



**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*

|                                 |                                               |
|---------------------------------|-----------------------------------------------|
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## 1. Purpose

These Standard Operating Procedures set out the complete procedure for registering Institutional Ethical Review Boards (IERBs) — also styled Institutional Review Boards (IRBs) or Ethics Review Committees (ERCs) — with the National Bioethics Committee (NBC-HRI) through its Secretariat at the Health Research Institute, NIH.

The purpose is to ensure that every IERB reviewing research involving human participants meets the national minimum standard set by the Framework and the Policy, and to give institutions, sponsors, regulators and collaborators a transparent, time-bound and auditable registration process for the protection of human research participants.

This SOP governs registration. It does not govern enforcement: offences, penalties, inquiry and adjudication are governed by the Framework, which is incorporated by reference at Section 20.

## 2. Scope

This SOP applies to all institutions in Pakistan that conduct, host or supervise research involving human participants and therefore require IERB registration with NBC-HRI. This includes:

- federal and provincial institutions, including those in Azad Jammu and Kashmir and Gilgit-Baltistan;
- public and private universities, degree-awarding institutions, and medical, dental, nursing and allied-health colleges;
- hospitals, healthcare facilities and research institutes;
- Clinical Research Organizations (CROs), consultancy firms, donors, sponsors and industry; and
- independent researchers relying on IERB approval.

Institutions and applicants without their own IERB are covered through Section 13.

## 3. Authority and Mandate

### 3.1 Statutory basis

These SOPs are issued under the powers conferred by the **Health Research Institute – NIH Act, 2021**, read with the NBC Gazette Notifications of 2004 and 2010. Under the Act, the National Bioethics Committee (NBC-HRI) is the sole statutory body mandated to oversee the ethical governance of human health research in Pakistan and is the central authority for the accreditation, registration and standardization of all health-related ethics review bodies.

No ethical review, approval or oversight of health-related research — whether in the public or the private sector — may be undertaken by a committee that is not registered with NBC-HRI.

### 3.2 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 and protocols submitted to it. NBC-R does not register IERBs and has no function at any stage of registration, assessment, decision or appeal under this SOP.

### 3.3 Administration

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 officers through the IERB Registration Committee (Section 5), acting under delegation from, and reporting to, NBC.

## 4. Responsibilities

| Party                                         | Responsibility                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Applicant Institution</b>                  | Establish and maintain an IERB meeting the minimum standard in Section 8; submit a complete, certified application; keep registration current; report changes, serious adverse events and disbandment; submit quarterly returns and annual reports.                                               |
| <b>Head of Institution</b>                    | Constitute the IERB; personally evaluate and certify the registration application and all supporting material; guarantee the IERB's independence from administrative and financial pressure; remain liable under the Framework for the operation of any unregistered IERB within the institution. |
| <b>IERB Registration Committee (IRC), HRI</b> | Receive, validate and assess applications and reach a recommendation within the timelines; maintain the national IERB register; conduct monitoring and audits; process renewals; refer suspected violations for enforcement under Section 20.                                                     |
| <b>Chairperson, IRC / NBC Focal Person</b>    | Sign and issue all first-instance registration decisions on behalf of NBC; act as custodian of the register and of registration numbers.                                                                                                                                                          |
| <b>Executive Director, HRI–NIH</b>            | Sit as the first-level appellate authority under Section 15. The Executive Director takes no part in first-instance decisions.                                                                                                                                                                    |
| <b>National Bioethics Committee (NBC)</b>     | Own the registration policy; approve and revise this SOP, the minimum standard and the fee schedule; receive periodic reports on the register and on decisions; constitute Inquiry Committees under the Framework.                                                                                |

## 5. The IERB Registration Committee (IRC)

Because NBC and 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 IERB Registration Committee seated at HRI, while retaining policy ownership.

