



**National Bioethics Committee (NBC)  
Health Research Institute  
National Institutes of Health (NIH)**



# STANDARD OPERATING PROCEDURES

## FOR THE REGISTRATION OF Institutional Review Boards (IRBs) / Ethics Review Committees

*Comprehensive Edition — incorporating the registration committee, decision mechanism, minimum standard, appeals and re-submission procedures*

<b>SOP Number</b>	NBC/SOP/IRB-REG/01
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<b>Registering Authority</b>	National Bioethics Committee (NBC)
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## Table of Contents

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Document Control .....	<b>Error! Bookmark not defined.</b>
Table of Contents.....	2
1. Purpose .....	3
2. Scope .....	3
3. Authority and Mandate .....	3
4. Responsibilities .....	3
5. The IRB Registration Committee (IRC) — who approves or disapproves.....	4
6. Definitions.....	4
7. Pre-Registration Preparation .....	5
8. Minimum Standard for Approval .....	5
9. Submission of the Registration Application .....	6
9A. Registration Fee.....	6
10. Review of the Application and Timelines.....	7
11. Decision-Making Mechanism (Consensus and Voting) .....	8
12. Decisions, Registration Number and Certificate .....	8
13. Adopted / Affiliated IRB Arrangements .....	9
14. Post-Registration Obligations .....	9
15. Appellate Authority (where Registration is Refused, Conditional, Suspended or Terminated) .....	10
16. Time to Re-submit After Refusal.....	10
17. Record Keeping .....	11
18. Grievance Redressal.....	11
19. References.....	11
20. Annexes (Templates).....	12

## 1. Purpose

These Standard Operating Procedures (SOPs) set out the complete procedure for registering Institutional Review Boards (IRBs) / Ethics Review Committees (ERCs) with the National Bioethics Committee (NBC) in Pakistan, through its Secretariat at the Health Research Institute (HRI-NIH). The purpose is to ensure that every IRB reviewing research involving human participants meets a defined national minimum standard, and to give institutions, sponsors, regulators and collaborators a transparent, time-bound and auditable registration process for the protection of human research subjects.

## 2. Scope

This SOP applies to all institutions in Pakistan that intend to conduct, host or supervise research involving human subjects and therefore require IRB registration with the NBC. This includes federal and provincial institutions, public and private universities and medical/dental/nursing/allied-health colleges, hospitals and research institutes, Clinical Research Organizations (CROs), consultancy firms, donors, industry, and independent researchers.

**Institutions without their own IRB** are covered through the adopted/affiliated-IRB route in Section 13.

## 3. Authority and Mandate

**Registering authority — NBC.** The National Bioethics Committee (NBC) is the broad, gazette-notified federal body responsible for upholding bioethical principles across all sectors of health care in Pakistan. The registration and recognition of IRBs falls within this broad mandate of NBC.

**Distinction from NBC-R.** The National Bioethics Committee for Research (NBC-R) is a sub-committee whose mandate is limited to reviewing individual research projects/protocols submitted to it. NBC-R does not register IRBs. Registration is owned by NBC and administered as set out below.

**Administration by salaried staff.** Members of NBC and NBC-R serve in an honorary, uncompensated capacity. The time-bound administrative and assessment work of registration is therefore carried out by salaried HRI-NIH Government officers through the IRB Registration Committee (Section 5), acting under delegation from, and reporting to, NBC.

## 4. Responsibilities

Party	Responsibility
<b>Applicant Institution</b>	Establish and maintain an IRB meeting the NBC minimum standard (Section 8); prepare and submit a complete application; keep registration current; report changes and disbandment; submit annual reports.
<b>IRB Registration Committee (IRC), HRI</b>	Receive, validate, assess and decide registration applications within the timelines; maintain the national IRB register; conduct monitoring and audits; process renewals, suspensions and appeals at first stage.

Party	Responsibility
<b>Executive Director, HRI</b>	Chair the IRC; act as the final approving authority who signs and issues registration decisions on behalf of NBC; report registrations to NBC.
<b>National Bioethics Committee (NBC)</b>	Own the registration policy; receive periodic reports; act as the higher appellate authority; ratify policy and standards.
<b>NBC Secretariat (HRI)</b>	Day-to-day correspondence, tracking, record-keeping, certificate issuance, register maintenance and public disclosure.

