

As a consultant who has worked with around 20 institutions on AAHRPP accreditation (12 of which have been accredited), I am very familiar with both the positives and negatives of the existing standards. While there are some elements that are duplicative and difficult to address, overall I find the existing standards an excellent basis for evaluating an organization's human research protection program. Therefore, I approached the revisions with both anticipation and trepidation.

Overall, I would say that the revised standards are a great improvement and should facilitate the accreditation process. I strongly agree with the decision to eliminate Domains IV & V; they were always a distraction from the main effort to describe an HRPP. The three new domains address all of the important aspects of an effective HRPP. The new standards and elements have a better organization and flow than the current ones, which required a lot of skipping around to address. The only general critique I have is about the "sub-elements"; these are confusing and should be incorporated into the element as a list of aspects to be addressed.

I have attached the Comment Form which addresses my comments on specific standards and elements. However, I would also like to comment on two of the elements that were eliminated:

1.1.A I believe that eliminating this element is a mistake. There is now no longer an element that requires that an organization have written policies and procedures with appropriate authority and that are reviewed periodically.

1.2.D While many organizations have difficulty addressing this element, I have found that having a formal mechanism that "...provides for communication and interaction for its units that might be involved in the conduct of human research" significantly improves the organization's HRPP. Without an element requiring this, most organizations will not do this.

Thank you for this opportunity to comment on the revised standards.

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**Comment Form for the  
Proposed Revised Accreditation Standards**

**June 1, 2009**

Are you from an AAHRPP-Accredited Organization?     Yes     No

<i>Completion of this table is voluntary</i>	
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When you have completed your comments save this file and e-mail to:

[standards.revision@aahrpp.org](mailto:standards.revision@aahrpp.org).

## Domain I: Organization

<p><b>Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants regardless of funding source. Individuals within the Organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.</b></p>	<p>Comment: By eliminating the previous Element I.1.A, there is no longer a specific element requiring an organization to have a set of written policies and procedures with the appropriate authority and that is periodically reviewed.</p>
<p><b>Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program. Laws, codes, regulations, and guidance are applied when defining the activities that the Human Research Protection Program oversees.</b></p>	<p>Comment:</p>
<p><b>Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.</b></p>	<p>Comment:</p>
<p><b>Element I.1.C. The Organization has and follows written policies and procedures that allow the IRB or EC to function independently of other organizational entities in its role in protecting research participants.</b></p>	<p>Comment: There should be an element that requires a clear statement of the authority of the IRB</p>
<p><b>Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Organization. These policies and procedures are available to Sponsors, Researchers, Research Staff, research participants, and the IRB or EC.</b></p>	<p>Comment:</p>
<p><b>Element I.1.E. The Organization has and follows written policies and procedures for an education program that evaluates, and contributes to the improvement of, the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.</b></p>	<p>Comment:</p>

<p><b>Element I.1.F. The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.</b></p>	<p>Comment:</p>
<p><b>Element I.1.G. The Organization has and follows a process in policies and procedures that identifies applicable laws in the localities where it conducts research and takes them into account in the review and conduct of research.</b></p>	<p>Comment:</p>
<p><b>Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants, taking into consideration the research activities that the Organization conducts or oversees.</b></p>	<p>Comment: Why is this a separate Standard?</p> <p>Why isn't an element in Standard I.1?</p> <p>Standards without Elements are difficult to apply.</p>
<p><b>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.</b></p>	<p>Comment: Same as above</p>
<p><b>Standard I-4: The Organization responds to the concerns of research participants.</b></p>	<p>Comment: The title of the Standard does not reflect all that is covered in the</p>

	Elements.
<p><b>Element I.4.A. The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol.</b></p>	Comment:
<p><b>Element I.4.B. The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate.</b></p>	Comment:
<p><b>Element I.4.C. The Organization or Researchers involve community members in the design and implementation of research and the dissemination of results, when appropriate.</b></p>	<p>Comment: How is an organization to determine when this is appropriate? Too vague.</p>
<p><b>Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, codes, regulations, and guidance. The Organization also measures and improves, when necessary, the effectiveness and efficiency of the Human Research Protection Program.</b></p>	Comment:
<p><b>Element I.5.A. The Organization conducts audits or surveys, or uses other methodologies to assess compliance with the policies and procedures and the efficiency and effectiveness of the Human Research Protection Program.</b></p>	Comment:
<p><b>Element I.5.B. Based on objective data, the Organization identifies strengths and weaknesses of the Human Research Protection Program, makes improvements, when necessary, and monitors the effectiveness of the improvements.</b></p>	Comment:

<p><b>Element I.5.C. The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.</b></p>	<p>Comment:</p>
<p><b>Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The Organization works with the IRB or EC to ensure that participants are protected when non-compliance occurs.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>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</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment: Non-financial COI is difficult to identify or evaluate. It would be better to require that Researchers and Research Staff be educated on possible non-financial COI</p>

