

Regulatory Perspectives of Clinical Trials

ICH-GCP Guidelines

Origin of ICH-GCP

- ICH started in 1990.
- ICH was formed by regulatory authorities and pharmaceutical industry experts from Europe, Japan, and the United States.
- The main aim of ICH was to make common rules for drug development and clinical research.
- Before ICH-GCP, different countries followed different rules for clinical trials.
- Because of different rules, the same drug studies sometimes had to be repeated in different countries.
- ICH-GCP helped to create one common standard so that clinical trial data could be accepted by many countries.
- The ICH-GCP guideline is also called ICH E6 Good Clinical Practice.
- The guidelines were finalized in 1996.
- ICH was originally called the International Conference on Harmonisation, and it is now known as the International Council for Harmonisation.

Principles of ICH-GCP

A. Ethical conduct of clinical trials

- Clinical trials should follow ethical principles.
- These ethical principles are based on the Declaration of Helsinki.
- The dignity, rights, safety, and welfare of participants should always be respected.

B. Risk and benefit assessment

- A clinical trial should begin only when the expected benefits are greater than the possible risks.
- The safety of the participant should be more important than the interest of science or society.
- Unnecessary risk should be avoided.

C. Protection of participants

- The rights, safety, and well-being of participants should be protected throughout the trial.
- Vulnerable participants should receive extra protection.
- Vulnerable participants may include children, pregnant women, poor people, prisoners, elderly people, mentally ill persons, and seriously ill patients.

D. Scientific soundness

- A clinical trial should be based on proper scientific knowledge.
- The study should have a clear objective.
- The study design should be strong enough to answer the research question.
- A poorly planned study is unethical because it may expose participants to risk without producing useful knowledge.

E. Approved study protocol

- Every clinical trial should follow a written protocol.
- A protocol is a detailed plan of the study.
- The protocol should explain the purpose, design, methods, treatment plan, safety measures, and data collection method.
- The protocol should be approved by an ethics committee before the study begins.

F. Informed consent

- Participants should receive complete information before joining the study.
- They should understand the purpose, procedures, risks, benefits, and their rights.
- They should join the study voluntarily.
- They should have the right to refuse or withdraw from the study at any time.

G. Qualified investigator

- The clinical trial should be conducted by qualified and trained persons.
- The investigator should have proper education, training, and experience.
- The investigator is responsible for the medical care and safety of participants during the study.

H. Proper documentation

- All clinical trial records should be written clearly and accurately.
- Proper documentation helps to prove that the study was conducted correctly.
- Trial data should be complete, reliable, and verifiable.

I. Confidentiality

- The personal information of participants should be protected.
- The identity of participants should not be revealed without permission.
- Study records should be stored safely.

J. Quality assurance

- Systems should be used to check the quality of the clinical trial.

- Monitoring, auditing, and inspection may be done to make sure that the study follows the protocol and guidelines.

