Annexure # 49-13

IQRA UNIVERSITY

RESEARCH ETHICS POLICY & ESTABLISHMENT OF ETHICS REVIEW COMMITTEE/ INSTITUTIONAL REVIEW BOARD

Table of Contents

1 PREFACE

Iqra University is committed to upholding a broad ethical framework in all its endeavour's, including research, teaching, business, and various activities. The primary guiding principle in ethical evaluations is to ensure that the university endeavors to promote positive outcomes rather than causing harm in the conduct of research, consulting, enterprise activities, or research projects. This document delineates Iqra University's policy and protocols for establishing ethical review processes. Faculty and students engage in diverse research activities, actively supported and encouraged by the university. At the core of high-quality research lies research integrity. Iqra University is dedicated to conduct research in alignment with the highest ethical standards, and any research with the potential to raise notable ethical concerns must undergo independent ethical review.

2 OBJECTIVE

The goal is to strengthen a culture embedded in ethics, integrity, and academic honesty throughout Iqra University's research initiatives. This entails guiding researchers, strengthening ethical considerations, and guaranteeing commitment to ethical standards.

3 SCOPE OF RESPONSIBILITIES

a) The IU Institutional Review Board (IU-IRB) is entrusted with the task of conducting comprehensive, pertinent, and timely assessments of research applications submitted by students, faculty, and staff of its various faculties.

b) The IU-IRB autonomously reviews the research ethics of these applications and addresses related matters in a thorough manner.

4 INSTITUTIONAL REVIEW BOARD COMPOSITION

Board Members	Role and Responsibilities
Chair (Dean, Faculty of Health Sciences)	• Preside over meetings of committees. • Examines and resolves complaints. • In the event of a tie vote, casts the deciding vote.
Members (at least one faculty member from the relevant faculties of the 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/Non-Scientific Member (at least two Members from other	• 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, and religious issues. • Provides assistance in the value addition, overall conduct and further improvements.

Legal Advisor (Part-time legal member)	• Provides legal implications and assessments in accordance with the law if required
Secretary/Coordinator (Director / Manager ORIC)	• Acts as the board'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. • Record keeping/maintenance of complete record of the committee such as peer-review reports, decisions

5 TENURE

The term of IU - Institutional Review Board (IU-IRB) shall be (02) years for the nominated members.

6 TERMS OF REFERENCE

a) The Institutional Review Board (IU-IRB) is meant to conduct an independent, comprehensive examination of the ethical aspects of potential research projects.
b) The integrity of the Institutional Review Board (IU-IRB) will be upheld at the highest level and will be protected from any political, institutional, or professional influences.
c) IU-IRB will ensure the proficient review and evaluation of the ethical standards of submitted research proposals.
d) The Board is entrusted with disseminating appropriate ethical research standards to all departments and researchers, ensuring strict adherence to these standards.
e) IU-IRB holds the responsibility of issuing the Research Ethics Clearance Certificate to the Principal Investigator before the commencement of any research project and its associated activities.
f) IRB will follow SOP for its functioning according to international standards.
g) No research involving living animals or objects can proceed within the University without a thorough ethical review by the IU-Institutional Review Board (IU-IRB) of the respective department.
h) The IU-Institutional Review Board (IU-IRB) is also responsible for addressing broader ethical concerns related to the University's teaching and research, particularly those involving human subjects or organizations.
i) The IRB Secretary (ORIC Dpt.) within the constituent campuses will coordinate with the relevant department's head and Deans to schedule meetings as required.

7 FREQUENCY OF MEETINGS

The IU-IRB shall hold meeting on quarterly bases or if and when required.

8 PRINCIPLES AND PROCEDURES FOR CONDUCTING RESEARCH

The following ethical values are recognized and encouraged by the Policy:

a) Prevention of harm: Throughout the study process, it's crucial for university students and staff to prioritize safeguarding respondents from physical and psychological harm. Researchers must avoid using participants for unethical purposes and take measures to protect their well-being during the study.
b) Informed consent: Obtaining informed consent is essential for ensuring participant safety. Without proper information, participants may feel deceived or mistreated by researchers. Unless there are compelling reasons for limited consent, securing full participant agreement is vital. Researchers should inform participants in advance about all relevant details influencing their willingness to join the research. The consent process should also include plans for keeping participants informed about ongoing study findings.
c) Rights of participants: Participants have the right to withdraw their consent even after initially agreeing. Researchers should specify when participants can withdraw their consent, if applicable.
d) Minimizing risk with vulnerable participants: Certain groups, such as patients, widows, or others with limited consent capacity, should be recognized as vulnerable in research. Additionally, circumstances might render other groups, like the unemployed, migrants, or refugees, vulnerable.
e) Appropriate use of rewards and incentives: Encouraging participation in research should focus on fostering genuine interest rather than solely relying on rewards. Exceptions are for cases where individuals are unable to resist such rewards.
f) Honesty and integrity: Upholding transparency, truthfulness, and sound judgment goes beyond meeting professional standards. Our commitment involves operating ethically, avoiding conflicts of interest, and refraining from decisions made solely for personal financial gain. We pledge to disclose and manage any conflicts of interest, maintain openness, and honesty in our evaluations and interactions.