## 5. The IRB Registration Committee (IRC) — who approves or disapproves

**Design principle.** Because NBC/NBC-R members are honorary, the registration workload is carried by salaried HRI–NIH officers who can be held to deadlines. NBC delegates the assessment-and-decision function to a standing IRB Registration Committee (IRC) seated at HRI, while retaining policy ownership and the higher appeal.

### 5.1 Composition of the IRC

Role on IRC	Holder (HRI–NIH salaried officers)
<b>Chairperson</b>	NBC Focal Person (HRI), custodian of the IRB register and registration numbers.
<b>Secretary</b>	National Coordinator(s), NBC Secretariat (HRI).
<b>Members— legal / regulatory (as needed)</b>	03 trained HRI legal/regulatory officer or co-opted legal resource.
<b>Co-opted technical expert (non-voting)</b>	Subject specialist co-opted per application (e.g., an honorary NBC/NBC-R member or external expert) where specialized judgement is needed.
<b>Secretariat support (non-voting)</b>	HRI staff for minutes and records.

**Quorum:** the Chair (ED HRI) or Co-Chair plus at least two other members, including at least one with a scientific background and one with an ethics/compliance background.

### 5.2 Final approving authority

**The Executive Director, HRI — as Secretary, NBC — is the final approving authority.** The IRC deliberates and reaches a recommendation; the ED HRI signs and issues the decision (grant / conditions / defer / refuse) on behalf of NBC. Decisions and the register are tabled at NBC meetings for oversight.

### 5.3 Conflict of interest

Any IRC member connected to an applicant institution must declare the interest to the Chair before the case is taken up and withdraw from its assessment and decision; the withdrawal is minuted. If the ED HRI has a conflict, the Co-Chair (CRO) acts as approving authority for that case.

## 6. Definitions

Term	Meaning
<b>Research</b>	A systematic investigation designed to develop or contribute to generalizable knowledge.
<b>Human subject</b>	An individual from whom data is obtained through intervention, interaction, or identifiable private information for research purposes.
<b>IRB / ERC</b>	An Institutional Review Board / Ethics Review Committee established to review and approve research involving human subjects.
<b>Minimal risk</b>	The probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or routine examinations.
<b>NBC</b>	National Bioethics Committee — the gazetted body and registering authority.
<b>NBC-R</b>	NBC for Research — the protocol-review sub-committee; not involved in registration.
<b>IRC</b>	IRB Registration Committee — the HRI-based committee that assesses and decides applications.
<b>ED / CRO</b>	Executive Director, HRI (Secretary, NBC) / Chief Research Officer.
<b>Registration Number</b>	Unique NBC IRB Registration Number assigned on approval (national equivalent of an IORG number).
<b>Adopted / affiliated IRB</b>	An external registered IRB that an institution without its own IRB formally relies upon.

## 7. Pre-Registration Preparation

### 7.1 Establishment of the IRB

Institutions must establish an IRB meeting the requirements of the national policy for the protection of human research subjects and the minimum standard in Section 8. The IRB should comprise members of diverse educational backgrounds and professional competence, sensitive to community attitudes, and must include at least one member from a non-scientific area and at least one member unaffiliated with the institution.

### 7.2 Documentation to be prepared

1. a written assurance of compliance with NBC policies;
2. a list of IRB members with qualifications, roles, gender, affiliation and any conflicts of interest;
3. the IRB's written SOPs for reviewing proposals, reporting adverse events, continuing review and record-keeping;
4. the constituting notification/order from the Head of Institution;
5. evidence of members' research-ethics / GCP training; and
6. documentation of the institution's ethical principles and relevant federal/provincial policies.

## 8. Minimum Standard for Approval

Registration is granted only if every element below is present and verified by the IRC:

Required element	Verified by
≥ 5 members of varying backgrounds; ≥ 1 non-scientific and ≥ 1 member unaffiliated with the institution; both genders represented	Membership list + CVs
Named Chairperson and Member Secretary, with continuity/deputy arrangements	Constituting order
Valid constituting notification from the Head of Institution	Notification / order
Complete written SOPs (review, decisions, appeals, amendments, continuing review, AE/SAE reporting, records)	IRB SOP document
Defined quorum (≥ one-third of members, including ≥ 1 scientific and ≥ 1 non-scientific/lay) and a consensus-then-voting rule	IRB SOPs
Conflict-of-interest policy with declaration and recusal	COI policy
Documented meeting schedule (at least quarterly business) and adequate secretariat support	Schedule + institutional letter
Members' research-ethics / GCP training	Training certificates
Secure record-keeping with ≥ 3-year retention after study completion	Records / archiving policy
Written assurance of compliance with NBC policies	Signed assurance

Failure on any single mandatory element results in a conditional or negative decision rather than approval. Registration confirms only that the IRB met these elements; it does not certify the quality of any individual protocol review the IRB later performs.

