INSTITUTIONAL ETHICS COMMITTEE

G.M.E.R.S. MEDICAL COLLEGE, SOLA, AHMEDABAD
PROTECTING PATIENTS AND GUIDING DOCTORS FOR HUMANE CLINICAL RESEARCH

Standard Operating Procedure (SOP) For Institutional Ethics Committee for Human Research

1. Objective:

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) 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.

Scope

The SOP applies to all activities performed by the Ethics Committee for Research on Human Subjects.

2. Role of IEC

IEC 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 IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken careof, in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as 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 committees will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IECs will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.

3. Composition of IEC

IECs shall be multidisciplinary and multisectorial in composition. Independence and Competences are the two hallmarks of an IEC.
The number of persons in this committee shall be 7-12
The composition shall be as follows:-
1. Chairperson
2. 1-2 basic medical scientists.
3. 2-4 clinicians from the institute
4. One legal expert (lawyer or 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

IEC shall be constituted in the following pattern:
i) A Chairperson
ii) A Deputy Chairman if need be,
iii) A Member Secretary,
iv) Other members from different Departments / Specialties / disciplines or areas.

4. Authority under which IEC is constituted:

The Institutional Head shall constitute the IEC.

5. Membership requirements & tenure:

a. The duration of appointment will initially be for a period of 3 years

b. At the end of 3 years, as the case may be, the committee may be reconstituted, and the members may be replaced by a defined procedure.

c. A member can be replaced in the event of death or long-term nonavailability 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 IEC

6. Quorum requirements:

The minimum of 5 members are required to compose a quorum. All decisions preferably should be taken in meetings and not by circulation of project proposals. In some special cases submission of comments in absentia may be allowed by the chair EC.

7. Document Submission and Review

All the documents related to studies should be submitted to all IEC members at least 7 days prior to conduct of meeting. All members should review the same before the meeting and give his/her opinion during meeting.

8. Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or member Secretary will conduct the meeting. The Member Secretary or his designee 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 Chairman before communicating to the researchers about the approval/ disapproval/ suggestions of the committee.

9. Independent consultants

IEC 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 involve only the members of the IEC.

10. Application Procedures:

a. All proposals should be submitted in the prescribed application form, the detailed under subtitles; ‘ 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.

11. Documentation:

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).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance
13. An agreement to report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.
16. 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.
17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study

12. Review procedures:

a. The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.
b. The proposals will be sent to members at least 1 week 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.

13. Element of review

a. Scientific design and conduct of the study.
b. Approval of appropriate scientific review committees.
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

14. Expedited review

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. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

15. 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 participate in the decision making process. 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. It should be quorum
h. Procedures for appeal by the researchers should be clearly defined.

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 SAEs 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

a. Signed and dated Curriculum Vitae (CV) of all members of IEC.
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.

18. Updating IEC 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.

19. Conduct of Meeting

The progression of conduct of meeting should be as follows

1 Meeting announcement – The member secretary will announce the date of the meeting.

2 Clinical Trial protocol/ Bioequivalence Protocol /Site approval presentation from Sponsor/Sponsor Representative/Principle Investigator

3 Updates on protocol approved in previous meeting.

4 Question/Answer from IEC members if any.

5 Voting with reason if not approved.

6 Minutes of meeting preparation.

7 IEC members should review not more than four protocols per meeting.

20. Archival

The committee will retain the following records for a period of at least three (3) years after the completion of a study:

i. Standard operating procedures (SOPs) in effect at the time of review
ii. Membership list at the time of review
iii. Occupation/affiliations of the members at the time of review
iv. All documents pertinent to the research proposal
v. Minutes of meetings and all correspondence with the Principal Investigator
vi. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

These records will be made available to relevant statutory regulatory authority upon request.

21. Document Discard Policy

After completion of 5 years of the study the study documents would be shredded if not indicated to archive longer.

Composition of the Committee:

Sr. No.	Name	Role	Designation
1	Dr. Kirti Patel	Chairperson	Deam , GCS Medical College
2	Dr. Mukeshkumar Vora	Member Secretary/ Clinical Pharmacologist	Professor and Head, Department of Pharmacology
3	Dr. Nitin S Vora	Member	Dean
4	Dr. H K Bhavsar	Member	Superintendent Civil Hospital, Sola, Ahmedabad
5	Dr. Parul Bhatt	Member	Professor and Head, Department of Medicine
6	Dr. Nehal Naik	Member	Professor and Head, Department of Surgery
7	Dr. Ajesh Desai	Member	Professor and Head, Department of Obstetrics and Gynecology
8	Dr. Parloop Bhatt	Member (Biological Scientist)	Associate Professor in Pharmacology, LM College of Pharmacy
9	Dr. Krina Patel	Member	Associate Professor in Dermatology
10	Dr. Shailendra Vora	Member (Social worker)	Social Worker
11	Mrs. Nayana H Bhavsar	Member/Theologist/Educationis	Project Officer, NMO
12	Mr Manoj N Popat	Member (Legal Expert)	Advocate

Committee Composition Updated Date: May 13, 2016

APPENDIX A

Confidentiality and Conflict of Interest Agreement

In the course of my activities as a member of the G.M.E.R.S. Medical College and Hospital, Sola, Institutional Ethics Committee , I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.
Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me towards a quorum for voting.

I, _____have read and accept the aforementioned terms and conditions as explained in this Agreement. I acknowledge that I have received a copy of this Agreement signed by the G.M.E.R.S. Medical College and Hospital, Sola, Institutional Ethics Committee, Chairperson and me.

_____	_____
Undersigned Signature	Date
_____	_____
Chairman	Date