### 5.1 Composition

| Seat                                                    | Holder                                                                                         | Voting |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------|--------|
| <b>Chairperson</b>                                      | NBC Focal Person (HRI); custodian of the register and of registration numbers                  | *Yes   |
| <b>Secretary</b>                                        | National Coordinator, NBC Secretariat (HRI)                                                    | No     |
| <b>Legal / regulatory member regulatory (as needed)</b> | 04 trained HRI legal/regulatory officer or co-opted legal resource.                            | Yes    |
| <b>Co-opted technical expert</b>                        | Subject specialist co-opted for a particular application where specialized judgement is needed | No     |
| <b>Secretariat support</b>                              | HRI staff for minutes and records                                                              | No     |

**Quorum:** Three (03) voting members, including the Chairperson or a nominated deputy, and including at least one of the scientific members and the bioethics member. The Chairperson votes only to resolve a tie. Any decision so taken is recorded as such in the minutes and the decision letter.

## 5.2 Final approving authority

The IRC deliberates and reaches a recommendation. The Chairperson / NBC Focal Person signs and issues the decision — grant, grant with conditions, defer or 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 Chairperson before the case is taken up, and must withdraw from its assessment, discussion and decision. The withdrawal is minuted. Where the Chairperson is conflicted, the case is chaired by the bioethics member and the decision is signed by the Executive Director acting in the Chairperson's place; in that event the first-level appeal under Section 15 lies to a senior officer nominated by the Chairperson, NBC.

## 6. Definitions

| Term                               | Meaning                                                                                                                                                                                                                                                                                                                       |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Research</b>                    | A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.                                                                                                                                                                             |
| <b>Human subject / participant</b> | An individual (alive or dead) about whom an investigator, whether professional or student, obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information or identifiable biospecimens obtained, used, studied, analysed or generated for the purposes of the research.   |
| <b>IERB (IRB / ERC)</b>            | Institutional Ethical Review Board — also styled Institutional Review Board or Ethics Review Committee — established to review, approve, require modification in, or disapprove research involving human participants. The three terms are used interchangeably; "IERB" is the term used on the register and on certificates. |
| <b>Lay Member</b>                  | A member who is neither a medical practitioner nor a researcher — for example a lawyer, teacher or community leader — and who is not affiliated with the institution.                                                                                                                                                         |
| <b>External Member</b>             | A member from outside the applicant institution, additional to the Lay Member.                                                                                                                                                                                                                                                |
| <b>Minimal risk</b>                | The probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.                                                                                                       |
| <b>Serious Adverse Event (SAE)</b> | Any untoward occurrence in a research participant that results in death, is life-threatening, requires or prolongs hospitalisation, results in persistent or significant disability, or is otherwise judged medically significant.                                                                                            |
| <b>NBC / NBC-HRI</b>               | National Bioethics Committee — the statutory body and registering authority under the HRI-NIH Act 2021.                                                                                                                                                                                                                       |
| <b>NBC-R</b>                       | NBC for Research — the protocol-review sub-committee; no role in registration.                                                                                                                                                                                                                                                |
| <b>IRC</b>                         | IERB Registration Committee — the HRI-based committee that assesses applications and recommends decisions.                                                                                                                                                                                                                    |
| <b>Registration Number</b>         | The unique NBC IERB Registration Number assigned on approval.                                                                                                                                                                                                                                                                 |



| Term                 | Meaning                                                                                                                     |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>The Framework</b> | The Regulatory Framework for the Registration of Institutional Ethical Review Boards (IERBs) and Enforcement of Compliance. |
| <b>The Policy</b>    | The National Policy for Institutional Review Boards (IRBs) — NBC guidelines for IRB standardization in Pakistan.            |
| <b>The Board</b>     | The appellate body identified in the Framework as the second and final level of appeal.                                     |

## 7. Pre-Registration Preparation

### 7.1 Establishment of the IERB

The IERB must be formally constituted by the Head of Institution, must operate independently of administrative or financial pressure to approve specific studies, and must meet the requirements of the Policy and the minimum standard in Section 8.

