Policy Document

Establishment of Ethical Review Committee (ERC)/ Institutional Review Board (IRB) for Research Activities of University of Central Punjab (UCP)

Directorate of Research (DOR)

1. Introduction

The Ethical Review Committee (ERC) or Institutional Review Board (IRB) is a regulatory body within institutional academic/research structure, where the group of individuals is formally appointed to scrutinize, review, and approve the proposed research studies/investigations in the context of maintaining the appropriate protocols of ethical standards in accordance with National/International rules & regulations. Usually, the research studies are of medical or clinical centric in which humans and/or living species are involved as study subjects. Further, the potential impact on the environment can also be considered within the domain of ERC/IRB. In this sense, the main responsibility of ERC/IRB is to ensure the protection of the rights, dignity, safety, and well-being of human/living species and environmental impact during the execution of research studies.

1.1 Aims of ERC/IRB

The main aims of ERC/IRB are:

a. Overall governance and management to ensure quality assessment and original scholarly work in compliance with the ethical guidelines.
b. Devising guidelines and relevant policies for the working model of ERC/IRB.
c. The protection of humans, living species, and environmental impact.
d. Withdrawal of research approval if dissatisfied with the conduct of the investigation.

1.2 Spectrum of ERC/IRB

The following research activities executed in any form such as research proposal submissions for grants, research publications, patents, thesis, and projects, should undergo through proper screening of ERC/IRB.

a. If the research involves in gathering the data from people, which is linked to their behavioral responses, reactions, opinions, measurements, and experiences or data acquired by someone else (in person, online, in writing, over the phone, or by any other means).
b. When human biological materials are used in research and the sample is taken from a human body.
c. When research uses the people's data from students/commercial records, which was previously collected by some else.
d. When secondary data is used in research, which is publicly available, publically not available, and data acquired through paid subscriptions.
e. When research requires the data of health information.

f. When research requires the data of animals or their participation.
g. When research can lead to the potential impact on the environment.

2. ERC/ IRB at UCP – Existing Practice and Rationale

At a centralized level, UCP does not contain the facility of ERC/IRB; however, an ethical committee was constituted in Faculty of Life Sciences (FOLS), which is currently in dormant state. In addition to FOLS, research taking place in other activities has implication related with human/animal life and potential impact on environment. Therefore, there is a necessity to establish the institutional ERC/IRB, which serves all the faculties.

3. Working Model of ERC/IRB at UCP

3.1 Structure of ERC/IRB and Committee Members

The Pro-Rector will approve the committee members for the period of 2 years, where the Directorate of Research will provide the assistance to Pro-Rector office in the finalization of members. During the composition of committee members in ERC/IRB, special considerations to the following factors will be given: 1) the relevant research areas will be covered to the maximum extent, and 2) the nominations will not be made public to ensure impartiality and neutrality. The Table 1 shown below describes the committee members and their respective roles and responsibilities.

Apart from the special cases, the ERC/IRB operates in standard mode i.e., the meeting will take place biannually. The procedural mechanism of submission of normal cases in the committee in the context of new registration/initiation, progress review, or requiring a clearance certificate is presented in the form of flowchart in Annex A. Any subcommittees at departmental level which are working on similar lines should adopt these guidelines.

Table 1: Committee members & their roles

Committee Members	Role and Responsibilities
Chair Pro-Rector, UCP	• Preside over meetings of committees. • Examines and resolves complaints. • In the event of a tie vote, casts the deciding vote.
Co-Chair (Dean/Senior Faculty Member)	• Assumes Chair responsibilities in her/his absence. • Participates in voting.
Members (at least two faculty member from the relevant faculties of research area under concern)	• Review of research work/projects of relevant field in an appropriate manner. • Timely submission of review reports/scores. • Expert opinions, suggestions, and resolving the conflicting matters. • Participates in voting.

