



ETHICAL INSTITUTIONAL REVIEW BOARD POLICY DOCUMENT

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1. Introduction

The **Ethical Institutional Review Board (EIRB)**, operates as a critical regulatory panel within institutional research and academic architectures. This officially appointed body evaluates, monitors, and approves experimental protocols to ensure strict compliance with statutory national and global ethical guidelines. Under the mandatory directives of the **Higher Education Commission (HEC) Pakistan**, the existence of an active and functional institutional EIRB is a core prerequisite for the mandatory Office of Research, Innovation, and Commercialization (ORIC) notification and formal research funding clearances.

Within the framework of **Green International University (GIU), Lahore**, this board explicitly oversees advanced scholarly work across diverse fields, including the Faculty of Medicine and Applied Health Sciences, the Faculty of Pharmaceutical Sciences, and evolving technical domains. While traditional evaluations focus on biomedical, clinical, or nursing trials involving human participants or living models, GIU's mandate explicitly extends to assessing environmental footprints. Consequently, the core responsibility of the EIRB is to safeguard the dignity, safety, legal protections, and well-being of subjects, while aligning local academic output with HEC Pakistan's national quality and anti-plagiarism metrics.

1.1 Core Objectives of the EIRB

Aligned with **GIU Lahore's vision** of civic engagement and global scholarly excellence, alongside the compliance baselines set by HEC Pakistan, the primary targets of the EIRB encompass:

- **Quality & Integrity Assurance:** Exercising administrative oversight to validate the authenticity, originality, and moral compliance of scientific investigations in accordance with the **HEC Anti-Plagiarism Policy** and journal accreditation requirements.
- **Framework Development:** Formulating institutional policies and operational models tailored to modern, multidisciplinary, and international research collaborations.
- **Risk & Subject Safeguarding:** Minimizing risks to subjects, evaluating data-safety monitoring frameworks for clinical trials, and defending the fundamental rights of humans, animal models, and local ecosystems throughout a project's lifecycle.
- **Sanction Revocation:** Nullifying existing experimental approvals and enforcing punitive measures if researchers breach established regulatory protocols, default on ethical standards, or exhibit unsatisfactory procedural conduct.

Constitution of Ethical Institutional Review Board (EIRB)

The constitution of **Ethical Institutional Review Board (EIRB)** of Green International University comprising following members:

- | | |
|---|------------------|
| 1. (Director ORIC) | Chairman |
| 2. (Executive Director A&IP) | Member |
| 3. (Head, Department of RIT/Deputy Director Research) | Member |
| 4. (Head, Department of Rehabilitation Sciences) | Member |
| 5. (Head, Department of Pathology) | Member |
| 6. (Head, Department of Pharmacy) | Member |
| 7. (Head, Department of Law) | Member |
| 8. (Head, Green Business School) | Member |
| 9. (Head, Department of Computer Science) | Member |
| 10. (Head, Department of Health Technology) | Member |
| 11. (External Legal Expert Sr Advocate) | Member |
| 12. (External Expert Academic Evaluator) | Member |
| 13. (Dy Director ORIC Operation) | Member/Secretary |

(TORs) for the Green International University (GIU-EIRB)

EIRB is established as an autonomous regulatory gatekeeper. The board is legally and operationally mandated to review, approve, require modifications in, or reject all research protocols involving human participants, biological materials, or personal datasets conducted under the auspices of GIU to ensure absolute alignment with the Higher Education Commission.

1. Primary Mandate and Scope of Authority

- I. **Prior Clearance Rule:** No investigator at GIU shall initiate data collection, recruitment, tissue sampling, or archival data mining without an official, written EIRB Ethical Clearance Certificate bearing a unique registration ID.
- II. **Override Authority:** The decision of the EIRB regarding the ethical rejection or suspension of a research protocol is final. It cannot be overturned by any academic dean, department head, or university administrative office.
- III. **Monitoring Jurisdiction:** The EIRB retains the authority to conduct unannounced operational audits of ongoing approved studies to verify compliance with the initially cleared protocols.

The GIU-EIRB operates under four functional pillars:

Pillar A: Protocol Evaluation & Risk Mitigation

- I. **Risk-Benefit Minimization:** Evaluate all research interventions to ensure that physical, psychological, social, legal, or economic risks to human subjects are minimized and fully justified by the project's anticipated social or scientific value.
- II. **Vulnerable Population Safeguards:** Apply heightened scrutiny and mandatory protective benchmarks to protocols targeting cohorts vulnerable to institutional or financial coercion, including students, minors, prisoners, pregnant women, and economically disadvantaged labourers.
- III. **Emergency Safety Infrastructure:** Confirm that investigators have written, operational medical or psychological crisis referral pathways in place to handle unexpected adverse events during data gathering.