## 9. Submission of the Registration Application

7. The institution submits a complete application with all documents in Section 7.2 to the NBC Secretariat (HRI), in soft copy (portal).
8. The application must be signed by the Head of Institution or an authorized representative.
9. The Secretariat acknowledges receipt and assigns a unique tracking number.
10. Incompletely filled or undocumented applications are not entertained and are returned with a deficiency checklist.

**Fees:** a non-refundable registration fee applies according to the category of the applicant institution, as set out in Section 9A. Proof of fee payment must accompany the application; an application is not placed before the IRC until the applicable fee is received.

### 9A. Registration Fee

A non-refundable registration fee is payable with every application, based on the category of the applicant institution and the nature of the research it undertakes:

Applicant category	Fee (PKR)	Code
Any institute / college / university involved in clinical trials	200,000	Cat. A
HEC-recognized universities / NGOs NOT involved in clinical trials	100,000	Cat. B

**Notes on the fee:**

- The fee is non-refundable, including where an application is refused, deferred, withdrawn, or marked Null and Void.
- Category is determined by whether the institution conducts (or intends to conduct) clinical trials. An institution that undertakes clinical trials falls under Category A even if it is HEC-recognized or an NGO.
- Proof of payment (deposit slip / transaction reference) must be enclosed with the application; the assessment clock in Section 10 starts only once both a complete application and the applicable fee are received.
- Renewal of registration (Section 14.4) attracts the same category-based fee as a fresh application, unless NBC notifies otherwise.
- A re-submission after refusal (Section 16) is a fresh application and attracts the applicable fee afresh; no fee is charged for merely supplying clarifications or missing documents within an open, already-paid application.
- Adopted / affiliated-IRB registrations (Section 13) are charged according to the category of the applicant institution seeking the affiliation.
- The fee is paid to the designated NBC / HRI-NIH account as notified in the public registration notice; the Secretariat issues an official receipt.
- NBC may revise the fee schedule from time to time by notification; the fee prevailing on the date a complete application is received applies.

## 10. Review of the Application and Timelines

### 10.1 Administrative (completeness) review

The Secretariat checks that all required documents are present and meet basic criteria. Missing or incomplete items are notified to the institution with a deadline to supply them.

### 10.2 Substantive review

The IRC conducts a detailed assessment against the minimum standard (Section 8): the qualifications of IRB members, adequacy of IRB procedures, the institution's assurance of compliance, and the IRB's capacity to protect human subjects.

### 10.3 Indicative timelines

Step	Action	Timeline
1	Acknowledgement and tracking number	On receipt
2	Administrative completeness check; deficiencies notified	Within 10 working days
3	Institution supplies missing documents	Within 4 weeks of notice
4	IRC substantive assessment	Within 4–6 weeks of a complete file
5	Clarifications / virtual or site verification (if required)	Institution responds within 8 weeks
6	IRC recommendation finalized	On completion of assessment
7	Decision signed by ED HRI (Secretary, NBC)	Within 1 week of recommendation
8	Decision letter + (if approved) certificate & number; register updated	Within 2 weeks of decision

**Expedited registration:** for time-critical public-health research, the ED HRI may authorize an expedited assessment by at least two IRC members and the Chair, reported to the next NBC meeting. Expedited handling compresses timelines but never lowers the minimum standard.

**Non-response / abandonment:** if the institution does not respond to a deficiency or clarification notice within eight (8) weeks, the Secretariat issues a reminder allowing a further one (1) month, after which the application is marked “Null and Void” and must be lodged afresh.

