



AAHRPP Standards: Incorporating Flexibility, Compliance and High Performance

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Association for the Accreditation of
Human Research Protection Programs, Inc.[®]

Before We Begin

Background Assumptions:

Regulatory Guidance may be incorporated into Standards:

e.g. who may serve as an unaffiliated member

AAHRPP Standards may require **demonstrating** that a regulatory requirement is followed

e.g. Regulatory approval criteria are considered for approval of research projects

Organizational Policies are followed

e.g. Organizational policies regarding individual financial conflicts are followed even when it may exceed regulatory criteria

Individuals tasked with a responsibility will be **knowledgeable** about the relevant regulations and guidance

Ethical Standards such as the **Belmont Report** are also included

AAHRPP Standards

- I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

AAHRPP Standards

I.4. B. Conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate.

QA and QI Activities

- Standard I.5.: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Organizational Conflict of Interest

- I.6.A. The Organization has and follows written policies and procedures to identify, manage and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.

Contract Provisions

- I.8.B. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety or participants or influence the conduct of the study.
- I.8.C. When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization.

Contract Provisions

- 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.
- I.8.E. When participant safety could be directly affected by study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants

Grounded in Regulations; AAHRPP Standard Operationalizes

- Element II.1.B. The IRB or EC has qualified leadership (e.g. chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.
- Element II.1.A. One or more members who represent the general perspective of participants.
- Element II.2.B. This element looks for a process to address the ethical concerns of research that is exempt.

Grounded in Regulations: AAHRPP Standard Operationalizes

- Element II.2.C. Policies should have a minimum attendance requirement for the unaffiliated member.
- Element II.2.H. The IRB of EC has and follows policies and procedures for managing multisite research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as the reporting of unanticipated problems or interim reports.



Thank you!

Questions and Discussion