Pillar B: Informed Consent and Disclosure Verification

- I. **Language Accessibility Verification:** Enforce the mandate that all Patient Information Sheets (PIS) and Informed Consent Forms (ICF) are available in clear, non-technical, fluent Urdu or relevant local languages to ensure true participant comprehension.
- II. **Voluntariness Enforcement:** Review documentation to confirm that participant entry is entirely voluntary and that an explicit, penalty-free "Opt-Out" mechanism is clearly stated.

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- III. **Process Modifications:** Evaluate and rule on applications requesting a waiver of written informed consent (e.g., in low-risk, completely anonymous digital surveys) on a case-by-case basis.

Pillar C: Data Governance and Confidentiality Auditing

- I. **Anonymization Standards:** Audit data handling logs to ensure participant identities are replaced with randomized alphanumeric codes (proxy trackers) at the point of collection.
- II. **Storage and Encryption Oversight:** Verify that hardcopy consent documents are stored in secure, fireproof, restricted-access cabinets, and digital databases reside on password-protected, encrypted local server environments.
- III. **Data Lifecycle Regulation:** Enforce strict data-retention boundaries, requiring investigators to explicitly define timeline parameters for the permanent destruction or shredding of collected datasets (typically a 5-year limit post-publication).

Pillar D: Administrative and Conflict Management

- I. **Expedited vs. Full Board Routing:** Maintain a dual-review pipeline, allowing the Chairperson to grant expedited 7-working-day clearance to documented minimal-risk archival or anonymous survey projects, while routing greater-than-minimal-risk projects to the full monthly board assembly.
- II. **Conflict of Interest (COI) Adjudication:** Enforce the mandatory submission of COI declarations from all board reviewers and investigators, compelling immediate recusal from deliberations if an active personal, academic, or financial bias is detected.
- III. **Post-Meeting Turnaround SLA (Service Level Agreement):** Issue formal notification letters (Approval, Conditional Approval, or Rejection) to applicant Principal Investigators within exactly **07 working days** of the conclusion of the review cycle.

Step-by-Step SLA Breakdown

Phase 1: Minutes and Verdict Compilation-Timeline: Within Three (03) Working Days

Immediately following the adjournment of the EIRB session, the Member Secretary of the committee is required to draft the official minutes. This includes documenting the specific ethical reasoning behind every approved, conditionally revised, or rejected case. Rulings are permanently logged into the **GIU ORIC Information Management System**.

Phase 2: Executive Endorsement -Timeline: Within Two (02) Working Days

All dossiers achieving an "Approved" status are batched and routed to the office of the **Rector / (or designated academic authority)**. This step fulfills the institutional governance requirement, securing the legal executive signature necessary to authorize the release of institutional certification.

Phase 3: Applicant Notification and Certificate Issuance -Timeline: Within Two (02) Working Days

Upon receiving executive sign-off, the **GIU Directorate of Research / ORIC** must instantly execute the board's decision:

- I. **For Approved Cases:** The system automatically generates and dispatches the unique digital **Ethical Clearance Certificate** to the PI, while the physical copy is prepared for collection.

For Conditionally Revised Cases: A detailed amendment matrix compiled by the board is emailed to the PI, specifying the required protocol edits.

- II. **For Rejected Cases:** A formal Rejection Notice outlining the ethical non-compliance factors is issued, alongside a summary of the appeal process.

- III. **Maximum Turnaround Cap**

Under no circumstances shall the total elapsed time between the **conclusion of the board meeting** and the **issuance of the final certificate/verdict notification** exceed **Seven (07) Working Days**.

- IV. **Fast-Track / Expedited Exception**

For urgent international grant deadlines or minimal-risk postgraduate thesis corrections, the Chairperson may authorize a **Fast-Track SLA**, reducing the total post-meeting processing and executive signature window to **Forty-Eight (48) Hours**

2. Record Keeping and Audit Readiness

- I. **Archiving Requirement:** The EIRB Secretariat must preserve all official meeting agendas, verified attendance logs, signed member NDAs, protocol evaluation scorecards, and final clearance certificates for a minimum rolling period of **10 years** to ensure seamless audit compliance during annual HEC performance evaluations.

3. Research Categories Subject to Ethical Auditing by the EIRB

Ethical clearance from the EIRB is generally required across four distinct scientific domains, detailed as follows:

3.1 Grant Applications and Funded Research Proposals

When seeking financial endorsements from domestic or international funding bodies, an ethical clearance certificate is indispensable for the official documentation and submission process. This applies regardless of whether the research involves human/animal models. The EIRB works in tandem with the **GIU Office of Research, Innovation, and Commercialization (ORIC)** to verify the authenticity, originality, and rigorous design of the proposed work, actively preventing any scientific malpractice or risk to subjects. The Principal Investigator (PI) must apply for ethical clearance well before the funding agency's formal submission deadline. The complete dossier including the concept paper, explicit research milestones, and details regarding human or animal involvement must be routed to the EIRB as outlined in **Annex A**.

