STANDARD I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

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.

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.

ELEMENT I.1.C.: The organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.

ELEMENT I.1.D.: The organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to sponsors, researchers, research staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.

ELEMENT 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.

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.

ELEMENT I.1.G.: The organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.

ELEMENT I.1.H.: The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.

STANDARD I-2: The organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the organization conducts or oversees.

STANDARD I-3: The organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the organization's principal location while complying with local laws and taking into account cultural context.

STANDARD I-4: The organization responds to the concerns of research participants.

> **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 or plan.
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> **ELEMENT I.4.B.**: The organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.
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> **ELEMENT I.4.C.**: The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

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.

> **ELEMENT I.5.A.**: The organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization makes improvements to increase compliance, when necessary.
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> **ELEMENT I.5.B.**: The organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program.
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> **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.

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 Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

STANDARD I-6: The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.

ELEMENT 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.

ELEMENT I.6.B.: The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

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.

ELEMENT I.7.A.: When research involves investigational or unlicensed test articles, the organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.

ELEMENT I.7.B.: The organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

ELEMENT I.7.C.: The organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.

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.

> **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.
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> **ELEMENT 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 of participants or influence the conduct of the study.
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> **ELEMENT 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.
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> **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.
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> **ELEMENT 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.

STANDARD I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.