### 7.2 Documentation to be prepared

1. A written assurance of compliance with NBC policies, signed by the Head of Institution.
2. The constituting notification or order from the Head of Institution, naming the Chairperson and Member Secretary.
3. A list of IERB members with qualification, role, gender, profession, affiliation and declared conflicts of interest, identifying which member serves as the Lay Member and which as the External Member.
4. Curricula vitae for each member.
5. Evidence of each member's certified research-ethics or GCP training.
6. The IERB's written SOPs covering initial review, continuing review, expedited review, decisions, amendments, appeals, adverse-event and SAE reporting, conflict-of-interest management, and record-keeping.
7. The IERB's quorum rule and its annual meeting schedule.
8. A signed declaration of institutional non-interference in the IERB's decisions.
9. Documentation of the institution's ethical principles and of relevant federal and provincial policies applicable to it.

## 8. Minimum Standard for Approval

Registration is granted only where every mandatory element below is present and verified by the IRC. The standard reproduces the requirements of the Framework and the Policy; it does not add to them.

| Required element                                                                                | Verified by           |
|-------------------------------------------------------------------------------------------------|-----------------------|
| An odd number of members, minimum five (5), of varying educational and professional backgrounds | Membership list + CVs |

| Required element                                                                                                                              | Verified by                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 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 ( $\geq$ one-third of members, including $\geq 1$ scientific and $\geq 1$ 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 $\geq 3$ -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 IERB met these elements; it does not certify the quality of any individual protocol review the IERB later performs.

## 9. Submission of the Registration Application

1. The institution submits a complete application, with all documents listed in Section 7.2, to the NBC Secretariat (HRI) in soft copy, through the NBC-HRI website or the Secretariat email address published in the registration notice, until a dedicated online portal is notified.
2. The application must be signed and personally certified by the Head of Institution, who evaluates and certifies all material submitted. This certification may not be delegated; delegation is permitted for routine correspondence only.
3. The Secretariat acknowledges receipt and assigns a unique tracking number.
4. Incompletely filled or undocumented applications are not entertained and are returned with a deficiency checklist.
5. The application must include a declaration stating whether the IERB, or any committee performing its functions, has conducted any ethical review of research prior to registration, and if so, particulars of the protocols reviewed and approvals issued.
6. Proof of payment of the applicable fee under Section 9A must accompany the application.

## 9A. Registration Fee

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

| Tier          | Priority level     | Eligible institutions                                                                             | Fee (PKR) |
|---------------|--------------------|---------------------------------------------------------------------------------------------------|-----------|
| <b>Tier 1</b> | Very High Priority | Clinical trial sites and units registered with DRAP                                               | 200,000   |
| <b>Tier 2</b> | High Priority      | HEC-registered and ORIC research-intensive institutes, CROs, consultancy firms                    | 100,000   |
| <b>Tier 3</b> | Priority           | Independent research units within secondary-level healthcare establishments and comparable bodies | 50,000    |

- The fee is non-refundable, including where an application is refused, deferred, withdrawn or marked Null and Void.
- Acknowledgement and the completeness check under Section 10.1 are carried out on receipt. The substantive assessment clock in Section 10.3 starts only once both a complete application and the applicable fee have been received.
- Renewal under Section 14.5 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 fee afresh. No fee is charged for supplying clarifications or missing documents within an open, already-paid application.
- Affiliated-IERB registrations (Section 13) are charged according to the category of the applicant seeking the affiliation.
- The fee is paid to the designated NBC / HRI–NIH account notified in the public registration notice; the Secretariat issues an official receipt.
- NBC may revise the schedule 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 on receipt 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 assesses the file against the minimum standard in Section 8: the qualifications and composition of the IERB, the adequacy of its procedures, the institution's assurance of compliance and declaration of non-interference, and the IERB's capacity to protect human participants. The IRC may require virtual or on-site verification.