Non-Medical Member (at least two Members from other faculties)	• Provides input and valuable feedback regarding overall conduct and future improvements.
External Member (at least one external member with relevant research area and expert)	• Expert opinions, suggestions, and resolving the conflicting matters. • Provides assistance in the value addition, overall conduct, and future improvements
Legal Advisor	• Provides legal implications and assessments in accordance with the law.
Secretary/Coordinator (Directorate of Research/Registrar Office)	• Acts as the committee's focal person(s) and in-charge point of contact. • Receiving of applications and activation of the review process. • Communication and correspondence with members of the committee and with applicants. • Calls a meeting of the committee in the event of a comprehensive evaluation. • Recording of minutes of each meeting. • Record keeping/maintenance of complete record of the committee such as peer-review reports, decisions etc.

3.2 Coverage & Objectives

The primary coverage of ERC/IRB revolves around the medical and clinical investigations, in which humans and/or living species are involved in as study/trial subject. In connection to this, the objective of ERC/IRB is to ensure the protection of the rights, dignity, safety, and well-being of human and living species during the execution of research studies. Moreover, ERC/IRB also covers the research studies which can lead to potential impact on the environment.

3.3 Terms of References (ToRs) of the institutional ERC/ IRB

By following the rules and regulations of ethical standards, the TORs of ERC/IRB and expected outcomes are mentioned below:

a. Policy making, modification in existing policies with evolving research trends, and overall hierarchy of review process in line with the international and/or local standards.
b. Implementation of ethical standard policy at the university level.
c. Procedural mechanism with sequential flow and guidance for the research applicants to submit their initial, ongoing, final report and publication research studies for review.
d. Proposed research study is scientifically sound and original by reviewing the study related contents and materials.
e. Protection of study subjects (animals, human beings, environment) and adherence to ethical values throughout the research project should be ensured.
f. Evaluate the scientific, medical and clinical research at all stages.

g. Conduct unbiased effective review at different stages of research studies: Preliminary designing study, on-going methodology, final report after trials are completed, and publication.
h. Coordination with National Ethics Committee (NEC), if available and ORIC/Directorate of Research, wherever necessary.
i. Formation of subcommittees, if some extra-ordinary cases under special circumstances require.

4. Research Cases for Ethical Review by ERC/IRB

In general, there are four research domains, where ethical clearance may be required from the ERC/IRB, the details of which are mentioned below:

4.1 Research proposal/projects for grants

With an aim to secure the research grants from national and international funding agencies, where the ethical clearance certificate is required for the documentation and submission process of research proposals, whether the study subjects are humans/animals or not, the role of ERC/IRB becomes inevitable. In this regard, the ERC/IRB is responsible to ensure the originality and higher standard of scholarly work presented in the research proposals while any scientific wrongdoings towards human and animal subjects are prevented if involved.

The principal investigator (PI) must apply well in advance for the ethical clearance certificate before the formal submission of his/her research proposals to the funding agencies. The complete version of research proposals including concept paper/note, research objectives & outcomes, and potential involvement of human/animal subjects etc. should be submitted to ERC/IRB as mentioned in Annex A.

It is mandatory for research community of UCP that the projects must be cleared by ERC/IRB before the commencement of the project, wherever an ethical clearance certificate is required.

4.2 Research Publication

The research publication which is derived from the research project already cleared by the ERC/IRB does not require any further clearance certificate. However, the research publication should meet the prescribed plagiarism limits as per UCP plagiarism and HEC plagiarism policies. Any misconduct in this regard can be forwarded to Plagiarism Standing Committee and serious consequences in the form of fines, suspensions, and legal proceedings may take place.

In case, a publisher demands the ethical clearance certificate for the research publication, a similar procedure can be adopted to request the certificate as mentioned in Annex A.

4.3 Research Patents

The research patent which is produced from the research project already cleared by the ERC/IRB does not require any further clearance certificate. However, any complaint with regard

to plagiarism in patents can be forwarded to IP and technology transfer committee for scrutiny, review, and verdict. Any misconduct in this regard can lead to serious consequences such as fines, suspensions, and legal proceedings may take place.