	<p>and provide a mechanism for them to</p> <p>report such to the IRB</p>
<p><b>Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.</b></p>	<p>Comment:</p>
<p><b>Element I.7.A. The Organization secures assurances from the Sponsor that the manufacture and formulation of investigational or unlicensed test articles conform to legal and regulatory requirements.</b></p>	<p>Comment:</p>
<p><b>Element I.7.B. The Organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles meets organizational standards relating to pharmacy requirements, inventory control, and documentation.</b></p>	<p>Comment: Mention of "pharmacy requirements" is not always appropriate to medical devices. It would be better to leave that out.</p>
<p><b>Element I.7.C. The Organization has and follows written policies and procedures for compliance with federal regulations governing emergency use of an investigational or unlicensed test article.</b></p>	<p>Comment:</p>

<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element I.8.A. The Organization has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate.</b></p>	<p>Comment:</p>
<p><b>Element I.8.B. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written plan with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element I.8.D. Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.</b></p>	<p>Comment:</p>
<p><b>Element I.8.E. When participant safety could be directly affected by study results, the Organization addresses in the written agreement with the Sponsor how results will be communicated to study participants.</b></p>	<p>Comment:</p>
<p><b>Domain II: IRB or EC</b></p>	
<p><b>Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed.</b></p>	<p>Comment:</p>
<p><b>Element II.1.A. The IRB or EC has and follows written policies and procedures requiring protocols or research plans to be reviewed by individuals with appropriate scientific or scholarly expertise.</b></p>	<p>Comment:</p>
<p><b>Element II.1.B. The Organization has and follows written policies and procedures to separate competing business interests from ethics review functions.</b></p>	<p>Comment: While this is appropriate for</p>

	<p>commercial IRBs, it is not particularly relevant to other IRBs. This should be incorporated into the requirement for an institutional COI policy.</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element II.1.D. The IRB or EC has a qualified chair and vice-chair and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed.</b></p>	<p>Comment: Not all IRBs have a Vice-Chair</p>
<p><b>Element II.1.E. The IRB or EC is comprised of members to permit appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. One or more unaffiliated members are represented on the IRB or EC, and one or more members can represent the general perspective of participants.</b></p>	<p>Comment: The requirement to have members represent participants is not a regulatory requirement and is very difficult to evaluate. Who is qualified to do this?</p>

	<p>Must it be a former participant? A</p> <p>community activist? A physician?</p> <p>Compliance with his will be very difficult.</p>
<p><b>Element II.1.F. The IRB or EC meets regularly, members have sufficient time to review materials prior to meeting, and meeting workloads allow for appropriate discussion of each item on the agenda</b></p>	<p>Comment:</p>
<p><b>Standard II-2: The IRB or EC evaluates each research study to ensure the protection of participants.</b></p>	<p>Comment:</p>
<p><b>Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations. Such policies and procedures indicate that exemption determinations are not to be made by Researchers or others who might have a conflict of interest regarding the studies. This function may be delegated to an entity other than the IRB or EC</b></p>	<p>Comment:</p>
<p><b>Element II.2.B. The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable regulations. This function may be delegated to an entity other than the IRB or EC.</b></p>	<p>Comment: This is generally addressed in</p> <p>the policies and procedures which address</p> <p>II.2.A; therefore, it would be best not to</p>

	<p>make it a separate Element, but incorporate it into II.2.A</p>
<p><b>Element II.2.C: The IRB or EC has and follows written policies and procedures for conducting operations and meetings by the convened IRB or EC.</b></p> <ol style="list-style-type: none"> <li>1. <b>Element II.2.C.1 – Development and use of the agenda</b></li> <li>2. <b>Element II.2.C.2 – Recording of members present and absence, alternate members, and establishment of quorum</b></li> <li>3. <b>Element II.2.C.3 – Determination and management of IRB member conflict of interest.</b></li> <li>4. <b>Element II.2.C.4 – Use of materials and technology during meetings</b></li> <li>5. <b>Element II.2.C.5 – Voting mechanisms and options</b></li> <li>6. <b>Element II.2.C.6 – Role of the chair and vice-chair</b></li> </ol>	<p>Comment: Sub-Elements are very confusing. Rather just list what should be included in addressing this Element.</p>
<p><b>Element II.2.D. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.</b></p> <ol style="list-style-type: none"> <li>1. <b>Element II.2.D.1. – Initial review</b></li> <li>2. <b>Element II.2.D.2. – Continuing review</b></li> <li>3. <b>Element II.2.D.3. – Review of proposed modifications to research studies</b></li> </ol>	<p>Comment: Same as above</p>
<p><b>Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by the expedited procedure.</b></p> <ol style="list-style-type: none"> <li>1. <b>Element II.2.E.1. – Initial review</b></li> <li>2. <b>Element II.2.E.2. – Continuing review</b></li> <li>3. <b>Element II.2.E.3. – Review of proposed modifications to research studies</b></li> </ol>	<p>Comment: Same as above</p>
<p><b>Element II.2.F. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to research participants or others.</b></p>	<p>Comment:</p>
<p><b>Element II.2.G. The IRB or EC has and follows written policies and procedures for suspending or terminating previously approved research, if warranted, and for reporting these actions as appropriate.</b></p>	<p>Comment:</p>