### 10.3 Indicative timelines

| Step     | Action                              | Timeline   |
|----------|-------------------------------------|------------|
| <b>1</b> | Acknowledgement and tracking number | On receipt |



| Step | Action                                                                                  | Timeline                                      |
|------|-----------------------------------------------------------------------------------------|-----------------------------------------------|
| 2    | Administrative completeness check; deficiencies notified                                | Within 10 working days                        |
| 3    | Institution supplies missing documents                                                  | Within 8 weeks of notice                      |
| 4    | IRC substantive assessment                                                              | Within 4–6 weeks of a complete, fee-paid file |
| 5    | Clarifications; virtual or site verification if required                                | Institution responds within 8 weeks           |
| 6    | IRC recommendation finalised                                                            | On completion of assessment                   |
| 7    | Decision signed and issued by the Chairperson, IRC / NBC Focal Person                   | Within 1 week of the recommendation           |
| 8    | Decision letter and, if approved, certificate and registration number; register updated | Within 2 weeks of decision                    |

Expedited registration. For time-critical public-health research, the Chairperson may authorise an expedited assessment by at least two IRC voting members and the Chairperson, reported to the next NBC meeting. Expedited handling compresses timelines but never lowers the minimum standard in Section 8.

Non-response and 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

The IRC reaches its recommendation as follows, before the Chairperson issues the decision:

1. Consensus first. Decisions are made by consensus wherever possible after deliberation on the merits.
2. Voting as fallback. Where consensus appears unlikely, the matter is decided by a vote of the voting members present and eligible, conflicted members having withdrawn.
3. Simple majority. A vote is carried by a simple majority of those present and voting. The Chairperson holds a casting vote in the event of a tie.
4. Quorum required. A decision is valid only if the quorum in Section 5.1 is met.
5. Recusal. A member who withdrew for conflict of interest is excluded from both discussion and vote, and this is minuted.
6. Transparency. Where consensus is not reached, the decision letter and the minutes record that the decision was taken by vote.
7. Issuance. The Chairperson, IRC / NBC Focal Person signs and issues the decision reflecting the IRC outcome.

## 12. Decisions, Registration Number and Certificate

### 12.1 Possible decisions

1. Registration granted — a registration number and certificate are issued.

2. Registration granted with conditions — minor gaps to be closed within a stated period.
3. Deferred — a sound application pending clarification or documents; the file stays open.
4. Registration refused — the IERB does not meet the minimum standard. Clear reasons and the appeal and re-submission routes are provided.

## 12.2 Registration number, certificate and register

- On approval the Secretariat issues a Registration Certificate bearing a unique NBC IERB Registration Number, to be quoted on all subsequent correspondence, updates and renewals.
- The IERB is entered in the national NBC IERB register, which is published on the NBC-HRI website for verification by institutions, sponsors, DRAP, funders and international collaborators.
- The institution must additionally publish information about its registered IERB on its own website, including the list of members and their qualifications.
- Registration is valid for three (3) years from the date of the decision, unless earlier suspended or cancelled.

## 12.3 Effect of registration

Registration takes effect prospectively from the date of the decision. It does not validate, and may not be relied upon to validate, any ethical review conducted or approval issued by the IERB before that date. Where the declaration under Section 9(5) or any other information discloses ethical review conducted before registration, the Secretariat refers the matter for enforcement under Section 20; the grant of registration is not a bar to that referral and is not a defence to it.

## 13. Adopted / Affiliated IERB Arrangements

The Policy requires each institution involved in research to establish its own independent IERB registered with NBC. This section applies only within that requirement and is limited accordingly:

1. Applicants that are not institutions within the meaning of the Policy — CROs, consultancy firms, donors, sponsors and independent researchers — may register a formal arrangement to rely on the IERB of an institution whose IERB is registered with NBC.
2. An institution that is required to hold its own IERB but has not yet constituted one may register an affiliation as a transitional arrangement for one registration cycle only. The arrangement is not renewable except by express waiver of NBC, granted on written reasons.
3. There is no emergency exemption. A committee may not be constituted for a single study, and no research may be reviewed under an affiliation before the affiliation is registered.

The application must include:

- a signed agreement between the parties defining the scope and duration of the arrangement;
- the registration number and details of the host IERB; and
- a written assurance that the host IERB will review the applicant's research under the same NBC standards, and will report SAEs and suspensions under Section 14.3 in respect of that research.

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

## 14. Post-Registration Obligations

## 14.1 Change notification

The institution must notify the Secretariat within thirty (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 IERB permanently ceases to operate.

