AAHRPP®

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

Addendum: The Hashemite Kingdom of Jordan

Governing Research Involving Human Participants

General Comments

Standards and Elements listed below address areas where policies and procedures must address specific requirements in the Law of Clinical Studies and the Stem Cell By-law.

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

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.	Research, or a clinical study, includes therapeutic clinical studies performed on sick or healthy volunteers, and non-therapeutic clinical studies performed on healthy volunteers in terms of effectiveness, kinetics, bioavailability and bioequivalence of a drug. Organizations that conduct other types of research in addition to clinical studies extend their HRPP to all non-clinical research: • "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or an equivalent definition.
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.	Clinical studies must be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice.
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.	Written materials require the IRB or EC to review the scientific review performed by the Clinical Studies Committee in the Ministry of Health.
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.	Clinical studies may only be conducted by: • Public and Private Hospitals which possess technical potential to provide the required emergency and intensive care, and laboratory tests. • Universities, academic institutions, specialized scientific research institutions, and pharmaceutical manufacturing companies, provided they have the required technical potential in compliance. In case they do not have such potential, any of them may perform the clinical part of the study at authorized Hospitals and centers.

	Analyses of biological samples related to clinical studies shall only be done by laboratories approved by the Ministry of Health, which have the requirements for conducting such analyses and assure they are accurate and precise. Private companies are not allowed to use human embryotic human stem cells for research.
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.	Clinical studies may only be conducted with approval of the Ministry of Health, based upon a recommendation from the Clinical Studies Committee. • Written materials describe the process for obtaining approval from the Ministry of Health. • Written materials describe the process for the IRB or EC to verify approval by the Clinical Studies Committee.
Domain II: Institutional Review Board or Ethics Committee	
Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.	
Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.	Each IRB or EC has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization, including: • No IRB or EC has members who are all males or all females • No IRB or EC has members who represent a single profession • Each IRB or EC has at least one member whose primary concerns are in scientific areas • Each IRB or EC has at least one member whose primary concerns are in nonscientific areas • Each IRB has at least one member who is a legal advisor • Each IRB has a representative from the local community • Each IRB or EC has at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization. • Each IRB or EC has at least one member who represents the perspective of research participants. Written materials describe the process to request approval from the Ministry of Health for the formation of an IRB or EC.
Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.	
Element II.2.D. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.	At convened meetings: • At least two thirds of the members have to be present, including the chair or deputy.

1. Element II.2.D.1. – Initial review **2. Element II.2.D.2. – Continuing review** **3. Element II.2.D.3. – Review of proposed modifications to previously approved research**	• At least one member whose primary concerns are in a non-scientific area has to be present. For research to be approved it has to receive the approval of a majority of members present at the meeting.
Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.	Written materials describe the review and reporting to the Clinical Studies Committee in the Ministry of Health of any negative, unknown, or serious side effects related to the drug, which would appear during or after the clinical study. • The maximum time frame allowed between the recognition of a reportable event and fulfilling reporting requirements is no longer than 30 days. In addition to reviewing negative, unknown, or serious side effects related to drugs, written materials must also address the review of non-clinical unanticipated problems involving risks to participants or others (such as breeches of confidentiality).
Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.	
Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.	For studies involving biological samples, the consent document must contain a statement the samples cannot be used for purposes other than study purposes.
Domain III: Researcher and Research Staff	
Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.	
Element III.2.A. Researchers and Research Staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.	The researcher conducting the clinical study must ensure: • The research team consists of scientifically qualified members with enough practical experience to perform the study in accordance with its requirements. The head of this team shall be responsible for executing this study in the most proper manner. • The availability of one or more physicians to supervise the conduct of the clinical study and to be responsible for medical care during the clinical study.