In case, any patent registering agency demands the ethical clearance certificate for the research patent, the procedure mentioned in Annex A can be followed.

4.4 M.S/M.Phil/PhD Thesis & Final Year Projects

The research thesis or projects which are produced from the findings and outcomes of the ethically cleared research projects are exempted from any clearance certificate. Nevertheless, any ethical concerns related to other research thesis/projects can be solved at the departmental level via local/departmental ethical committee, where the Deans/HoDs and supervisors can be involved as members of the committee. Note that the thesis/project research should fulfill the plagiarism requirements as per UCP plagiarism policy.

5. Ethical Clearance Certificate: Types, Request, Process and Research Lifecycle

On the basis of four research cases mentioned in Sec. 4, the applicant can apply for the clearance certificate by following the procedural mechanism mentioned in flowchart in Annex A. Mainly, the request for ethical clearance certificate can be of four types:

- Ethical Clearance Certificate for Research Proposal/Project Submission
- Ethical Clearance Certificate for On-going Research
- Ethical Clearance Certificate on Completion of Project
- Others – In case some other scenario occurs

5.1 Questionnaire/ Forms for submission

The applicant can request for the ethical clearance certificate by filling the questionnaire and submission of necessary documents as mentioned in flowchart in Annex A. The details of the Questionnaire are mentioned in Annex. B, which is based on the type of ethical clearance certificate, type of research case, risks involved, and research area. The application should be submitted well in advance, and research activity should not be initiated, unless the ethical clearance certificate is awarded.

5.2 Status of Application, Review Process, and ERC/ IRB Clearance

Once the application is submitted to the Directorate of Research, the registration email is generated.

- The complete dozier is sent to the committee members of ERC/ IRB.
- The publication/ project proposal will enter into the review process.
- If the committee members demand additional material/data, the information will be communicated to applicant via email.

In case of modifications/revisions in the light of comments of committee members, the applicant will be asked to modify the research work accordingly. Maximum of two revisions are allowed.

All the cases will be presented in ERC/IRB meeting for discussion and final decision. Based on the opinion, the final decision will be made through the majority consensus between members, which can be one of the followings:

