

Human Research Protection Program Plan

Related Accreditation Elements: I.1.A, I.2.A, I.2.B, I.3.B, I.3.M, II.1.D, and V.2.B

A human research protection program should have a written plan that describes the organization's overall strategy to protect participants. A written plan is analogous to a strategic plan, business plan, or a corporate compliance plan. The plan may be a comprehensive document or a single document that references other policies and procedures. The plan should be approved at the level of the organizational official or higher.

Recommended Content:

Suggested elements of a human research protection plan:

1. The governing principles and standards for the human research protection program.
 - a. The organization's mission or goal statement regarding the protection of research participants.
 - b. The ethical principles that the organization follows to govern the conduct of research involving participants.
 - c. Applicable laws that govern the conduct of research involving participants and when they are applied.
2. A description of the research conducted or overseen by the organization.
 - a. Criteria for defining when an activity is research involving human participants. Such criteria should include all activities the organization is legally obligated to cover (e.g., DHHS and FDA regulations). Note: these criteria differ from those for whether a protocol must be reviewed by the organization's IRB.
 - b. For organizations with a federal assurance of compliance, the criteria for when the organization becomes "engaged in research."
 - c. For organizations with a federal assurance of compliance, the criteria for when someone acts as an agent of the organization.
 - d. The types of research typically overseen or conducted by the organization and the categories of participants typically involved in research.
 - e. The types of research or research involving certain categories of participants that the organization does not conduct or oversee.
3. The overall organizational structure for protecting research participants.
 - a. Designation of title of the person who has overall responsibility for the human research protection program and the authorities granted to this person.
 - b. The components of the organization and the relationships among them that are involved with the conduct or oversight of human research protection.
 - c. The roles and responsibilities for each component.

4. The organization's activities that enhance compliance with regulations and the requirements of the human research protection program.
 - a. The actions taken so that activities do not commence until the research has received all required approvals.
 - b. A description of the plan to maximize compliance with the regulations and policies and procedures of the organization.
 - c. How employees or agents of the organization may communicate concerns or suggestions to the organizational official, and how those concerns and suggestions are addressed.

- d. How employees or agents of the organization may communicate allegations of coercion or undue influence to the organizational official, and how those allegations are handled.
- e. Plans for periodic review of the human research protection program, including, but not limited to, resources, policies and procedures, personnel, composition and number of IRBs, and participant outreach.
- f. Other activities designed to enhance compliance.