## 11. Decision-Making Mechanism (Consensus and Voting)

The IRC reaches its recommendation as follows, applied at the committee level before the ED HRI issues the decision:

11. Consensus first. Decisions are made by consensus wherever possible after deliberation on the merits.
12. Voting as fallback. Where consensus appears unlikely, the matter is decided by a vote of the members present and eligible (conflicted members having withdrawn).
13. Simple majority. A vote is carried by a simple majority of those present and voting; the Chair (ED HRI) holds a casting vote in the event of a tie.
14. Quorum required. A decision is valid only if the quorum in Section 5.1 is met.
15. Transparency. Where consensus is not reached, the decision letter and minutes record that the decision was taken by vote.
16. Recusal. A member who withdrew for conflict of interest is excluded from both discussion and vote, and this is minuted.
17. Issuance. The ED HRI signs and issues the decision reflecting the IRC outcome.

## 12. Decisions, Registration Number and Certificate

### 12.1 Possible decisions

18. Registration granted — a registration number and certificate are issued.
19. Registration granted with conditions — minor gaps to be closed within a stated period.
20. Deferred — sound application pending clarification/documents; the file stays open.
21. Registration refused (disapproved) — the IRB does not meet the minimum standard; clear reasons and the appeal/re-submission routes are provided.

## **12.2 Registration number, certificate and register**

- On approval, the Secretariat issues a Registration Certificate bearing a unique NBC IRB Registration Number, quoted on all subsequent correspondence, updates and renewals.
- The IRB is entered in the national NBC IRB register, which is made publicly available for verification by institutions, sponsors, DRAP and international collaborators.
- The institution must additionally publish information about its registered IRB on its own website, including the list of IRB members and their qualifications.

## **13. Adopted / Affiliated IRB Arrangements**

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An institution that does not operate its own IRB (including CROs, consultancy firms, donors and independent researchers) may register a formal arrangement to use the IRB of another institution whose IRB is registered with NBC. The application must include:

22. a signed agreement between the two institutions defining the scope and duration of the arrangement;
23. the registration number and details of the host IRB; and
24. a written assurance that the host IRB will review the applicant's research under the same NBC standards.

The IRC verifies the arrangement and records the affiliation in the register against both institutions.

## **14. Post-Registration Obligations**

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### **14.1 Change notification**

The institution must notify the Secretariat within ninety (30) days of any change to the Chairperson, Member Secretary or contact official, and promptly of any material change in composition, scope or address. The institution must notify NBC in writing if the IRB permanently ceases to operate (disbandment).

### **14.2 Annual reporting**

Registered IRBs submit an annual report to the Secretariat covering IRB meetings, numbers of protocols reviewed, approvals and exemptions, adverse-event reports, and any change in membership or procedures.

### **14.3 Continuing compliance and audit**

The IRC, on behalf of NBC, may conduct periodic audits or verification visits and request records at any time to confirm ongoing compliance.

### **14.4 Renewal**

Registration is valid for three (3) years. The Secretariat issues a renewal reminder at least ninety (90) days before expiry; the institution applies on the same form with an updated document set, certifying what has and has not changed. A complete renewal lodged before expiry keeps the existing registration in force until decided.

#### 14.5 Suspension or termination

The IRC may suspend or terminate a registration where an IRB is non-compliant, fails to report, or is associated with serious harm to research subjects. Such a decision is reasoned, taken by the consensus-then-voting mechanism, communicated in writing, and is itself appealable under Section 15.

### 15. Appellate Authority (where Registration is Refused, Conditional, Suspended or Terminated)

An aggrieved institution may appeal. The structure ensures the appeal is heard by persons other than those who took the original decision, escalating from HRI to the parent NBC:

Stage	Appellate authority	Nature & timeframe
<b>First — Reconsideration</b>	Executive Director, HRI with the IRC, on fresh material	Written appeal within 30 days of the decision letter, stating grounds and attaching corrective documents. Decided within 4–6 weeks.
<b>Second — NBC Appeals Sub-Committee</b>	Sub-committee of NBC-R members (honorary) who did NOT take part in the original decision, constituted by the Chairperson, NBC	Lodged within 30 days of the first-stage outcome; recommendation placed before NBC.
<b>Final — NBC / Ministry</b>	Full National Bioethics Committee; thereafter, on points of process/jurisdiction, the Ministry of NHR&C	Final administrative recourse once internal remedies are exhausted.