9.ETHICAL FRAMEWORK

a) Research interventions must not cause harm to humans, animals, or public property.
b) Any form of risk or harm—physical, mental, emotional, financial, or otherwise—is strictly prohibited in research endeavors.
c) Research activities must not result in damage to public property, harm to the environment, or involve hazardous activities for people and animals.
d) Personal identities of research participants, respondents, or observed individuals must not be disclosed or published without their consent.
e) Upholding integrity and honesty is of utmost importance in all interactions involving humans, animals, public property, and institutional research.
f) A neutral and unbiased approach is essential concerning ethnicity, religious beliefs, gender, and
g) specific societal groups.
h) No coercion or force should be employed to compel individuals to participate in research.
i) Obtaining consent for participation and ensuring comprehension of the research activity are mandatory requirements.

10. INDEMNITY

IU-Institutional Review Board shall not be responsible for any financial damages to any research sponsor or industrial partner; including but not limited to, demands, liabilities, settlements, damages, costs, and expenses, attorneys' fees and expenses, arising out of, or in any way connected with non-performance of the researcher in any IU-IRB approved project.

11.CONTINGENCIES

a) The research ethics policy and permission of the board do not cover any commitment made by the researcher. Any dispute that arises between the researcher and the board may be referred to Director/ Manager ORIC or a subcommittee formed for dispute resolution.
b) Disputes arising between the researcher and collaborators/participants/third parties should be brought to the attention of IU-IRB.
c) It is solely the researcher's responsibility to adhere to universally acknowledged principles and norms of research ethics.
d) To contact the designated head of the IU-Institutional Review Board (IU-IRB), an official form must be submitted.

12.HUMAN-RELATED RESEARCH (DEFINITION)

All human-related research which includes one or more of the following requires ethical assessment and approval at the appropriate level:

a) Direct engagement involving physically intrusive methods, like blood sample collection.
b) Direct engagement through non-invasive methods, including laboratory experiments, interviews, surveys, questionnaires, and observations.
c) Indirect involvement via access to personal information.
d) Involvement that necessitates consent from others, like parental consent for a child participant.

13. RESEARCH CASES FOR ETHICAL REVIEW BY IU-IRB

In general, there are three research domains, where ethical clearance will be required from the IU-IRB, the details of which are mentioned below:

13.1 Research proposal/projects for grants

a) With an aim to secure the research grants from such 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 IU-IRB becomes inevitable. In this regard, the IU-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 is prevented if involved.
b) 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 along with the application to ORIC. It is mandatory for research community that the projects must be cleared by IU-IRB before the commencement of the project, wherever an ethical clearance certificate is required.

13.2. Research Publication

The research publication which is derived from the research project already cleared by the IU-IRB does not require any further clearance certificate. However, the research publication should meet the prescribed plagiarism limits as per HEC plagiarism policies. Any misconduct in this regard can be forwarded to IU-IRB and serious consequences in the form of fines and suspensions 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. NO re-opinion shall be required for publication

13.3. MBA/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 project are exempted from any clearance certificate. Nevertheless, any ethical concerns related to other research thesis/projects can be solved at the departmental level, where the Deans/HoDs and supervisors can be involved as members of the committee. Note that the thesis/project research should fulfil the plagiarism requirements as per HEC plagiarism policy. Final year projects may be received firstly by the Departmental Research Committee, and only projects needing Ethical review should be sent to IU-IRB.

14. OBTAINING ETHICAL CLEARANCE CERTIFICATE (Types, Request, Process and Research Lifecycle)

On the basis of three research cases mentioned in Sec. 13, the applicant can apply for the clearance certificate by following Annex A. Mainly, the request for an 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.

IU-IRB reserves the right to continuously monitor ethical aspects for all ongoing research projects even after a Ethical Clearance Certificate has been granted. The certification's validity will depend on the project's duration or the applicant's request.

14.1 Questionnaire/ Forms for submission

The applicant can request for the ethical clearance certificate by filling the questionnaire and submission of necessary documents. The details of the Questionnaire are mentioned in Annex. A, 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.

14.2 Status of Application, Review Process, and IU-IRB clearance

Once the application is submitted to the ORIC , the registration email is generated.

- The complete dozier is sent to the committee members of IU-IRB
- The publication/ project proposal will enter into the review process.
- If the IRB members demand additional material/data, the information will be communicated to the 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 IU-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 Registrar, the decision will be convened to the applicant. In case of positive outcome, the Ethical Clearance Certificate will be awarded with the decision.

IU-IRB would also be authorized to audit and monitor the research during ongoing research

15. DURATION FOR DATA RECORD

The duration of saving data and samples of research by the IU-IRB would be a minimum of 5 years and a maximum of 7 years.

Annex A: Questionnaire

1. Select the type of ethical clearance certificate required from IU-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?

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