



AAHRPP®

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

Addendum: India Law
Governing Research Involving Human Participants

General Comment

Standards and Elements listed below address areas where policies and procedures must address specific requirements in Schedule Y of the Drugs and Cosmetics Rules, Good Clinical Practices for Clinical Research in India (India GCP), and the Ethical Guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research.

Domain I: Organization

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

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.

Research must be conducted in accordance with the ethical principles contained in the current revision of Declaration of Helsinki and the following additional principles (India GCP, Section 2.4.1 a-1):

- Principles of essentiality.
- Principles of voluntariness, informed consent and community agreement.
- Principles of non-exploitation.
- Principles of privacy and confidentiality.
- Principles of precaution and risk minimization.
- Principles of professional competence.
- Principles of accountability and transparency.
- Principles of the maximisation of the public interest and of distributive justice.
- Principles of institutional arrangements.
- Principles of public domain.
- Principles of totality of responsibility.
- Principles of compliance.

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.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.

Contracts and funding agreements must describe, before the research begins, the sponsor's plans to provide compensation for any serious physical or mental injury for which participants are entitled to compensation or agree to provide insurance coverage for an unforeseen injury whenever possible.

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.

When research is regulated by Schedule Y of the Drug and Cosmetics Rules:

- Permission to conduct the clinical trial must be obtained from the Licensing Authority in order to conduct the study, and prior to any change in the study.
- Ethics committee approval must be obtained and communicated to the Licensing Authority in order to conduct the study, and prior to any change in the study.

Studies involving drugs regulated by Schedule Y must also comply with drugs and cosmetic rules 122A, 122 B, and 122D.

Clinical trials must be registered in the Indian Council of Medical Research Clinical Trial Registry, www.ctri.in, before the trial commences.

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 Ethics Committee shall have at least seven members with appropriate gender representation:

- Basic medical scientists (preferably one pharmacologist). Should have post graduate qualification and adequate experience in their respective fields.
- Clinicians from various institutes. Should have post graduate qualification and adequate experience in their respective fields.
- Legal expert or retired judge.
- Social scientist or representative of non-governmental voluntary agency.
- Philosopher or ethicist or theologian.
- Lay person from the community.
- At least one member who represents the perspective of research subjects, such as a former or current research subjects or a research subject advocate.
- At least one member whose primary area of interest or specialization is nonscientific.
- At least one member who is independent of the hospital.
- A licensed physician, if research involving a DCGI-regulated or FDA-regulated article is involved.
- The chairperson must be from outside the hospital.
- There should be adequate representation of age, gender, and community on the ethics committee to safeguard the interests and welfare of all sections of the community.

Consultants may be used but they cannot vote.

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.

The chairperson of the committee must be from outside the organization. The member secretary should be affiliated with the organization, and conducts the business of the committee, including:

- Appointing members and specifying their defined functions
- Appointing alternate members and specifying the defined functions of alterate members
- Communicating the decisions of the ethics committee to researchers in writing, in the format specified in Schedule Y.

Members should be conversat with the provision of clinical trials and Good Clinical Practice Guideline for clinical trials in India.

Standard II-2: The Research Review Unit systematically evaluated each research protocol or plan to ensure the protection of participants.

Element II.2.C: The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.

A quorum must be present for research to be approved.

- A quorum consists of at least five ethics committee members present.
 - Basic medical scientis (preferably one pharmacologist)
 - Clinican
 - Legal expert

	<ul style="list-style-type: none"> ○ Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person ○ Lay person from the community.
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.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.	<p>The ethics committee must analyze a serious adverse effect and forward its opinion on financial compensation to the Chair of the ethics committee with a copy to Drug Controller General of India within 21 calendar days for the occurrence of the serious adverse event.</p>
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.	<p>When conducting research covered by Schedule Y of the Drugs and Cosmetics Rules, the investigator must obtain approval from the ethics committee for a patient information sheet, in addition to approval of the consent document.</p> <p>Consent documents, and changes to consent documents, must be approved by the licensing authority in addition to the ethics committee prior to implementation.</p> <p>Consent documents must include the following additional disclosures:</p> <ul style="list-style-type: none"> • Participants have a right to prevent use of his or her biological sample (DNA, cell-line, etc.) at any time during the conduct of the research. • The foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others. • The risk of discovery of biologically sensitive information. • The plans for publication, if any, including photographs and pedigree charts. • That research participants who suffer physical injury as a result of their participation in the clinical trial are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability subject to confirmation from ethics committee, and that in case of death, their dependents are entitled to material compensation. <p>Consent documents must follow the format specified in Schedule Y.</p>
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 prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.	<p>Pregnant or nursing women shall only be enrolled in research when:</p> <ul style="list-style-type: none"> • The research carries no more than minimal risk to the fetus or nursing infant. • The object of the research is to obtain new knowledge about the fetus, pregnancy and lactation. • The trial is designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants. • Women who are not pregnant or nursing are not be suitable

participants.

- Women in clinical trials are not to be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.
- Women in clinical trials are not encouraged to discontinue nursing for the sake of participation in research and in case a woman in a clinical trial decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant.
- Women who desire to undergo medical termination of pregnancy are only enrolled in research as per The Medical Termination of Pregnancy Act, GOI, 1971.
- Research related to pre-natal diagnostic techniques in pregnant women should be limited to detect the fetal abnormalities or genetic disorders and not for sex determination of the fetus as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994.

When children are enrolled in research:

- Children will not be involved in research that can be carried out equally well with adults.
- The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults.
- For studies prior to phase III the drug has a therapeutic value in a primary disease of the children.
- The settings of the research provides the child and parent adequate medical and psychological support.
- Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.
- The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- A parent or legal guardian of each child has given proxy consent.
- The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors or adolescents, unless there is no medically acceptable alternative to the therapy provided or tested, and consent has been obtained from at least one parent or guardian.

If research involves adults unable to consent, the ethics committee must consider additional safeguards to protect their rights and welfare:

- When conducting non-therapeutic research, consent must be obtained directly from the participant, unless:

	<ul style="list-style-type: none"> ○ The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally. ○ The foreseeable risks to the participants are low. ○ The negative impact on the participant’s wellbeing is minimized and low. ○ The clinical trial is not prohibited by law. ○ The opinion of the ethics committee is expressly sought on the inclusion of such participants, and the written opinion covers this aspect. ○ Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
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Domain III: Researcher and Research Staff

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Staff have the protection of the rights and welfare of research participants as a primary concern.

<p>Element III.1.C. Researchers employ sound study design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants.</p>	<p>The investigator must have qualifications prescribed by the Medical Council of India.</p>
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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.

<p>Element III.2.D. Researchers and Research Staff follow reporting requirements in accordance with applicable laws, regulations, codes, and guidance; the organization’s policies and procedures; and the IRB’s or EC’s requirements.</p>	<p>The investigator must report a serious adverse effect to the ethics committee within 10 calendar days of the occurrence of the serious adverse event.</p>
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