## 14.2 Periodic reporting

Registered IERBs submit:

- a quarterly return, within thirty (30) days of the end of each quarter, stating the meetings held, the quorum at each, the number of protocols received, reviewed, approved, modified and disapproved, and any serious adverse events notified; and
- an annual report covering the year's meetings, protocols reviewed, approvals and exemptions, continuing reviews, adverse-event reports, audits, and any change in membership or procedures.

Delay of up to thirty (30) days in submitting a report is a Category A minor violation under the Framework; failure to report is an offence under the Framework.

## 14.3 Serious adverse events, unanticipated problems and suspensions

Independently of periodic reporting, the IERB must notify NBC-HRI of:

| Event                                                                                                 | Deadline                                                                                 |
|-------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Death of a research participant, or a life-threatening serious adverse event                          | Within 24 hours of the IERB becoming aware, with a written report within 7 calendar days |
| Any other serious adverse event                                                                       | Within 7 calendar days of the IERB becoming aware                                        |
| Any unanticipated problem involving risks to participants or others                                   | Within 7 calendar days                                                                   |
| Any serious or continuing non-compliance by an investigator or the institution                        | Within 7 calendar days                                                                   |
| Any suspension or termination by the IERB of its approval of a study, with the reasons for the action | Within 7 calendar days                                                                   |
| Written follow-up and corrective and preventive action for any of the above                           | Within 15 calendar days of the initial notification                                      |

Reports are made to the NBC Secretariat through the channel published in the registration notice. Failure to report serious adverse events to NBC-HRI is an offence under the Framework, and repeated failure resulting in harm to participants is a Category C severe violation.

## 14.4 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. Institutions must give access to minutes, membership records, training records, protocol files and correspondence.

## 14.5 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 it is decided. Continuing to review or approve research after expiry without having lodged a renewal is an offence under the Framework.

#### 14.6 International and externally funded research

A registered IERB must refer all international collaborative research and all internationally funded research for NBC approval, in addition to its own review. Ethics approval granted by a foreign institution, sponsor or collaborator does not substitute for review by a registered IERB in Pakistan or for referral under this clause, and no funder agreement may displace either requirement.

#### 14.7 Non-compliance, suspension and cancellation

Where the IRC has reason to believe that a registered IERB is non-compliant, has failed to report, or is associated with serious harm to research participants, it prepares a reasoned reference and transmits it to NBC for action under the Framework. Suspension, cancellation and all other penalties follow the Framework's procedure:

1. a Show Cause Notice is issued to the IERB Chairperson and the Head of Institution, stating the allegations;
2. NBC-HRI constitutes an Inquiry Committee, which may summon minutes, interview members and inspect institutional records;
3. the institution is given an opportunity to respond before any penalty is imposed; and
4. the penalty, if any, is imposed in accordance with the classification of offences in the Framework and is appealable under Section 15.

Pending the inquiry, the Chairperson, IRC may impose an interim hold on the registration where necessary to protect research participants from immediate risk. An interim hold is reasoned, is communicated in writing, is limited to sixty (60) days unless extended by NBC on written reasons, and is itself appealable.

### 15. Appeals

An institution or IERB aggrieved by a refusal, a condition, an interim hold, a suspension or a cancellation may appeal. The structure follows the Framework:

| Stage                   | Appellate authority         | Nature and timeframe                                                                                                                                                                                                                         |
|-------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>First</b>            | Executive Director, HRI–NIH | Written appeal within 15 working days of the decision or penalty notification, stating grounds and attaching any corrective documents. The Executive Director reviews the case record and issues a reasoned decision within 15 working days. |
| <b>Second and final</b> | The Board                   | Where the institution remains dissatisfied, an appeal to the Board within 15 working days of receipt of the Executive Director's decision. The Board examines the merits and issues a final judgment                                         |

| Stage | Appellate authority | Nature and timeframe                                            |
|-------|---------------------|-----------------------------------------------------------------|
|       |                     | within 6 weeks. The decision of the Board is final and binding. |

### Principles:

- no person who took part in the original decision sits in judgement of the appeal against it, at any stage;
- the institution is entitled to the reasons for the decision and a fair opportunity to respond in writing and, if allowed, in person or by video link;
- each appellate decision is reasoned, minute and communicated in writing;
- appellate decisions are reported to NBC for oversight and for the register; and
- pursuing an appeal does not bar the institution from simultaneously correcting deficiencies and re-applying under Section 16.