<p><b>Element II.2.H. The IRB or EC has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.</b></p>	<p>Comment:</p>
<p><b>Standard II-3: The IRB or EC approves each research study according to criteria based on applicable laws, codes, regulations, and guidance.</b></p>	<p>Comment:</p>
<p><b>Element II.3.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing potential sources of risk and measures to minimize risk. The analysis of risk includes a determination that the risks to participants are reasonable in relation to potential benefits to participants and to society.</b></p>	<p>Comment:</p>
<p><b>Element II.3.B. The IRB or EC has and follows written policies and procedures for reviewing the plans for data and safety monitoring in research protocols, when applicable, and determines that the plans provide adequate protection for participants.</b></p>	<p>Comment:</p>
<p><b>Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants, when applicable.</b></p>	<p>Comment:</p>
<p><b>Element II.3.D. The IRB or EC has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and participation payment arrangements and permits them when they are fair, accurate, and appropriate.</b></p>	<p>Comment:</p>
<p><b>Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants during and after their involvement in the research</b></p>	<p>Comment: Is this referring to HIPAA? If so, make it explicit. In the past, AAHRPP has not addressed HIPAA.</p>
<p><b>Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research and during and after the conclusion of the research.</b></p>	<p>Comment:</p>
<p><b>Element II.3.G. The IRB or EC has and follows written policies and procedures to evaluate the consent process.</b></p>	<p>Comment:</p>

<p><b>Element II.3.H. The IRB or EC has and follows written policies and procedures to evaluate the consent document and to require that the Researcher and Research Staff properly document the consent process.</b></p>	<p>Comment:</p>
<p><b>Element II.3.I. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.</b></p>	<p>Comment:</p>
<p><b>Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.</b></p>	<p>Comment:</p>
<p><b>Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to vulnerable populations and ensuring that additional protections are provided as required by the proposed research and applicable law, codes, regulations, and guidance.</b></p>	<p>Comment:</p>
<p><b>Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.</b></p>	<p>Comment:</p>
<p><b>Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to informed consent requirements in protocols for emergency situations and appropriately reviews such protocols.</b></p>	<p>Comment: Although this may be relevant to this Standard, it seems more appropriate to include it in Standard I-7</p>
<p><b>Standard II-5: The IRB or EC maintains documentation of its activities.</b></p>	<p>Comment:</p>
<p><b>Element II.5.A. The IRB or EC maintains a complete set of materials relevant to review of the research for a period of time sufficient to meet legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures</b></p>	<p>Comment:</p>
<p><b>Element II.5.B. The IRB or EC documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.</b></p>	<p>Comment:</p>

## Domain III: Researchers and Research Staff

<p><b>Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.</b></p>	<p>Comment:</p>
<p><b>Element III.1.A. Researchers and Research Staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element III.1.C. Researchers and Research Staff employ sound study design in accordance with the standards of the discipline.</b></p>	<p>Comment:</p>
<p><b>Element III.1.D. Researchers and Research Staff determine that the resources necessary to protect participants are present before conducting each research study.</b></p>	<p>Comment:</p>
<p><b>Element III.1.E. Researchers and Research Staff minimize risk and maximize potential benefits when designing research.</b></p>	<p>Comment:</p>
<p><b>Element III.1.F. Researchers and Research Staff recruit participants in a fair and equitable manner, weighing the potential benefits of the research against their vulnerability and the risks to participants.</b></p>	<p>Comment:</p>
<p><b>Element III.1.G. Researchers and Research Staff employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of participant comprehension and voluntary participation.</b></p>	<p>Comment:</p>

<p><b>Element III.1.H. Researchers and Research Staff have a process to address participants' concerns, complaints, or requests for information.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable federal, state, and local regulations; relevant professional standards; and the Organization's policies and procedures regarding the protection of research participants.</b></p>	<p>Comment:</p>
<p><b>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.</b></p>	<p>Comment:</p>
<p><b>Element III.2.C. Researchers and Research Staff report unanticipated problems involving risks to participants or others, non-compliance, suspensions or terminations of research, complaints, data and safety monitoring reports during a research study in accordance with applicable laws, codes, regulations and guidance, the Organization's policies and procedures, or the IRB's or EC's requirements.</b></p>	<p>Comment:</p>
<p><b>Element III.2.D. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities.</b></p>	<p>Comment:</p>

When you have completed your comments save this file and e-mail to: [standards.revision@aahrpp.org](mailto:standards.revision@aahrpp.org).