HUMAN RESEARCH ETHICS COMMITTEE
OF

H.M.PATEL CENTRE FOR MEDICAL CARE & EDUCATION

Standard Operating Procedures (SOP) 2005-06
For Human Research Ethics Committee

1. Objective: The objective of this SOP is to contribute to the effective functioning of the Human Research Ethics Committee of H.M.PATEL CENTRE FOR MEDICAL CARE & EDUCATION, Karamsad so that **a quality and consistent ethical review mechanism** for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR (2000).

2. Role of HREC : HREC **will review and approve all types of research proposals involving human participants** with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects. The HREC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - malaficence and Justice are taken care of in planning, conducting and reporting of the proposed research.

For this purpose, it will look into the aspects of

(i)Informed consent process,
(ii)risk benefit ratio,
(iii)distribution of burden
(iv)benefit and provisions for appropriate compensations wherever required.

It will (a) **review** the proposals before start of the study (b) **examine** compliance with all regulatory requirements, applicable guidelines and laws (c) **monitor** the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc.

The **mandate of the HREC** will be to review all research projects involving human Subjects including those for postgraduate dissertations / theses to be conducted at the Institute, irrespective of the funding agency.

3. Composition of HREC of H.M.PATEL CENTRE FOR MEDICAL CARE & EDUCATION: HREC should be multidisciplinary and multisectorial in composition. **Independence and competence** are the two hallmarks of HREC of PSMC.

The number of persons in the ethical committee should be kept fairly small (7-9, maximum 12-15 members). A minimum of five persons is required to compose a quorum.
As per ICMR Guidelines, the Chairperson of the Committee will not be the head of the institution to maintain the independence of the Committee. The Member Secretary should conduct the business of

the Committee. Other members should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.
The composition may be as follows :-
1. Chairperson
2. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

The ethical committee at PSMC can have as its members, individuals from other institutions or communities if required. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of HREC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc They should be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.
HREC, PSMC should be constituted in the following pattern:
i) A Chairperson
ii) A Deputy Chairman if need be,
iii) A Member Secretary,
iv) 5-15 members from different Departments / Specialties / disciplines or areas etc.
(vide Annexure 1)

4. Authority under which HREC is constituted: The Institutional Head constitutes the HREC based on current guidelines of ICMR.

5. Membership requirements:

a. The duration of appointment is initially for a period of 3 years
b. At the end of 3 years, as the case may be, the committee may be reconstituted, and 50% of the members may be replaced by a committee constituted by the Head of the institution, the Chairperson, HREC and the Member Secretary, HREC of PSMC
c. A member can be replaced in the event of death or discontinued someone who has not attended consecutive 3 meetings or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
d. A member can tender resignation from the committee with proper reasons to do so.
e. All members should maintain **absolute confidentiality** of all discussions during the meeting and sign a confidentiality form.
f.Conflict of interest should be declared by members of the HREC

6. Quorum requirements: The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

7. Offices : The Chairperson will conduct all meetings of the HREC of PSMC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority.

8. Independent consultants: HREC of PSMC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the HREC of PSMC.

9. Application Procedures:

a. All proposals should be submitted in the prescribed application form (Annexure 2), the details of which are given under Documentation
b. All relevant documents should be enclosed with application form
c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.
d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period: 2 weeks from the date of receiving the copy as specified in the communication or before the next meeting.

10. Documentation: (Annexure: 2) For a thorough and complete review, all research proposals should be submitted with the following documents :

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution
4. Protocol of the proposed research
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s) (Annexure 3).
8. **For any drug / device trial**, following are the minimum requirements

•All relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
•Curriculum vitae of all the investigators with relevant publications in last five years.
•Any regulatory clearances required.
•Source of funding and financial requirements for the project.
•Other financial issues including those related to insurance
•An agreement to report only Serious Adverse Events (SAE) to HREC.

•Statement of conflicts of interest, if any.
•Agreement to comply with the relevant national and applicable international guidelines.
•A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

9. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
10 Any other information relevant to the study.

11. Review procedures:

a. The meeting of the HREC should be held on scheduled intervals and additional meetings may be held as and when the proposals are received for expedited review.
b. The proposals will be sent to members at least 2 weeks in advance.
c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
d. Researchers will be invited to offer clarifications if need be.
e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
f. The decisions will be minuted and Chairperson's approval taken in writing.

12. Element of review

a. Scientific design and conduct of the study.
b. Approval of CAM research Society for proposals which have sought funding from same society.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
f. Management of research related injuries, adverse events.
g. Compensation provisions.
h. Justification for placebo in control arm, if any.
i. Availability of products after the study, if applicable.
j. Patient information sheet and informed consent form in local language.
k. Protection of privacy and confidentiality.
l. Involvement of the community, wherever necessary.
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements and applicable guidelines
o. Competence of investigators, research and supporting staff
p. Facilities and infrastructure of study sites
q. Criteria for withdrawal of patients, suspending or terminating the study

13. Expedited review: This can be done for the following reasons:
(i)Re-examination of a proposal already examined by HREC,
(ii)Research study of minor nature e.g. examination of case records,

(iii)Urgent proposal of national interest.
All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. However, decisions taken should be brought to the notice of the main committee.

14. Decision-making:

a.Members will discuss the various issues before arriving at a consensus decision.

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d.Only members can make the decision. The expert consultants will only offer their opinions.

e.Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

g.Modified proposals may be reviewed by an expedited review through identified members.

h.Rejected proposals may be reviewed by a full committee if the research proposal is presented properly and supported by appropriate evidence of validity of research problem and protocol.

15. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.
b. Suggestions for modifications, if any, should be sent by HREC.
c. Reasons for rejection should be informed to the researchers.
d. The schedule / plan of ongoing review by the HREC of PSMC should be communicated to the Principal Investigator.

16. Follow up procedures

a. Reports should be submitted at prescribed intervals for review.
b. Final report should be submitted at the end of study.
c.All serious adverse effects (SAE) and the interventions undertaken should be intimated.
d. Protocol deviation, if any, should be informed with adequate justifications.
e. Any amendment to the protocol should be resubmitted for renewed approval.
f. Any new information related to the study should be communicated.
g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
h. Change of investigators / sites should be informed.

17. Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of HREC.
b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
c. Minutes of all meetings duly signed by the Chairperson.
d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
e. Copy of all correspondence with members, researchers and other regulatory bodies.
f. Final report of the approved projects.
g. All documents should be archived for prescribed period (minimum 5 years after the submission of the final report.)

18. Updating HREC members

a. All relevant new guidelines should be brought to the attention of the members.
b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

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- Any regulatory clearances required.
- Source of funding and financial requirements for the project.
- Other financial issues including those related to insurance
- An agreement to report only Serious Adverse Events (SAE) to HREC.
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