## 16. Re-submission After Refusal

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

| Situation                                                                       | Re-submission rule                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Refused for documentary or administrative deficiencies                          | Re-submit as soon as corrected; no minimum waiting period. Treated as a fresh application with a new tracking number.                                                                                                                                                                               |
| Refused for substantive failures of composition, SOPs or capacity               | Re-submit after addressing the cited reasons. A minimum interval of ninety (90) days applies to allow genuine reconstitution and training, unless the decision letter specifies otherwise.                                                                                                          |
| Application marked "Null and Void" for non-response                             | Lodge afresh whenever ready. The earlier file is closed. Any ethical review conducted in the interim remains referable under Section 12.3.                                                                                                                                                          |
| Registration under interim hold or suspended for cause                          | Restoration on evidence that the cause is remedied, within the period stated in the order; otherwise, a fresh application is required.                                                                                                                                                              |
| Institution or IERB Chairperson blacklisted under a Category C severe violation | No application is entertained until (i) a minimum of three (3) years has elapsed, (ii) all legal penalties and fines are discharged, (iii) the previous IERB structure has been dissolved and a wholly new committee formed, and (iv) a successful NBC-HRI audit and inspection has been completed. |
| While an appeal is pending                                                      | 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, fee-paid application is received.



## 17. Record Keeping

### 17.1 Records held by the Secretariat

- The national IERB register, and the record of registration numbers and certificates issued, are maintained permanently.
- Individual registration files — applications, assessments, minutes, decisions, appeals and correspondence — are retained for the life of the registration and for at least three (3) years after it expires, is cancelled, or the IERB is disbanded.
- Records are held securely with access restricted to authorized Secretariat and IRC personnel, and are accessible for inspection by authorized representatives.

### 17.2 Records held by the IERB

Records relating to research reviewed by the IERB are retained by the institution for at least three (3) years after completion of the research, in accordance with the Policy, and must be produced on request under Section 14.4.

## 18. Grievance Redressal and Reporting of Violations

### 18.1 Grievances about the registration process

Grievances 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.

### 18.2 Reporting of unregistered or non-compliant IERBs

Research coordinators, administrators, investigators and members of the public may report to NBC-HRI the operation of an unregistered IERB or any other violation of the Framework. Reports may be made in confidence. A person who reports in good faith is protected against retaliation under the NBC-HRI whistleblower protection policy, and the institution may not take adverse action against them on account of the report. Reports are assessed by the Secretariat and, where substantiated, referred for action under Section 20.

## 19. References

- Health Research Institute – NIH Act, 2021.
- Regulatory Framework for the Registration of Institutional Ethical Review Boards (IERBs) and Enforcement of Compliance, NBC-HRI.
- National Policy for Institutional Review Boards (IRBs) — NBC guidelines for IRB standardization in Pakistan.
- Drug Regulatory Authority of Pakistan (DRAP) Act, 2012; PM&DC Code of Conduct.
- NBC Gazette Notifications (2004, 2010); NBC and NBC-R Terms of Reference.
- NBC-R Operational Manual, 1st Edition (2023).
- NBC Advisory on Mandatory IERB 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. Enforcement and Penalties

This SOP governs registration. Offences, penalties, inquiry and adjudication are governed by the Framework, which is incorporated here by reference. In summary, and without limiting the Framework:

| Category          | Nature                                                                                                                                                                 | Consequences under the Framework                                                                                                                                                                                                     |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>A — Minor</b>  | Procedural lapses; delay of up to 30 days in reporting; administrative errors in minutes; temporary lapse in quorum where no approval was granted                      | Show cause notice to the IERB Chairperson and Head of Institution; corrected documentation within 14 working days; increased scrutiny of the next quarterly report                                                                   |
| <b>B — Major</b>  | Operating with expired registration; missing mandatory Lay Member; approving research without a proper quorum                                                          | Suspension of the IERB's ability to review new protocols for 6 months; institutional fine; approvals issued during non-compliance may be declared void                                                                               |
| <b>C — Severe</b> | Willful operation of a fake or ghost board; forging a registration certificate; repeated failure to report SAEs resulting in harm; research fraud approved by the IERB | Referral for criminal prosecution; permanent blacklisting of the institution and the IERB Chairperson; recommendation to PM&DC, HEC or DRAP for licence revocation; further penalties on the recommendation of the Inquiry Committee |

