Institutional Review Board

Process of Review

- The protocols should be submitted at least 3 weeks in advance of the meeting or 6 weeks before the study team plans to start the study.
- The ethical review is done through formal meetings and the committee do not resort to decision through circulation of proposal.
- All members review the proposals, and one primary reviewer is assigned for each proposal to review in detail.
- In case of studies that entails minimal risk (criteria will be set by the IRB), minimal risk review may be carried out instead of formal meetings. Chair, secretary & 1-2 scientific members may review the minimal risk study and arrive at decisions.
- The principal investigator is required to present at the meeting to present the study.
- Decision is made through consensus, where possible, when it appears unlikely, IRB voting is recommended.
- Most of the studies require clarifications, minor amendments, scientific justifications, or major amendments. IRB's suggestions/comments has to be incorporated into the revised version which is to be sent within 2 weeks after the meeting.
- A conditional decision on applications will be re-reviewed following revision.
- A negative decision on an application will be supported by clearly stated reasons.
- The IRB may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the risk/benefit ratio.
- The discontinuation of a trial may be recommended if the IRB finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
- Subject experts may be invited to offer their views but should not take part in the decision making process. However, her/his opinion must be recorded