It is mandatory for the **GIU academic community** to secure formal EIRB clearance prior to launching any field operations or utilizing allocated funds.

3.2 Scholarly Publications

Manuscripts or papers derived directly from an active project already certified by the EIRB do not require separate, standalone clearance. However, all manuscripts must strictly comply with **HEC Pakistan's Plagiarism Policy** and GIU's similarity thresholds. Any evidence of data fabrication, falsification, or plagiarism will be immediately referred to the **GIU Plagiarism Standing Committee**, which can enforce severe penalties, including administrative suspension, financial fines, and formal legal action. If an international publisher explicitly requests a distinct ethical validation certificate for a specific paper; authors can request one via the fast-track mechanism detailed in **Annex A**.

3.3 Intellectual Property and Patents

Patents produced from research initiatives that hold active EIRB clearance are exempt from additional certification. Nevertheless, any copyright or academic theft allegations regarding a patent application will be sent directly to the **GIU Intellectual Property (IP) and Technology Transfer Committee** for formal auditing and final verdict. Proven intellectual misconduct will result in severe institutional penalties, asset forfeiture, and legal prosecution. Should an external patent-registering agency require standalone ethical documentation, inventors must follow the protocol in **Annex A**.

3.4 Postgraduate Theses (MS/M.Phil/PhD) and Capstone Projects

Graduate theses and final-year undergraduate projects that stem directly from larger, already-cleared institutional research projects are exempt from independent certification. For localized or low-risk departmental student projects, ethical considerations are managed directly at the departmental level through a **Local/Departmental Ethical Subcommittee**, consisting of the respective Dean, Head of Department (HoD), and the research supervisor. All student submissions must strictly pass the Turnitin similarity criteria enforced by **HEC Pakistan**.

4. Ethical Clearance Framework: Typologies, Processing, and Research Lifecycles

Based on the four categories defined in Section 4, researchers can secure certification by following the steps detailed in the **Annex A** process map. Applications fall under four primary classifications:

- a) Ethical Validation for External Funding Submissions
- b) Ethical Oversight for On-going/Active Longitudinal Studies
- c) Final Ethical Clearance upon Project Closure
- d) Specialized/Ad-hoc Scenarios (unforeseen or hybrid research designs)



4.1 Submission Protocols and Documentation

Applicants initiate the review process by completing the unified compliance questionnaire and attaching the support files designated in **Annex A**. The core questionnaire detailed in **Annex B** adapts dynamically based on the requested certificate type, the nature of the

study, identified risk variables, and the specific academic faculty. Applications must be logged early; **no experimental data collection or subject recruitment may commence** until the formal certificate is issued.

4.2 Application Tracking, Review Operations, and Final Certification

Upon submission of the complete file to the **GIU ORIC**, an automated system tracking number and registration email are generated. The process follows these operational steps:

1. **Dossier Distribution:** The complete digital folder is dispatched to the designated panel of EIRB evaluators.
2. **Peer Review Phase:** The proposal enters a rigorous compliance review. If reviewers require data extensions or safety clarification, a request is emailed to the applicant.
3. **Revisions Management:** If modifications are demanded based on panel feedback, the researcher must amend their protocol. A maximum of two revision cycles is permitted to address issues.
4. **Board Deliberation:** All finalized dossiers are presented during formal EIRB board sessions for open discussion and collective decision-making. Final rulings are achieved via a majority consensus among board members, resulting in one of three statuses:
 - a) **Approved:** Authorized for immediate certificate generation.
 - b) **Conditional Revision:** Re-evaluation required after specific protocol adjustments.
 - c) **Rejected:** Definitively denied due to unresolved ethical flaws or severe risk profiles.

*With the executive endorsement of the **Rector**, the final verdict is officially communicated to the applicant. Approved projects receive their physical and digital **Ethical Clearance Certificate**, clearing them for active research operations as shown in **Annex A**.*

ANNEX-A: The Working Model & Lifecycle of the EIRB

1. Pre-Submission Phase

Step 1: Principal Investigator (PI) prepares the research dossier.

Step 2: PI determines the application category (Grants, Publications, Patents, or Post-graduate Theses).

Step 3: PI completes the unified compliance questionnaire and compiles support documents (Annex B).

2. Administrative Screening (ORIC)

Step 4: Dossier is formally submitted to the **GIU Directorate of Research / ORIC**.

Step 5: System generates an automated registration email and tracking reference number.

Step 6: ORIC conducts a checklist screening for completeness.

- I. *If Incomplete:* Document is returned to the PI immediately for adjustments.
- II. *If Complete:* Dossier is advanced and dispatched to the designated EIRB board panel.

