

Ethics Committee

An Ethics Committee is an independent group of medical and non-medical members responsible for protecting the rights, safety and well-being of participants involved in a clinical trial by reviewing and approving the trial protocol, checking the qualifications of the investigators, assessing the facilities and ensuring proper methods and materials are used to get and document participant's informed consent.

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines consistently refer to the ethics committee as the IRB/IEC, where IRB denotes the Institutional Review Board and IEC refers to the Independent Ethics Committee. IRB (Institutional Review Board) and IEC (Independent Ethics Committee) have the same fundamental role to protect the rights, safety, and well-being of participants in clinical trials. Their key differences lie mainly in terminology, geography and regulatory frameworks



Main roles and Responsibilities of Ethics Committee

Protect Participants: Ensure the rights, safety and well-being of all trial participants, especially vulnerable groups (those who cannot fully protect their interests or make decisions for themselves, such as children or people with mental health conditions)

Review Trial Documents: Evaluate the protocols, informed consent materials, investigator brochures, recruitment materials and other participant information before approval.

Assess Risks and Benefits: Check if the potential benefits of the trial justify the risks to participants

Monitor Ongoing Trials: Oversee the trial at intervals that match the level of risk to participants to ensure continued ethical conduct and participant safety

Review Informed Consent Process: Confirm that the consent process is clear, appropriate and respectful of participant's understanding

Handle Protocol Changes: Review and approve any changes to the trial protocol that could impact participant safety or rights

Special Consideration for Minors: Evaluate assent procedures for minors based on the population intended to be enrolled

Review Participant Payments: Ensure payments or reimbursements to participants are fair, timely and not coercive

Document Decisions: Keep records of all reviews, decisions and communications related to the trial

Thus, Ethics Committees protect the rights of participants and ensure ethical standards are maintained at every stage of a clinical trial, safeguarding their well-being throughout the process

IRB/ IEC Submission, Review and Approval:

IRB/IEC should review the following, where applicable:

- Study protocol and any amendments
- Informed consent , assent materials and any updates including how they will be obtained
- Investigator's Brochure or relevant product/scientific information and updates
- Information provided to participants, including the format/media used
- Recruitment advertisements and process details

- Participant compensation plans (if any)
- Ongoing safety updates
- Investigator's CV or proof of qualifications
- Any other documents needed to meet IRB/IEC responsibilities

The IRB/IEC is required to review clinical trials promptly and keep clear records showing:

- Which trial, documents were reviewed and the dates for the following:
 - approval or favourable opinion
 - Any required changes before approval
 - Disapproval or negative opinion
 - Termination or suspension of prior approval

IRB/ IEC Composition, Functions and Operations:

- The IRB/IEC should have enough qualified members with the right mix of experience to review the scientific, medical and
- ethical aspects of a clinical trial. It is recommended that the IRB/IEC should include:
 - At least five members;
 - At least one member should have a main interest outside of medical sciences, like law, community work etc.
 - At least one member should be completely separate from the trial site or institution—not connected in any way
 - Only those IRB/IEC members who are not connected to the investigator or sponsor should vote or give opinions. A list of IRB/IEC members and their qualifications should be maintained
 - The IRB/IEC should follow written procedures, keep records and meeting minutes, and comply with GCP and relevant regulations
 - The IRB/IEC should make decisions only during scheduled meetings where the minimum number of required members (quorum) is present, as defined in its written procedures
 - Only those IRB/IEC members who take part in the review and discussion should vote or give their opinion

- The investigator, site staff, or sponsor may share trial-related information, but they must not take part in IRB/IEC decisions or voting
- An IRB/IEC may invite non-members with expertise in special areas to assist in its review process

IRB/ IEC Procedures:

The IRB/IEC should set, document and follow procedures that include:

- Listing its members, their qualifications and the authority under which it operates
- Planning meetings, informing members and conducting reviews
- Performing initial and ongoing reviews of clinical trials
- Deciding how often continuing reviews should happen
- Allowing expedited review of minor trial changes, as per regulations
- Specifying no participant joins a trial before formal IRB/IEC approval
- Specifying that no changes or deviations from the protocol should be initiated without prior written IRB/IEC approval, unless urgently needed to prevent immediate harm to participants or if the changes are minor, administrative and allowed by regulations
- Specifying that the investigator or institution must promptly inform the IRB/IEC about:
 - a. Protocol changes made to prevent immediate hazards to participants
 - b. Any changes that raise risks or significantly affect how the trial is run
 - c. All suspected unexpected serious adverse reactions (SUSARs), as required by regulations
 - d. New information that could harm participant safety or impact the trial's conduct
- Ensuring that the IRB/IEC promptly notifies the investigator/institution or sponsor in writing (paper or electronically) about:
 - a. Its trial-related decisions or opinions
 - b. The reasons behind those decisions or opinions
 - c. The appeal process for those decisions or opinions

IRB/ IEC Records:

The IRB/IEC should keep all important records like procedures, member details, submitted documents, meeting minutes and correspondence as per regulations and share them if requested by regulatory authorities, investigators, or sponsors

Reference Guidelines

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS dated 2017: [ICMR_National_Ethical_Guidelines.pdf](#)

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019: As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022 : [Circulars](#)

ICH HARMONISED GUIDELINE – GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3) dated 06 Jan 2025: [ICH Official web site : ICH](#)