ETHICAL GUIDELINES OF FAKHRUDDIN ALI AHMED MEDICAL COLLEGE & HOSPITAL, BARPETA

Background

Development of Guidelines for the Ethics Committee

The Ethics Committee of Fakhruddin Ali Ahmed Medical College & Hospital, Barpeta, though has been functioning, keeping in view ICMR guideline of 2000; this guideline would be useful to both the Ethics Committee members as well as the faculty members submitting projects for Ethics Committee approval.

The following guidelines have been prepared for consideration of the Ethics Committee. These have been formulated on the basis of ICMR guideline (2000).

The project submitted to the Ethics Committee falls under the following categories.

1. The project funded by international and national organization as collaborative project or task project from agencies like WHO, ICMR and other organization. These projects oiginate from the founding organization and usually would have been reviewed by the respective review Committee for technical aspects. These need to be approved by the Institute Ethics Committee prior to initiating the work in the institute.

2. Institute funded research project : The projects which are submitted for institute level support from the institute research funds. The procedure will be that the technical review would complete and the ethics committee will review the same & approve for funding. In this situation time period between technical review and Ethics Committee review should be as little as possible or the two reviews could occur simultaneously.

3. Clinical Drug Trials : These are usually generated by pharmaceutical companies and have important ethical consideration. These are generally not reviewed independently for technical soundedness by external professionals from the institute other than the investigators as they are approved by Drug Controller. The Ethics Committee has a dual responsibility for looking into safety concerns of the participants as well as relevance of the clinical trial.

Medical and related research using human beings as subjects must necessarily ensure that :

1. The PURPOSE of such research is that it should be directed towards the increase of knowledge about the human condition in relation to its social & natural environment and that such research is for the betterment of all, especially the least disadvantaged.

2. Such research is CONDUCTED under conditions of dignity and well being, under conditions of professional competence, fair treatment and transparency.

3. Such research should be subjected to a regime of EVALUATION at all stages of the proposal.

General Principles

All research using the human beings as subjects of medical of scientific research or experimentation shall bear in mind the following principles.

1. Principles of essentially
2. Principles of voluntariness, informed consent & community agreement.
3. Principles of non-exploitation.
4. Principles of privacy & confidentiality.
5. Principles of precaution and risk minimization.
6. Principles of professional competency.
7. Principles of accountability and transparency.
8. Principles of maximization of the public interest & of distributive justice.
9. Principles of institutional arrangement.

10. Principles of public domain.
11. Principles of totality of responsibility.
12. Principles of compliance.

Ethical review procedures

It is mandatory that all proposals on biomedical research involving human subjects should be cleared by an appropriately constitute Institutional Ethics Committee to safeguard the welfare and the rights of the participants. The Ethics Committee is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programme till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research.

Basic responsibilities

The basic responsibility of an IEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. IECs should provide advice to the researchers on all aspect of the welfare and safely of the research participants after ensuring the scientific soundness of the proposed research.

The responsibilities of an IEC can be defined as follows –

1. To protect the dignity, rights and well being of the potential research participants.

2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

3. To assist in the development and the education of a research community responsive to local health care requirements.

Composition :

The Chairperson of the Committee will be the Principal-cum-Chief Superintendent, Fakhruddin Ali Ahmed Medical College & Hospital, Barpeta. The Institute Ethics Committee shall consist of 10 members –

1. Prof. (Dr.) B.P. Chakravarty - Chairperson
   Principal-cum-Chief Superintendent,
   Fakhruddin Ali Ahmed Medical College & Hospital, Barpeta

2. Lawyer, Mr. Gunajit Bayan - Legal Adviser

3. Dr.Dwijendra Kakati - Member
   Head of the Social Science, M.C. College, Barpeta

4. Sri Basistha Sharma, Satradhikar - Member
   Barpeta Satra

5. Dr. Prakash Sarma - Member
   Principal, M.C. College, Barpeta

6. Dr. Golap Hussain - Member
   Rtd. Jt. Director of Health Services
   Barpeta

7. Dr. (Mrs.) Arati Drka - Member
   Prof. & HOD, Deptt. of Paediatrics
   FAAMC&H, Barpeta

8. Dr. Dhiraj Das - Member
   Prof. & HOD, Deptt. of Medicine
   FAAMC&H, Barpeta

9. Dr. R. K. Kalita - Member
   Professor of Physiology
   FAAMC&H, Barpeta

10. Dr. M. K. Thakur - Member Secretary
    Prof. & HOD, Deptt. of Radiology
    FAAMC&H, Barpeta

If required subject experts could be invited to offer their views.

Terms of Reference :

1. The IEC member shall be made aware of their role and responsibilities
2. The Quorum for the ethics committee would be five members
3. The term of office of the members will be three years. The membership may be renewed. If any member resigns from the committee, a new member will be inducted with similar background.

Review Procedures:

The Ethics committee will review every research proposal on human subjects. It will ensure that a scientific evaluation has been completed before ethical review is taken up. The Committee will evolute the possible risks to the subject with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues. The ethical review will be done thorough formal meetings and will no resort to decisions through circulation of proposals.

Submission of Application:

The researcher will submit an approiate application in a prescribed format along with the study protocol at least three week in advance. The protocol will include the following-

1. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
2. Recent curriculum vitae of the Investigators indicationg qualification and experience.
3. Subject recruitment procedures.
4. Inclusion and exclusion criteria for entry of subjects in the study.
5. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any.
6. A description of plans to withdraw or withhold standard therapies in the course of research.
7. The plans for statistical analysis of the study.

