

FASEB Comments on Proposed Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation Standards

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.*

Consistent with Element I.1.G, FASEB believes that organizations should have policies and procedures in place to identify all applicable laws in the localities where it conducts research. However, we also believe that organizations have a responsibility to provide guidance to researchers, research staff, IRB members, and other relevant personnel regarding interpretation and compliance with these laws. This is especially important in cases where federal, state, and local laws differ. FASEB encourages AAHRPP to revise this element to reflect these organizational responsibilities. This revision will clarify the role of organizations in matters of regulatory compliance, assist personnel in adhering to human subjects protections laws, and improve the protection of human research participants.

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.*

FASEB encourages AAHRPP to revise proposed element I.4.C by eliminating the requirement that the organization or researchers involve community members in the *design* of research. While community members have an important role to play in IRB review of research as well as in research implementation and dissemination (particularly with regard to working with individuals from special populations), we do not believe that community involvement is appropriate during the study design process. Decisions about research design should be made by scientific experts. Although there may be cases in which investigators find it valuable to consult with community members on methodological issues, investigators are the best judges of when such consultation is appropriate. This element would enable AAHRPP to second guess investigators' decisions in this regard, potentially disrupting research that has been approved by an IRB. It may also compel researchers to involve community members in research design when it is not necessary, an outcome that could be detrimental to the research process. Identifying community members who have the expertise to evaluate scientific research is likely to be difficult; in some research settings it may not even be possible. Moreover, soliciting input from non-experts is unlikely to improve project design. To the extent that community members are involved in research design, implementation, or dissemination, it is important that their role be clearly communicated—there should be no expectation that an investigator will make changes to a study protocol that he or she does not judge to be in the best interest of the science.

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.*

FASEB believes that maintaining the public trust and preventing the introduction of bias into medical research is absolutely critical. We, therefore, support the inclusion of proposed element I.6.B, which states that the organization has written policies and procedures to identify, manage, minimize, or eliminate *financial* interests. We are, however, concerned about the inclusion of element I.6.C, which directs organizations to develop policies and procedures for addressing *non-financial* interests. Financial interests can be relatively objectively defined and quantified, enabling organizations to set a threshold at which a financial interest is considered to be a potential conflict. They can develop

policies to identify, manage, minimize, or eliminate those conflicts based on that threshold. While there may be situations in which investigators are biased by interests of a non-financial nature, these interests are neither objectively defined nor quantifiable. As such, we do not believe it is possible to set a threshold limit on which non-financial conflict of interest policies can be based. The inclusion of this element will place a considerable burden on institutions and researchers while doing little to prevent the introduction of bias into research studies or to protect research participants.

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.*

This element is unclear as to the circumstances under which medical care for research participants should be addressed by the organization and the sponsor. It also neglects to address the importance of providing information on the provision of medical care to research participants. Consistent with federal regulations, we believe that in research involving more than minimal risk, participants must be provided with an explanation as to the availability of medical treatment in the event of a research related injury as part of the informed consent process. To ensure the delivery of specified care, the language in the consent form should be consistent with any agreement between the organization and the sponsor regarding the provision of medical care. We encourage AAHRPP to revise this element to reflect the importance of communicating information about medical care to research participants and ensuring that this information is consistent with any agreement between the organization and the sponsor.

Standard II.4. *The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.*

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*

FASEB encourages AAHRPP to include a definition of vulnerable populations in Standard II.4 and Element II.4.A. Without a definition, investigators, IRBs, and AAHRPP auditors acting in good faith may interpret vulnerable populations differently. This could compromise the protection of research subjects, delay protocol approval, or lead to the disruption or termination of ongoing, IRB approved research projects. As in the current standards (Element II.4.C), we recommend that AAHRPP adopt a definition of vulnerable populations consistent with applicable federal regulations.

Element III.1.C. *Researchers and Research Staff employ sound study design in accordance with the standards of the discipline.*

FASEB believes that researchers and research staff should always employ sound study design in accordance with the standards of the discipline. In our current research system, human research project proposals are typically subject to multiple levels of scientific review, including by peer review panels and institutional review boards. Indeed, federal regulations mandate that in order to approve federally funded research, IRBs must determine that the research employs procedures which are consistent with sound research design. Likewise, AAHRPP element II.1.A states that “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.” We are concerned that the inclusion of Element III.1.C would encourage yet another level of review by AAHRPP and would give

AAHRPP accreditors the latitude to reinterpret the decisions made by review panels and IRBs regarding study design. We encourage AAHRPP to revise Element III.1.C to reflect that research must be determined by qualified scientific reviewers to be of sound study design in accordance with the standards of the discipline.

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

Human subjects research should be designed to minimize risk and maximize potential benefits, and we believe it is the role of the IRB or EC to evaluate the risks and benefits of a research project. Element III.1.E would give AAHRPP the authority to determine whether research risks and benefits are appropriately balanced and to reinterpret the risk/benefit decisions made by qualified IRBs or ECs. FASEB encourages AAHRPP to revise this element to reflect that research must be determined by an IRB or EC to minimize risk and maximize benefits.