict of interest," whereas the researcher's personal interest in these accomplishments is usually consistent with scientific excellence and sound research design.

PRIM&R believes that further consensus and empirical research about the manner in which institutions can identify and manage, minimize or eliminate non-financial conflicts of interest must be established in advance of the adoption of any specific accreditation standard. If AAHRPP decides to retain this element, it is essential that it provide examples of what constitutes "non-financial conflict of interests" and that it also provides specific guidance as to how institutions can manage, minimize or eliminate non-financial conflicts.

Domain I: Organization

Standard I-8: The Organization works with public, industry, and private Sponsors to apply the requirements of the Human Research Protection Program to all participants. Addition of **Element I.8.C:** The Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for periodically or urgently sending data and safety monitoring reports to the Organization. **New element.**

PRIM&R supports the addition of proposed Element I.8.C, which is clear and consistent with the goal of protecting human subjects. When Data Safety and Monitoring Committees are involved, written agreements between organizations and sponsors are essential to ensure that adequate communication occurs between and among the relevant parties.

Domain II: IRB or EC

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed. Addition of **Element II.1.B:** The IRB or EC has and follows written policies and procedures to separate competing business interests from ethics review functions. **New element.**

PRIM&R supports the separation of competing business interests from ethics review functions. Structures in which an IRB or EC reports to an office chiefly concerned with increasing the funding for the institution constitutes a conflict of interest. However, few top executives are entirely free of institutional financial concerns and responsibilities in

regard to the viability and profitability of their employers, so some overlap of business and ethical oversight is often intrinsic to the research enterprise. We believe that, given this reality, AAHRPP should make clear that it is not requiring any particular organizational structure, but rather that it requires “clear and transparent policies and procedures” to reduce the risk that the organization’s business interests will not supersede or negate the ethical review of human subjects research.

We also note that it is not clear how this requirement differs from existing Element I.1.D, which requires organizational-level policies that allow an IRB or EC to function independently of other organizational entities in its role in protecting research participants. We therefore suggest that this be clarified.

Domain II: IRB or EC

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed

Deletion of Former **Element II.8.A:** The Research Review Unit has and follows policies and procedures for communication among IRBs, when appropriate, for research conducted at multiple sites (e.g., multi-site clinical trials, epidemiology studies, or educational surveys). **Deleted from accreditation standards.**

PRIM&R supports the deletion of this element and retention of the standard, as proposed by AAHRPP. The deletion of this language appears to allow greater flexibility for coordinating IRB approvals among institutions in multi-center studies.

There are many practical challenges and overlapping requirements involved in ensuring human subject protections and facilitating administrative approvals within and between institutions in multi-center studies. Consistent with our June 3, 2009 response to OHRP on IRB Accountability, PRIM&R suggests that institutions engaged in research have a fundamental responsibility to ensure the rights and welfare of all individuals enrolled in their studies. However, external institutions involved in reviewing research on another organization’s behalf must also be responsible for the regulatory and accreditation requirements of the research review process. The implementation of a research project at a given institution in accordance with the approved protocol is an essential responsibility of the researcher and the institution.

Domain III: Researchers and Research Staff

Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, codes, regulations, and guidance; the Organization’s policies and procedures for protecting research participants; and the IRB’s or EC’s determinations. **(Formerly Standard III-2 with revisions)**

Addition of Element III.2.B: Researchers and Research Staff follow the requirements of the research plan or protocol, adhere to the Organization’s policies and procedures, and the determinations of the IRB or EC. **New element.**

PRIM&R strongly supports a requirement that researchers and research staff follow approved protocols and all of the applicable provisions thereof. PRIM&R also supports the implementation of organizational systems to ensure that approved protocols are followed.

Conclusion:

AAHRPP's proposed revisions to the accreditation standards demonstrate considerable sensitivity to and thoughtfulness about the contemporary challenges faced by HRPPs. We appreciate AAHRPP's efforts to respond to the concerns that have been voiced, and applaud AAHRPP's determination to ensure that best practices are employed at institutions engaged in human subjects research.

PRIM&R respectfully recommends the adoption of the above listed clarifications and/or modifications to further our shared goal of enhancing protections for human subjects.

Thank you again for offering us the opportunity to respond to these proposed revisions.

Respectfully submitted,

A handwritten signature in cursive script that reads "Joan Rachlin".

Joan Rachlin, JD, MPH
Executive Director
Public Responsibility in Medicine and Research
Cc: Board of Directors, Public Policy Committee