

Standard Operating procedure of IIPS-IRB

The IIPS-IRB meets once in every quarter or on receiving of at least three applications for reviewing of project proposals for human subject protection strategies. The project should either be funded by the Institute or from outside research agency/organization, where any faculty of the Institute is associated either in the capacity of PI or Co-PI or consultant.

Process of submitting applications

PI(s) should submit a duly filled-in IRB application with 12 copies of the proposal and other required documents (as mentioned in the application form available on the Institute's website) to the Convener, IIPS-IRB with a prior approval of Director and Senior Professor, IIPS, Mumbai.

1. The title with the signature of Principal Investigator (PI) and Co-investigators as an attestation for conducting the study.
2. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
3. Precise description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures.
4. All other relevant documents related to the study protocol like investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.

Decision-making process

The IIPS-IRB provides a complete and adequate review of the research proposals submitted to them. Once convener of the IIPS-IRB, in consultation with the chairperson and other members decides a date, PI or Co-PI of the project are requested to make a brief presentation and explain the issues of human subject protections and strategy to address it. IIPS-IRB reviews human subject issues and strategies for protecting it, irrespective of qualitative or quantitative data. In special case, chairperson of IRB in consultation with members may decide to review the applications through circulation or even provide exemption from review if there are negligible chances of violating human subject rights, safety and threats to their life.

Certificate

Once the IRB is satisfied that the study is in no way harmful to the subjects under study, IRB convener include it in the minutes of the meeting and share with all the members. Once it is ensured that all the points discussed in the meeting are included in the minute, it is signed by the Chair person and uploaded on the Institute's website. The committee will issue an Ethical Clearance Certificate, valid for the period of study specified. The committee will also advise the researcher about the "informed consent" to be obtained from the subjects, and "confidentiality" to be maintained vis-a-vis subjects. It is responsibility of the convener to get the certificate issued within two weeks of the meeting of IRB