University of Calicut
Standard Operating Procedures (SOP) for Calicut University Ethics Committee for Human Research

1. Objective:

(a) The objective of this SOP is to contribute to the effective functioning of the Calicut University Ethics Committee (CUEC) so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by this Committee.

(b) This Committee shall follow the Indian Council of Medical Research (ICMR) Ethical guidelines for biomedical research on human subjects.

2. Role of CUEC:

(a) The mandate of the CUEC shall be to review all biological research/research projects involving human subjects to be conducted under University of Calicut (University Departments/ Research Centres at Colleges/ Recognized Research Institutions), irrespective of the funding agency.

(b) CUEC shall 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.

(c) The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

(d) The CUEC shall take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken care of 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.

(e) CUEC shall 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 like annual reports, final reports, site visits etc.

(f) The committee shall also examine compliance with all regulatory requirements, applicable guidelines and laws.

3. Composition of CUEC:

(a) CUEC shall be multidisciplinary and multisectorial in composition.

(b) The number of persons in an ethical committee shall be kept fairly small (8-12 members).

(c) It is generally accepted that a minimum of five persons is required to compose Quorum.

3.1. The composition shall 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

(d) The Chairperson of the Committee shall be from outside the University.

(e) The Member Secretary shall be from any of the Science Departments, University of Calicut and shall conduct the business of the Committee.

(f) The CUEC shall have as its members, individuals from other institutions or communities if required.

(g) There shall be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community/society.

(h) Members shall 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.

(i) Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

(j) All the members of the CUEC shall be appointed by the Hon'ble Vice Chancellor, University of Calicut based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

3.2. CUEC shall be constituted in the following pattern:

(1)A Chairperson,

(2)A Deputy Chairman if need be,

(3)A Member Secretary,

(4)5-9members.

4. Authority under which CUEC is constituted:

The Calicut University Ethics Committee shall be constituted by the Hon'ble Vice Chancellor, University of Calicut.

5. Membership requirements:

(a) The duration of appointment shall be for a period of 3 years.

(b) At the end of 3 years the committee shall be reconstituted and 50% of the members will be replaced.

(c) A member shall 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) Chairperson or any member shall tender resignation from the committee with proper reasons to do so and shall submit the application for resignation to Hon'ble Vice Chancellor, University of Calicut.

(e) All members shall maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

(f) Conflict of interest shall be declared by members.

6. Quorum requirements:

(a)The minimum of 5 members shall be required to compose a quorum.

(b)All decisions shall be taken in meetings and not by circulation of project proposals.

7. Offices:

(a) The Chairperson shall conduct all meetings of the CUEC.

(b) If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson shall be elected from the members by the members present, who shall conduct the meeting.

(c) The Member Secretary shall be responsible for organizing the meetings, maintaining the records and communicating with all concerned.

(d) The Member Secretary shall prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the Committee.

8. Independent consultants:

(a) CUEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be.

(b) 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.

(c) They are required to give their specialized views but do not take part in the decision making process which shall be made by the members of the CUEC.

9. Application Procedures:

(a) All proposals shall be submitted in the prescribed application form provided by CUEC.

(b) All relevant documents shall 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 Research Scholar & Supervising Teacher {in case of Ph.D Research or Post-Graduate level projects/dissertation} shall be forwarded by the Head of the Departments / Institution to the CUEC.

(d) 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 {in the case of Research Project} shall be forwarded by the Head of the Departments / Institution to the CUEC.

(e) The date of meeting shall be intimated to the researcher, to be present, if necessary to offer clarifications.

(f) The decision shall be communicated in writing.

(g) If revision is to be made, the revised document in required number of copies shall be submitted within three months or before the next meeting of CUEC.

10. Documentation:

For a thorough and complete review, all research proposals shall be submitted with the following documents:

1. Name of the applicant with designation.
2. Name of the Department/ Institute/ Hospital / Field area where research will be conducted.
3. Approval letter of the University.
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address these issues.
6. Proposal shall 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 centers 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 only Serious Adverse Events (SAE) to CUEC.

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.

11. Review procedures:

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

12. 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) Subject's 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 Subjects, suspending or terminating the study.

12. Expedited review:

(a) All revised proposals, unless specifically required to go to the main committee shall be examined in a meeting of identified members convened by the Chairman to expedite decision making.

(b) Expedited review shall also be taken up in cases of nationally relevant proposals requiring urgent review.

(c) The nature of the applications, amendments, and other considerations that will be eligible for expedited review shall be specified.

13. Decision-making:

(a) Members shall discuss the various issues before arriving at a consensus decision.

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

(c) Decisions shall be made only in meetings where quorum is complete.

(d) Only members shall make the decision and the expert consultants shall only offer their opinions.

(e) Decision shall be to approve, reject or revise the proposals; Specific suggestions for modifications and reasons for rejection shall be given.

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

(g) Modified proposals shall be reviewed by an expedited review through identified members.

(h) Procedures for appeal by the researchers shall be clearly defined.

15. Communicating the decision:

(a) Decision shall be communicated by the Member Secretary in writing.

(b) Suggestions for modifications, if any, shall be sent by CUEC.

(c) Reasons for rejection shall be informed to the researchers.

(d) The schedule / plan of ongoing review by the CUEC shall be communicated to the Principal Investigator/ Research Scholar.

16. Follow up procedures

(a) Reports shall be submitted at prescribed intervals for review.

(b) Final report shall be submitted at the end of study.

(c) All Serious Adverse Events (SAEs) and the interventions undertaken shall be intimated.

(d) Protocol deviation, if any, shall be informed with adequate justifications.

(e) Any amendment to the protocol shall be resubmitted for renewed approval.

(f) Any new information related to the study shall be communicated.

(g) Premature termination of study shall be notified with reasons along with summary of the data obtained so far.

(h) Change of investigators / sites shall be informed.

17. Record keeping and Archiving:

(a) Curriculum Vitae (CV) of all members of CUEC.

(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 shall be archived for five years after the completion of Research/Project.

18. Updating CUEC members:

(a) All relevant new guidelines shall be brought to the attention of the members.

(b) Members shall 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.Financial Commitments of CUEC:

(a) All the members of CUEC shall be eligible for Sitting allowance, TA and DA as per existing rules of Calicut University.