Composition, Responsibilities, Procedures of IRB/IEC

Definition:

- An institutional review board (IRB), also known as an independent ethics committee (IEC) or ethical review board (ERB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.

Composition, functions and operations:

- The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects and ethics of the proposed trial.
- It is recommended that the IRB/IEC should include:
  - → At least Five members
  - → At least one member who is independent of the institution / trial site
  - → At least one member whose primary area of interest is in a nonscientific area.
  - → Only those IRB/IEC members who are independent

of the investigator and the sponsor of the trial should vote / provide opinion on a trial-related matter.

→ A list of IRB/IEC members and their qualifications should be maintained.

→ An IRB/IEC may invite non-members with expertise in special areas for assistance.

- Responsibilities:

-An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

- The IRB/IEC should obtain the following documents:

→ Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety

information, information about payments, and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.

→ The IRB/IEC should review a proposed clinical trial, within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- Approval / Favourable opinion
- Modifications required prior to its approval/favourable opinion
- Disapproval / Negative opinion
- Termination / Suspension of any prior approval/favourable opinion
- The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative, the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

- Procedures:

The IRB/IEC should establish, document in writing and follow its procedures, which should include:

1. Determining its composition (names and qualifications of the members) and the authority under which it is established.
2. Scheduling, notifying its members of, and conducting its meetings.
3. Conducting initial and continuing review of trials.
4. Determining the frequency of continuing review as appropriate.

5. Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.

6. Specifying (or otherwise) that no subjects should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

7. Specifying that no deviations from or changes of the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment.

8. Specifying that the investigator should promptly report to the IRB/IEC:

i- Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects

ii- Changes increasing the risk to subjects and/or

affecting significantly the conduct of the trial.
iii. All adverse drug reactions (ADRs) that are both serious and unexpected.
iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.

9. Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:
i- Its trial-related decisions/opinions
ii- The reasons for its decisions/opinions
iii- Procedures for appeal of its decisions/opinions

Records:

The IRB/IEC should retain all relevant records (e.g written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority (ies).

-The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.