8. Consent forms in English and vernacular languages
9. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
10. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to overdosage should be included.
11. Proposed compensation and reimbursement of incidental expenses.
12. Storage and maintenance of all data collected during the trial.
13. Plans for publication of result-positive or negative- while maintain the privacy and cofinentality of the study participants.
14. A statement of probable ethical issue and steps taken to tackle the same.
15. All other relevant documents related to the study protocol including regulatory clearances.
16. Agreement to comply with national and international GCP protocols for clinical trials.
17. Details of Funding agency/Sponsors and fund allocation for the proposed work.

Decision Making Process

The IEC will provide complete and adequate review of the research proposals submitted to them. It will meet as and when required to review mew proposals, evaluate annual progress of ongoing ones and assess final report of all research activates involving human beings through a previously scheduled agenda, amended wherever appropriate.

1. The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend/reject suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing.
2. A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest, which will be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes.
3. If one of the members has her/his own proposal for review, then the members should not participate when the project is discussed.
4. A negative decision will always be supported by clearly defined reasons.
5. An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit/risk ratio.
6. The discontinuation of trial will be ordered if the IEC finds that the goals of the trials have already been achieved midway or unequivocal results are obtained.
7. In case premature termination of study, notification will include the reasons for termination along with the summary of results for termination along with the summary of results for termination along with the summary of result conducted till date
8. The following circumstances require the matter to be brought to the attention of IEC.
    a. Any amendment to the protocol from the originally approved protocol with proper justification.
    b. Serious and unexpected adverse events and remedial steps taken tackle them.
    c. Any new information that may influence the conduct of the study.
9. If necessary, the applicant/investigator the protocol or offer clarification in the meeting. Representative of the patient groups or interest groups can be invite during deliberations to offer their viewpoint.
10. Subject expert may be invite to offer their views, but will not take part in the decision making process. However, her/his opinion must be recorded.
11. Meetings are to be minuted which will be approved and signed by the Chairperson.

Interim Review

Each IEC will decide the special circumstance and the mechanism when an interim review can be resorted to instead of waiting for the scheduled time of the meeting. However, decisions taken will be brought to the notice of the main committee. This can be done for the following reasons :

i) re-examination of a proposal already by the IEC :
ii) research study of a minor nature such as examination of case records etc
iii) an urgent proposal of national interest.

Record Keeping

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. Records should be maintained for the following :

i) the constitution and commission of the IEC ;
ii) the curriculum vitae of all IEC members ;
iii) standing operating procedures of the IEC ;
iv) national and International guidelines ;
v) Copies of protocols submitted for review,
vi) All correspondence with IEC members and investigators regarding application, decision and follow up;
vii) Minutes of all IEC meeting with signature of the Chairperson;
viii) Record of all notification issued for premature termination of a study with a summary of the reasons;
ix) Final report of the study including microfilms, CDs and video recordings.
x) It is recommended that all records must be safely maintained after the completion/termination of the study for at least a period of 15 years if it is not possible to maintain the same permanently.

Special consideration

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research, which require additional safe guards/protection and specific considerations for the IEC to take note of Examples of such inststances are research involving children , pregnant and lactating women, vulnerable subjects and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC should be given in writing in unambiguous terms in such instances.

General Ethical Issues

All the research involving human subjects should be conducted in accordance with the four basic ethical principles, namely autonomy (respect for person/subject) beneficence, non-maleficence (don no harm) and justice. The guidelines laid down are directed at application of these basic principles to research involving human subjects. The principal investigator is the person responsible for not only undertaking research but also for observance of the rights, health & welfare of the subjects recruited for the study. She/he should have qualification and compelince in biomedical research methods for proper conduct of the study and should be aware of and comply with the scientific, legal and ethical requirements of the study protocol.

Informed Consent process

1. ***Informed Consent of Subject :*** For all biomedical research involving human subject, the investigator must obtain the informed consent of the prospective subject or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not. Informed consent protects the individual's freedom of choice and respect for individual's autonomy. When research design involves not more than minimal risk (for example, where the research involves only collecting data from subject's records) the Institutional Ethics committee may waive off some of the elements of informed consent.

   Waiver of informed consent could also be considered during conditions of emergency. However, this would be permissible only if Ethical Committee has already approved the study or use of drug. However, the patient or the legal guardian should be informed after she/he regains consciousness or is able to understand the study.

2. Obligations of investigators regarding informed consent : The investigator has the duty to –

i. Communicate to prospective subjects all the information necessary for informed consent. There should not be any restriction on subjects right to ask any questions related to the study as any restriction on this undermines the validity to informed consent.

ii. Exclude the possibility of unjustified deception, undue influence and intimidation. Deception of the subject is not permissible. However, sometimes information can be withheld till the completion of study, if such information would jeopardize the validity of research.

iii. Seek consent only after the prospective subject is adequately informed. Investigator should not give any unjustifiable assurances to prospective subject, which may influence the subject's decision to participate in the study.

iv. As a general rule obtain from each prospective subject a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case of incompetence to do so, a legal guardian or other duly authorized representative.

v. Renew the informed consent of each subject, if there are material changes in conditions or procedures of the research or new information becomes available during the ongoing trial.

vi. Not use intimidation in any form which invalidates informed consent. The investigator must assure prospective subjects that their decision to participate or not will not affect the patient-clinician relationship or any other benefits to which they are entitled.