



REGULATORY FRAMEWORK FOR THE REGISTRATION OF INSTITUTIONAL ETHICAL REVIEW BOARDS (IERBs) AND ENFORCEMENT OF COMPLIANCE



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Preamble

This Regulatory Framework is issued under the powers conferred by the Health Research Institute – NIH Act, 2021. It is aligned with the Drug Regulatory Authority of Pakistan (DRAP) Act 2012, the Pakistan Medical and Dental Council (PM&DC) Code of Conduct, and international ethical standards for the protection of human research participants.

The National Bioethics Committee (NBC-HRI) is the sole statutory body mandated to oversee the ethical governance of human health research in Pakistan. Under the provisions of the NIH Act, the NBC-HRI serves as the central authority for the accreditation and standardization of all health-related ethics review bodies.

It is mandated that *"No institutional ethical review, approval, or oversight of health-related research—whether conducted in public or private sectors—may be undertaken by a committee that is not explicitly registered with the National Bioethics Committee (NBC-HRI)."*

Consequently, the operation of an unregistered Ethical Review Board undermines the national research integrity and exposes research participants to undue risk. Operating an IERB without registration, or failing to adhere to NBC-HRI standards is a violation of national standards.

Purpose: The purpose of this framework is to:

1. Mandate the registration of all IERBs reviewing human subject research with the NBC-HRI.
2. Establish standardized criteria for the composition, function, and operation of IERBs.
3. Define prohibited acts regarding the operation of unregistered or non-compliant IERBs.
4. Establish a penalty structure for institutions and individuals conducting research approved by unregistered boards.

Scope: This framework applies to all:

- Public and private research institutions, universities, and hospitals in Pakistan.
 - Universities and degree-awarding institutions (medical and non-medical).
 - Clinical Research Organizations (CROs).
 - Hospitals and healthcare facilities conducting research.

- Principal Investigators (PIs) relying on IERB approval.
- Sponsors and funding agencies utilizing unregistered ethics committees for trial oversight.

Definition of Violations (Offenses): A violation occurs when an institution or committee fails to adhere to the *Framework for Registration of IERBs*. Specific offenses include:

- Operation of an Unregistered Board: Conducting ethical reviews and issuing approval letters without a valid NBC-HRI Registration Certificate.
- Non-Compliant Composition: Operating an IERB that fails to meet the minimum quorum, lacks a lay member, or lacks independent external membership as defined by NBC guidelines
- Failure to Renew: Continuing to review and approve research proposals after the expiration of the three-year registration period without submitting a renewal application.
- Falsification of Records: Submitting fraudulent membership lists, CVs, or meeting minutes during the registration or annual reporting process.
- Non-Compliant Composition: Operating an IERB that fails to meet mandatory composition requirements (e.g., missing Lay Member, missing external member, or lack of gender diversity).
- Failure to Report: Neglecting to submit mandatory Annual Reports or failing to report Serious Adverse Events (SAEs) to the NBC-HRI.

Bypassing National Authority: Accepting directives from foreign sponsors or international collaborators to bypass national registration requirements or ethical standards.

Conflict of Interest: Approving research where IERB members had undisclosed conflicts of interest.

IMPLEMENTATION STANDARDS (MANDATORY REQUIREMENTS)

Institutions must ensure the following standards are met to achieve and maintain registration:

1. Establishment and Independence

- The IERB must be formally constituted by the Institutional Head.
- The IERB must operate independently of administrative or financial pressure to approve specific studies.

2. Membership Requirements

- Minimum Size: Five (5) members (total must be an odd number).
- Lay Member: At least one member who is not a medical practitioner or researcher (e.g., a lawyer, teacher, or community leader) and not affiliated with the institution.
- External Member: At least one member from outside the institution.
- Gender Balance: Representation of both genders is mandatory.

3. Standard Operating Procedures (SOPs)

- The IERB must maintain written SOPs for initial review, continuing review, reporting of adverse events, and conflict of interest management.

4. Training

- All IERB members must undergo mandatory certified ethics training

CLASSIFICATION OF OFFENSES AND PENALTIES

Violations of this framework are classified based on the risk to research participants and the integrity of the national research ecosystem.

Category A: Minor Violations (Administrative Non-Compliance)

- Description: Procedural lapses such as minor delays in submitting annual reports (up to 30 days), inadvertent administrative errors in meeting minutes, or temporary lapses in quorum where no study approval was granted.

Penalties:

- Written Warning: Notice to Show Cause (NTC) issued to the IERB Chairperson and Institutional Head.

- Remediation: Mandatory submission of corrected documentation within 14 working days.
- Monitoring: Increased scrutiny of the IERB's next quarterly report.
- Category B: Major Violations (Regulatory Breaches)
- Description: Operating with an expired registration, failing to include a mandatory lay member, or approving research without a proper quorum.