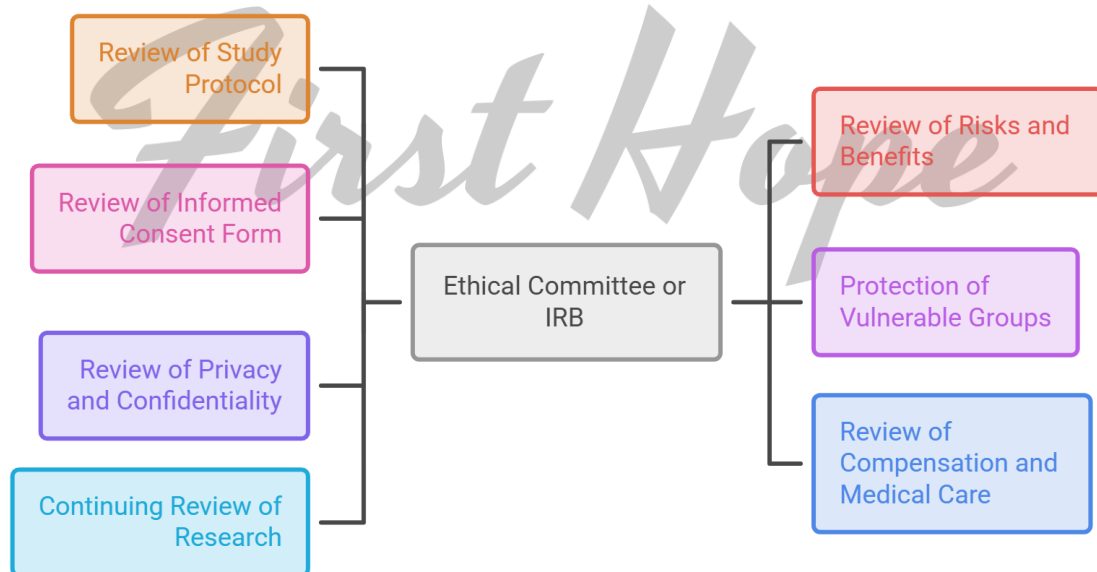
K. Safety reporting

- Any serious adverse event should be reported properly.
- Participant safety should be checked continuously during the study.
- Quick safety reporting helps prevent further harm.

Ethical Committee: Institutional Review Board

- An Ethical Committee is a group of people who review research studies involving human participants.
- It checks whether the research is ethical, safe, and scientifically acceptable.
- An Institutional Review Board is another name for an ethics committee, especially in many international settings.

Main Functions of an Ethical Committee or IRB



1. Review of study protocol

- The committee checks the complete study plan.
- It checks whether the research question is important.
- It checks whether the study design is suitable.
- It checks whether the methods are ethical and scientifically acceptable.

2. Review of risks and benefits

- The committee checks the possible risks to participants.
- It checks whether the expected benefits are greater than the risks.
- It may ask the researcher to reduce unnecessary risks.

- It does not allow studies where risks are not justified.

3. Review of informed consent form

- The committee checks whether the consent form is clear and complete.
- It ensures that the language is simple.
- It checks whether participants are informed about the purpose, risks, benefits, and rights.
- It makes sure that consent is voluntary and free from pressure.

4. Protection of vulnerable groups

- The committee gives special attention to vulnerable participants.
- Vulnerable groups may include children, pregnant women, prisoners, mentally ill persons, poor persons, elderly persons, and seriously ill patients.
- The committee checks whether extra safeguards are provided for such groups.

5. Review of privacy and confidentiality

- The committee checks how personal information will be collected.
- It checks how study data will be stored and protected.
- It ensures that the identity of participants is not revealed without permission.

6. Review of compensation and medical care

- The committee checks whether participants will receive medical care for research-related injury.
- It checks whether compensation is available according to rules.
- It also checks whether payment to participants is fair and not used as pressure.

7. Continuing review of research

- The committee may review progress reports during the study.
- It may check safety reports and serious adverse events.
- It may stop or suspend a study if participant safety is at risk.

Composition of an Ethical Committee or IRB

1. Chairperson

- The chairperson leads the committee meetings.
- The chairperson should preferably be from outside the institution to maintain independence.

2. Member secretary

- The member secretary manages documents, meeting records, communication, and committee files.

- The member secretary helps in organizing the review process.

3. Medical scientist

- A medical scientist reviews the medical and scientific parts of the study.
- This member checks whether the study methods are safe and suitable.

4. Non-medical scientist

- A non-medical scientist gives an independent scientific opinion.
- This member helps the committee avoid only medical viewpoints.

5. Legal expert

- A legal expert checks whether the study follows laws and regulations.
- This member helps protect the legal rights of participants.

6. Social scientist or philosopher

- A social scientist or philosopher reviews social and ethical issues.
- This member helps the committee understand the possible effect of research on society.

7. Lay person

- A lay person represents the general public.
- This member helps check whether study documents are understandable to ordinary people.

Ethical Guidelines for Biomedical Research and Human Participants: Schedule Y

Meaning of Schedule Y

- Schedule Y is a part of the Drugs and Cosmetics Rules, 1945 in India.
- It gives requirements for clinical trials and approval of new drugs.
- It explains how clinical trials should be planned, approved, conducted, recorded, and reported.
- It includes rules related to clinical trial permission, ethics committee approval, informed consent, safety reporting, and compensation.

Purpose of Schedule Y

- Schedule Y helps regulate clinical trials of new drugs in India.
- It ensures that clinical trials are conducted in an ethical and scientific manner.
- It protects the rights, safety, and well-being of participants.



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