

Mission of Institutional Review Board/ Ethical Review Committee

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An **institutional review board (IRB)**, also known as an 'independent ethics committee' ('IEC'), 'ethical review board' ('ERB'), or "Ethical review committee" ('ERC'), is a type of committee used in research in worldwide including Nepal that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be completed. The purpose of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. Hence, all health-related research, including surveys and interventional studies, must be reviewed and approved by an IRB prior to conducting the research.

Role of an IRB: The role of an IRB is to safeguard the dignity, rights, safety and well-being of all actual or potential research participants and ensure that animals, if used for research, are treated humanely. The IRB should ensure the full review and evaluation of all ethical aspects of health-related research proposals it receives prior to any research being carried out in field and/or laboratory settings, according to ethical guidelines. The IRB should provide independent, competent, and timely review of research proposals. The tasks of the IRB should be executed free of bias and influence (political, institutional, professional, market etc). The IRB has the authority to ask for research protocol modifications, and to enforce and monitor the conduct of research projects. This includes issues of informed consent and right of all research participants (human or animal) and to suspend or stop any health-related research that violates any ethical issues. This type of supervision and monitoring is applicable to those research projects that are approved by the IRB.

Formation of IRB: Each health institution shall set up a mechanism for the establishment of an IRB or ERC and for the selection of members to the IRB. The IRB should be multidisciplinary and pluralistic. The chief executive officer or head of the institution should not be the member of any IRB. The IRB should have the freedom to work independently and decide on the merits of research-related proposals without interference from within the institutional framework. The number of members in the committee shall, in general, depend on the number of fields from which they will be drawn. However, a minimum of 7 to a maximum of 15 is suggested, with an attention to gender, age and discipline balance. The committee should include at least one member who is not affiliated with the institution. Persons with expertise in the following disciplines will be eligible for IRB membership: Public health/epidemiology/ research methodology, Biomedical/laboratory science, Clinical science, Nursing, Behavioral and social sciences, Biostatistics, Pharmacy/Pharmacologist, Law/ Teaching/ Journalism/ Community Leadership

Expedited Review: Most projects will require formal review by the full IRB, but there may be some studies that do not pose any ethical problems ("ethically minor" investigations), where there is minimum risk of distress or injury, be it physical or psychological, to the human participants. This includes outbreak studies, assessments of patient information and education. Such projects may not require review by the full committee. Similarly, under exceptional circumstances of urgency (e.g. a patient with some rare or ill understood condition, epidemics, etc.) the Member-Secretary, in consultation with other IRB members, may give expedited approval. However, the Member-Secretary has the duty to report these approvals to the Chairperson of the IRB at the next meeting of the committee. In the case of any

confusion, an application should be reviewed by the full committee.

Exemption from Review: Ethical review may not be required for studies such as quality control, method validation, or medical audit on condition that the results are not made available in a form that identifies the participants. Use of personal medical records without approaching or involving the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved. Such studies are entitled for waiver of the requirement for obtaining informed consent.

IRB's Role in Supervision and Monitoring of Health-related Research: The IRB and the institution have the responsibility to ensure that the conduct of all health-related research approved by the IRB be monitored and supervised by procedures and/or by using existing appropriate mechanisms within the institution.

In conclusion the mission of the IRB is to help researchers, postgraduate students and PhD scholars toward their important studies in a way that protects the dignity, right, safety and welfare of the research participants. All research conducted in humans must obtain an approval of the IRB. The approval for research is granted after a meticulous review. The review process is guided mainly by the principle of protection of the research participants. The IRB ensures that all the cardinal principles of research ethics e.g., Autonomy, Beneficence and Justice are taken care of in planning, conducting and reporting of the proposed research in humans.

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