



Institute of Health Systems

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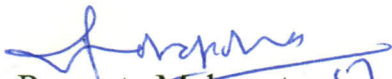
Memorandum

Sub: Ethics committee constitution and terms of reference.

- I. Research projects taken up by the Institute should follow high moral and ethical standards in choice of methodology to test various hypotheses.**
- II. There shall be an Ethics Committee to review proposals for research to assess among other considerations whether:**
 - A. The research is so designed that they would yield meaningful results that could not be obtained by other methods,
 - B. Voluntary and informed consent of the individual participating in the study is being obtained,
 - C. The study has been planned in a manner so that the degree of risk taken and inconvenience caused does not exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
 - D. Safeguards have been taken to see that the study will be conducted by persons who possess the requisite competence and qualities to carry out the research.
 - E. It will be made clear to study participants that (s)he would be at liberty to terminate participation in the study any time (s)he desires to do so.
 - F. The principal investigator / faculty in charge of the project is prepared to terminate the study or suitably modify the same if (s)he has probable cause to believe, in exercise of good faith, skill and careful judgement required of her / him, that continuation as such is likely to result in injury, disability or death to experimental subjects.
- III. Composition of the Ethics committee shall be as follows:**
 - A. The committee shall consist of about five members.
 - B. At least two of the members should be from outside the Institute.
 - C. Director of the Institute shall be a member and convenor of the committee.
 - D. Life of the committee will be permanent, with members joining it according to the terms of their appointment.
 - E. Terms of appointment of a member should include the period of validity. If no such period is mentioned, then it shall be assumed that the appointment is valid for a period of one year from the date of first meeting scheduled after communication of the letter of appointment.

IV. Rule of business:

- A. An executive summary of the research proposal covering treatment of ethical considerations in the study design shall be prepared by the principal investigator and made available to members of the committee sufficiently in advance.
- B. A copy of the full research proposal shall be made available in the Institute library for reference by any member of the committee.
- C. The principal investigator should be available at the time of ethics committee meetings to clarify any issues that may arise during the course of discussion on the particular project. In cases where the principal investigator is also a member of the committee, a member of the research team may be designated to explain and answer questions about the project.
- D. If for any reason the principal investigator can not be available at the time of the committee's meeting, a member of the research team should be designated to present the methodological details of the project as may be required by the committee.
- E. The committee after examining the details of a proposal, may either certify that the project has obtained the committee's clearance as such or with specific conditions, or advise appropriate modifications to methodology so as to meet social ethical considerations.


Prasanta Mahapatra, 5/11/98
President