Penalties:

- Suspension of Registration: Immediate suspension of the IERB's ability to review new protocols for a period of 6 months.
- Institutional Fine: Financial penalty imposed on the research organization (up to PKR 500,000 or as defined by the(..... After receiving recommendation from inquiry committee inquiry committee).
- Nullification of Approvals: All study approvals issued during the period of non-compliance may be declared void, requiring studies to halt.
- Category C: Severe Violations (Criminal/Statutory Offenses)

- Description: Willful operation of a fake IERB (ghost board), forging NBC registration certificates, repeated failure to report Serious Adverse Events resulting in harm to participants, or research fraud approved by the IERB.

Penalties:

- Criminal Prosecution: Refer to the Federal Investigation Agency (FIA) and relevant courts for prosecution and fraud statutes.
- Permanent Blacklisting: Blacklisting of the Institution and IERB Chairperson from receiving any government grants, NBC approvals, or participating in national health research.
- License Revocation: Recommendation to the PM&DC/HEC or DRAP to cancel the license or registration of the institution or principal investigators.
- Fines/others: may be decided as per recommendation of inquiry committee.

Enforcement and Adjudication:

- Detection: Violations may be detected through NBC-HRI site inspections, discrepancies in annual reports, whistle-blower complaints, or audit reports from funding agencies.
 - Investigation: The NBC-HRI shall constitute an Inquiry Committee to investigate allegations. The Committee has the power to summon meeting minutes, interview IERB members, and inspect institutional records.
 - Due Process: The accused institution or IERB Chairperson shall be given an opportunity to respond to the allegations (Show Cause Notice) before penalties are imposed.
- Additional Guidelines for Enforcement and Adjudication**
Policy on "Zero Tolerance" for Unregistered IERBs The NBC-HRI operates under a strict interpretation of the NIH Act 2021. When reviewing cases of unauthorized ethical review, the Committee must apply the following principles:
- The Committee does not accept an application for registration *after* a violation has been detected to excuse previous unauthorized activities. "Retroactive approval" is not a valid defense.
 - Policies from foreign universities or international sponsors stating that their internal ethics committee approval is sufficient are null and void in Pakistan. The NBC-HRI must reject any defense claiming that a "Funder Agreement" compelled the institution to bypass national registration protocols.
 - The responsibility lies solely with the Pakistani institution to ensure their IERB is registered before reviewing any protocol. Ignorance of the NIH Act 2021 requirements is not admissible as a defense.

FOR INSTITUTIONS AND RESEARCHERS: (What You Need to Know to Protect Yourself)

Important Warning: "My University Told Me To" is Not an Excuse As an institution or researcher in Pakistan, you are required by the Health Research Institute – NIH Act, 2021 to ensure your Ethics Board is registered with the NBC-HRI.

1. The "De Facto" Recognition Rule:

- Just because your university has *established* a committee does not mean it is *legal*. If the committee is not on the official NBC-HRI register, its approvals are invalid. You must verify the registration status on the NBC website before starting research.

2. The "Foreign Sponsor" Rule:

- International sponsors may claim their own ethics approval is enough. It is not. For studies in Pakistan, a locally registered IERB approval is mandatory. Do not rely solely on foreign ethics clearance.

3. No "Emergency" Exemptions:

- There are no exemptions for the registration process itself. You cannot set up a temporary board for a specific study without NBC-HRI registration. Failing to register is a violation, regardless of the urgency of the research.

Liability of Stakeholders

- Principal Investigator (PI): Bears primary responsibility for verifying that the IERB reviewing their protocol is registered. Relying on an unregistered board may result in the rejection of their research data and personal disciplinary action.
- Institutional Head: The head of the institution is equally liable for the operation of unregistered IERBs within their domain.
- IERB Chairperson: Personally liable for the accuracy of the registration application and the conduct of the board's meetings.

Appeal Procedure:

An Institution or IERB found in violation of this framework and subjected to penalties retains the right to a fair and transparent appeal process.

- First-Level Appeal: Executive Director HRI-NIH
- Appellate Authority: The first appeal against any decision or penalty imposed by the NBC-HRI Inquiry Committee must be submitted to the Executive Director of the Health Research Institute – NIH (HRI-NIH).
- Submission: The appeal must be submitted in writing within 15 working days of the issuance of the decision or penalty notification.
- Resolution: The Executive Director shall review the case record and issue a decision within 15 working days.

Second-Level Appeal: The Board

- Appellate Body: If the Institution remains dissatisfied, they may file a second and final appeal to the.....().
- Submission: The appeal to the Board must be filed within 15 working days of the receipt of the Executive Director's decision.
- Resolution: The Board shall examine the merits of the case and issue a final judgment within 6 weeks. The decision of the Board shall be final and binding.

Reporting Violations:

- Mandatory Reporting: Research coordinators and administrators are legally mandated to report the operation of unregistered IERBs to the NBC-HRI.
- Whistleblower Protection: Individuals reporting violations (e.g., researchers forced to use unregistered boards) in good faith shall be protected against retaliation under the NBC-HRI protection policy.

Reinstatement:

Institutions or IERBs blacklisted under Category C offenses may apply for reinstatement after a minimum period of 3 years, subject to:

- Completion of all legal penalties and fines.
- Dissolution of the previous IERB structure and formation of a completely new committee.
- Successful audit and inspection by the NBC-HRI.