3. Compliance & Peer Review Phase

Step 7: The board panel conducts a rigorous compliance review.

Step 8: Evaluation of amendment requirements:

- I. *If Changes Required:* A modification request is emailed to the applicant. The PI updates the protocol and re-submits (maximum of **two revision cycles** permitted).
- II. *If No Changes Required:* The dossier directly advances to the next step.

4. Board Deliberation & Executive Verdict

Step 9: The case is presented at the formal EIRB board session for final consensus.

Step 10: The board reaches a collective ruling:

- I. **Status A: Rejected:** A definitive rejection notice detailing ethical flaws is issued to the PI, and the case is closed.
- II. **Status B: Conditional:** The protocol is routed back to the minor modification loop for specific adjustments.
- III. **Status C: Accepted:** The dossier is successfully approved by the board and forwarded for executive sign-off by the **Rector**.

5. Document Issuance

Step 11: ORIC generates and issues the official digital and physical **Ethical Clearance Certificate**.

Step 12: The researcher is officially authorized to commence experimental data collection and project operations.

Annex B: Research Ethics Assessment Questionnaire

All Principal Investigators (PIs) must complete this questionnaire via the GIU ORIC Portal prior to commencing any research activities.

Section 1: Project & Investigator Profiles

1.1 Project Title: [Full Academic Title]

1.2 Principal Investigator (PI): [Name, Designation, Employee/Student ID]

1.3 Co-Investigators / Supervisors: [Names, Affiliations].

1.4 Faculty / Department:

- I. Faculty of Medicine and Applied Health Sciences
- II. Faculty of Pharmaceutical Sciences
- III. Faculty of Engineering & Technology
- IV. Faculty of Social Sciences / Management
- V. Other: (_____)

1.5 Target Domain (From Section 4):

- I. 4.1 Funded Grant / Proposal Submission (Specify Agency: _____)
- II. 4.2 Independent Research Publication
- III. 4.3 Research Patent Application
- IV. 4.4 Postgraduate Thesis / Final Year Project (MS / M.Phil / PhD)

Section 2: HEC Pakistan Quality & Plagiarism Alignment

2.1 Initial Turnitin Similarity Index Score: 17% (Must attach official Turnitin report)

2.2 Declaration of Originality:

- I. I certify that this research is free of text fabrication, falsification, and data manipulation as per the HEC Anti-Plagiarism Policy.

2.3 Funding Disclosures:

Section 3: Human & Living Subjects Risk Screening

3.1 Will the study involve direct interaction with human participants?

Yes /No

3.2 Will the study utilize vulnerable human populations? (Check all that apply)

- I. None
- II. Minors/Children (Under 18)
- III. Hospitalized patients / Clinical subjects
- IV. Pregnant women
- V. Cognitively impaired or economically disadvantaged individuals

3.3 Will the study involve animal models or other living species?

Yes /No (If Yes, specify species and sample size: _____)

3.4 Will the study collect Personal Identifiable Information (PII) or sensitive health records? Yes / No

Section 4: Clinical & Biomedical Protocols (If Applicable)

4.1 Does this project involve clinical trials, nursing interventions, or drug testing?

Yes / No

4.2 Safety and Monitoring Framework:

- I. Informed Consent Form (ICF) attached (*Mandatory for human trials; must include Urdu translation*).
- II. Data Safety Monitoring Board (DSMB) plan established.
- III. Adverse Event (AE) reporting mechanism defined.

Section 5: Environmental & Ecological Impact Assessment

5.1 Does the experimental design pose any threat to the local ecosystem?

Yes / No

5.2 Check any potential environmental hazards involved in this study:

- I. None (Purely computational, survey-based, or theoretical)
- II. Chemical runoff / Hazardous waste disposal
- III. Biological hazards / Infectious agents
- IV. High-radiation or electronic waste footprint

5.3 Mitigation Plan:

- I. *If hazards are checked, briefly describe your waste disposal and ecological safety protocols:*
- II. (_____)

Section 6: Required Attachments Checklist

Please ensure the digital dossier contains the following PDFs before submitting to ORIC:

- I. Complete Research Proposal / Concept Note (with Methodology)
- II. Turnitin Similarity Report (Verified by Department)
- III. Participant Informed Consent Form (English & Urdu versions)
- IV. Animal Handling & Procurement Permit (*If applicable*)
- V. Supervisor/HoD Sign-off Sheet



Section 7: PI Solemn Affirmation

I, the undersigned, solemnly declare that the information provided in this questionnaire is accurate to the best of my knowledge. I understand that initiating any subject recruitment, data collection, or laboratory experimentation prior to receiving the formal **GIU Ethical Clearance Certificate** constitutes a severe breach of academic integrity and will result in disciplinary action.

Signature **of** **PI:** _____
Date of Submission: [DD / MM / YYYY]