#### Principles:

- no person who took the original decision sits in judgement of its appeal at the NBC stages;
- the institution is entitled to the reasons for refusal and a fair chance to respond in writing and, if allowed, in person or by video link;
- each appellate decision is reasoned, minuted, and communicated in writing; and
- pursuing an appeal does not bar the institution from simultaneously correcting deficiencies and re-applying (Section 16).

### 16. Time to Re-submit After Refusal

Refusal is not permanent. The route back depends on the reason:

Situation	Re-submission rule
<b>Refused for documentary / administrative deficiencies</b>	Re-submit as soon as corrected — no minimum waiting period. Treated as a fresh application with a new tracking number.
<b>Refused for substantive failures of composition, SOPs or capacity</b>	Re-submit after addressing the cited reasons; a minimum interval of ninety (90) days is recommended to allow genuine reconstitution/training, unless the decision letter specifies otherwise.
<b>Application marked “Null and Void” for non-response</b>	Lodge afresh whenever ready; the earlier file is closed.
<b>Registration suspended for cause</b>	Re-instatement on evidence the cause is remedied, within the period stated in the suspension order; otherwise a fresh application is required.
<b>While an appeal is pending</b>	A fresh application may run in parallel; if the appeal succeeds, the parallel application is closed to avoid duplication.

*Each re-submission restarts the timeline in Section 10 from the date a complete application is received.*

## 17. Record Keeping

The Secretariat maintains records of all registration applications, reviews, decisions, certificates and the register. All records are retained for at least three (3) years after completion of the related research and are accessible for inspection by authorized representatives. Records are held securely, with access restricted to authorized Secretariat and IRC personnel.

## 18. Grievance Redressal

Grievances about the registration process that fall outside the formal appeal in Section 15 (for example, administrative delay or conduct concerns) may be submitted in writing to the NBC Secretariat, which acknowledges within ten (10) working days and resolves, or escalates to NBC, within a reasonable period. Use of grievance redressal does not extend or replace the appeal timelines in Section 15.

## 19. References

- National Policy for the Protection of Human Research Subjects by IRBs in Pakistan.
- Federal and Provincial Regulations on Human Research Subjects.
- NBC Gazette notifications (2004, 2010) and NBC/NBC-R Terms of Reference.
- NBC-R Operational Manual, 1st Edition (2023) — for composition, quorum, decision-making and documentation norms applied here by analogy.
- NBC Advisory on Mandatory IRB Approval; NBC Research Ethics Guidance Document (2022).
- International references: OHRP IRB/IORG registration (45 CFR 46); FDA (21 CFR 56); India CDSCO/DHR EC registration; WHO Standards and Operational Guidance for Ethics Review; SIDCER/FERCAP.

## 20. Annexes (Templates)

### Annex A — Application checklist (submitted by the institution)

Item	Enclosed (✓)
Covering letter + completed NBC IRB Registration Form, signed by Head of Institution	<input type="checkbox"/>
Constituting notification/order establishing the IRB	<input type="checkbox"/>
Membership list (name, qualification, role, gender, affiliation, COI)	<input type="checkbox"/>
CVs and research-ethics / GCP training evidence for each member	<input type="checkbox"/>
IRB written SOPs (review, decisions, appeals, amendments, continuing review, AE/SAE, records)	<input type="checkbox"/>
Quorum rule and meeting schedule	<input type="checkbox"/>
Conflict-of-interest policy and declaration forms	<input type="checkbox"/>
Written assurance of compliance with NBC policies	<input type="checkbox"/>
For adopted IRB: inter-institutional agreement + host IRB registration details	<input type="checkbox"/>

### Annex B — IRC assessment & decision sheet (internal)

Field	Entry
Tracking number / date complete	
Minimum-standard elements met (Y/N each)	
Quorum present / members recused	
Decision (grant / conditions / defer / refuse)	
Consensus or vote (tally if vote)	
Reasons / conditions	
Registration number assigned	
Approved & signed — ED HRI (Secretary, NBC)	

**Disclaimer:** This comprehensive SOP builds on NBC's existing internal SOP (v1.0, Aug 2024) and fills identified gaps using NBC/HRI public materials and international practice. The committee structure, timelines, thresholds and templates are recommendations for NBC to formally adopt or adjust; bracketed items (e.g., fee policy, effective date) require NBC's decision. It is not itself an official NBC notification until adopted.