Liability. The Principal Investigator bears primary responsibility for verifying that the IERB reviewing the protocol is registered; the Head of Institution is equally liable for the operation of any unregistered IERB within the institution; the IERB Chairperson is personally liable for the accuracy of the registration application and for the conduct of the board's meetings.

Defences that are not available. That the institution had established a committee but not registered it; that a foreign sponsor or international collaborator required or permitted otherwise; that the research was urgent; that the requirement was unknown. Registration granted after a violation has been detected does not excuse the violation.

## 21. Annexes

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

| Item                                                                                                                             | Enclosed                 |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Covering letter and completed NBC IERB Registration Form, signed and certified personally by the Head of Institution             | <input type="checkbox"/> |
| Constituting notification or order establishing the IERB, naming Chairperson and Member Secretary                                | <input type="checkbox"/> |
| Membership list (name, qualification, role, gender, profession, affiliation, COI) — odd number, minimum five                     | <input type="checkbox"/> |
| Identification of the Lay Member (non-medical, non-researcher, unaffiliated) and of the separate External Member                 | <input type="checkbox"/> |
| Confirmation that both genders are represented and that the board is not of a single profession                                  | <input type="checkbox"/> |
| Where vulnerable participants are regularly reviewed: identification of the member(s) with relevant experience                   | <input type="checkbox"/> |
| CVs and certified research-ethics / GCP training evidence for every member                                                       | <input type="checkbox"/> |
| IERB written SOPs (initial and continuing review, expedited review, decisions, amendments, appeals, AE/SAE, COI, records)        | <input type="checkbox"/> |
| Written prompt-reporting procedure to the IERB, institutional officials and NBC-HRI                                              | <input type="checkbox"/> |
| Quorum rule (majority of members, including at least one non-scientific member) and annual meeting schedule (at least quarterly) | <input type="checkbox"/> |
| Conflict-of-interest policy and signed declaration forms                                                                         | <input type="checkbox"/> |
| Signed institutional declaration of non-interference in IERB decisions                                                           | <input type="checkbox"/> |
| Written assurance of compliance with NBC policies                                                                                | <input type="checkbox"/> |
| Declaration under Section 9(5) regarding any ethical review conducted before registration                                        | <input type="checkbox"/> |
| Proof of payment of the applicable fee                                                                                           | <input type="checkbox"/> |
| For an affiliated IERB: inter-institutional agreement and host IERB registration details                                         | <input type="checkbox"/> |

**Annex B — IRC assessment and decision sheet (internal)**

| Field                                                                                   | Entry |
|-----------------------------------------------------------------------------------------|-------|
| Tracking number / date file complete and fee received                                   |       |
| Composition: odd number $\geq 5$ (Y/N)                                                  |       |
| Lay Member — non-medical and unaffiliated (Y/N)                                         |       |
| Separate External Member (Y/N)                                                          |       |
| Both genders represented; not a single profession (Y/N)                                 |       |
| Quorum rule is a majority including a non-scientific member (Y/N)                       |       |
| Independence declaration on file (Y/N)                                                  |       |
| Prompt-reporting procedure on file (Y/N)                                                |       |
| Training certificates for every member (Y/N)                                            |       |
| All other Section 8 elements met (Y/N each — attach sheet)                              |       |
| Pre-registration review declared under Section 9(5) (Y/N; referred under Section 12.3?) |       |
| IRC quorum present / members recused                                                    |       |
| Decision (grant / grant with conditions / defer / refuse)                               |       |
| Consensus or vote (tally if vote)                                                       |       |
| Reasons and conditions                                                                  |       |
| Registration number assigned                                                            |       |
| Signed and issued — Chairperson, IRC / NBC Focal Person                                 |       |