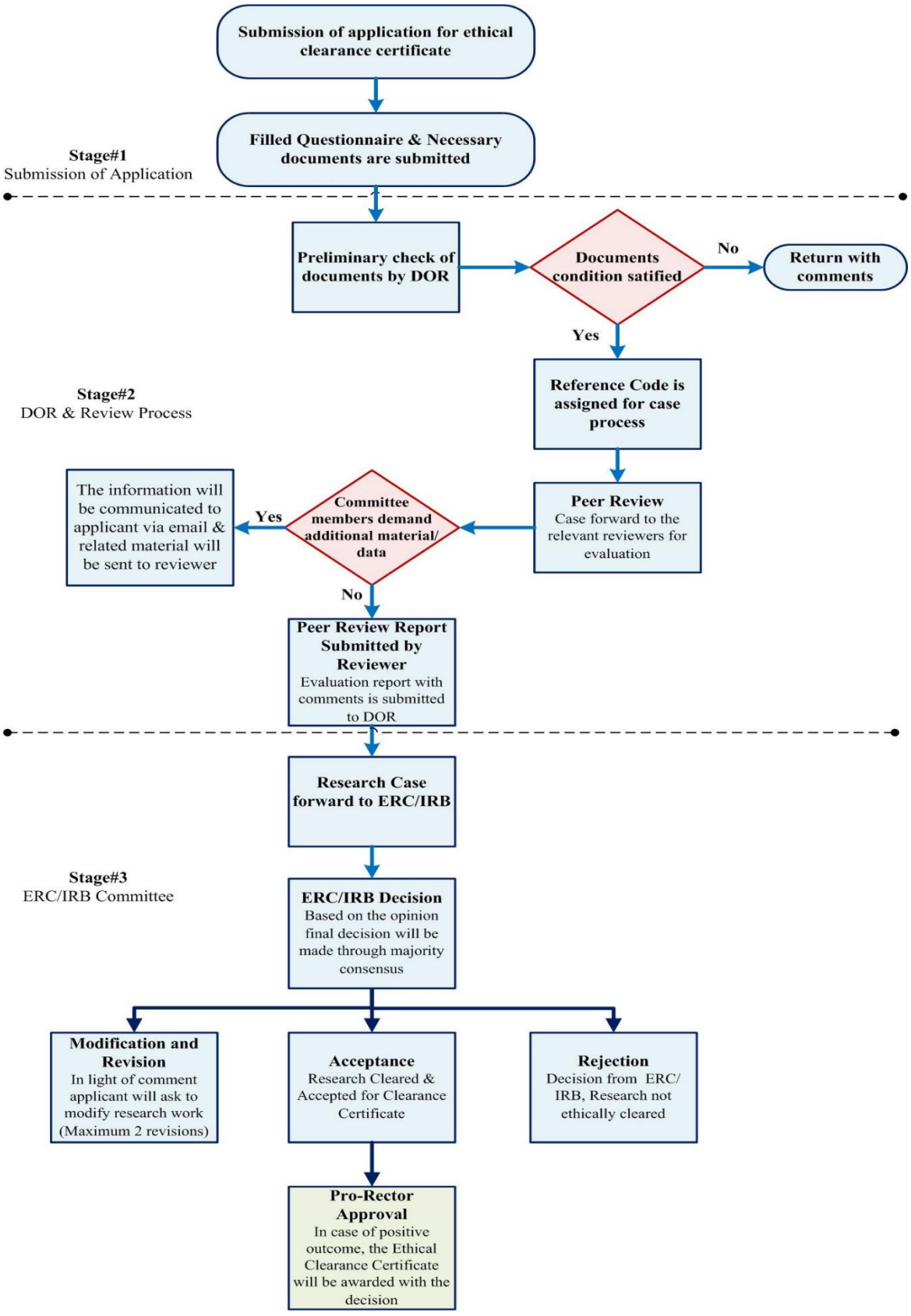
- Accepted for the award of clearance certificate
- Revisions
- Rejected

With the approval of Pro-Rector, the decision will be convened to the applicant. In case of positive outcome, the Ethical Clearance Certificate will be awarded with the decision. This complete procedure is mentioned in the form of flowchart in Annex. A.

Recommendation: ACM is recommended to approve the Establishment of Ethical Review Committee (ERC)/ Institutional Review Board (IRB) for Research Activities of UCP.

Ref - The policy is devised from ERC/IRC policy of NUST.

Annex A: The working model of ERC/IRB is illustrated below in the form of flowchart.



Annex B: Questionnaire

1. Select the type of ethical clearance certificate required from ERC/IRB
   - ☐ Ethical Clearance Certificate for Research Proposal/Project Submission
   - ☐ Ethical Clearance Certificate for On-going Research
   - ☐ Ethical Clearance Certificate on Completion of Project
   - ☐ Others – Please specify _____

2. Select the research case for which the ethical clearance certificate is needed
   - ☐ Research proposal/projects for grants
   - ☐ Research Publication
   - ☐ Research Patents
   - ☐ M.S/M.Phil/PhD Thesis & Final Year Projects
   - ☐ Others – Please specify _____

3. Is there any involvement of more than a minimal risk (toxic emissions, safety of workers/researchers/staff, environmental hazards)? If you answered yes, please explain.

4. Is there any subject data (records, equipment, premises, or vulnerable persons) in the study? If so, please ensure that the information will not be linked to specific individuals.

5. Is there any potential for a conflict of interest or an appeal?

6. Is there a risk to the indigenous population, the environment, human health, animal or fish habitats, endangered species, language, or culture?

7. Do you believe the initiative may have legal ramifications?

8. Is a literature review part of the study? If you answered yes, please list the sources.

9. Is complete version of research proposals including concept paper/note, research objectives & outcomes, and potential involvement of human/animals subjects have been incorporated in the application?
   - ☐ Yes
   - ☐ No