



# NATIONAL BIOETHICS COMMITTEE (NBC)

## Standard Operating Procedure (SOP)

For Applicants Submitting Clinical Trial Protocols for Ethical Review



|                       |                                                               |
|-----------------------|---------------------------------------------------------------|
| <b>SOP Title</b>      | Applicant Submission Procedure for Clinical Trials to the NBC |
| <b>SOP No.</b>        | NBC/SOP/CT-01                                                 |
| <b>Version</b>        | 1.0                                                           |
| <b>Effective Date</b> | [30 <sup>th</sup> /June/2026]                                 |
| <b>Review Cycle</b>   | Every 2 years, or as required                                 |
| <b>Owner</b>          | Secretariat, National Bioethics Committee                     |

## 1. Purpose

This SOP describes the procedure that applicants (Principal Investigators, Sponsors, or their authorized representatives) must follow when submitting clinical trial protocols and related documents to the National Bioethics Committee (NBC) for ethical review and approval. It defines the required documentation, submission timelines, meeting schedule, and the review process.

## 2. Scope

This SOP applies to all applicants submitting new clinical trial applications, protocol amendments, continuing/annual reviews, and related correspondence to the NBC for consideration by the Review Committee.

## 3. Definitions

- **Applicant:** The Principal Investigator, Sponsor, or an authorized representative submitting an application to the NBC.
- **Review Committee:** The NBC body responsible for the scientific and ethical review of clinical trial applications.
- **Submission Deadline:** The cut-off date and time by which a complete application must be received for it to be scheduled for the next Review Committee meeting.
- **Complete Application:** A submission that includes all mandatory documents listed in Section 5, correctly formatted and duly signed.

## 4. Responsibilities

- **Applicant:** Prepares and submits a complete application within the prescribed timelines and responds to Committee queries.
- **NBC Secretariat:** Receives applications, checks completeness, logs submissions, and prepares the agenda for Review Committee meetings.
- **Review Committee:** Reviews submitted applications and issues a decision (approval, conditional approval, deferral, or rejection).

## 5. Mandatory Submission Documents

Applicants must submit a complete dossier including, at minimum:

1. Duly completed NBC application form.
2. Study protocol (final version, with version number and date).
3. Informed consent form(s) and patient information sheet(s), in English and local language(s).
4. Investigator's Brochure or equivalent product/device information.
5. Curriculum vitae of the Principal Investigator and co-investigators (signed and dated).

6. Case report forms (CRFs) or data collection tools.
7. Insurance/indemnity certificate for trial participants.
8. Evidence of regulatory authority approval or submission status (where applicable).
9. Site suitability/feasibility documentation.
10. Any other document specifically requested by the Secretariat or Review Committee.

Incomplete applications will not be logged for review and will be returned to the applicant with a list of deficiencies.

## 6. Submission Process

1. Applicant submits the complete dossier (hard copy and/or electronic copy, as specified by the Secretariat) to the NBC Secretariat.
2. Secretariat performs a completeness check within 1 working day of receipt.
3. If incomplete, the Secretariat notifies the applicant in writing, specifying the missing items.
4. If complete, the Secretariat logs the application, assigns a reference number, and schedules it for the next available Review Committee meeting, subject to the submission deadline in Section 7.
5. The applicant receives written acknowledgment confirming the reference number and the meeting date at which the application will be considered.

## 7. Review Committee Meeting Schedule and Submission Deadline

The Review Committee meets fortnightly (once every two weeks), on Tuesdays.

Meetings will be conducted online (via video conferencing) where required, as determined by the Secretariat; applicants and Committee members will be notified of the meeting mode in advance.

**Submission cut-off:** Complete applications must be received by the NBC Secretariat no later than **2:00 PM on the Thursday preceding** the scheduled Tuesday meeting.

*Applications, or any supporting/supplementary documents, received after this deadline will not be considered for the upcoming meeting, regardless of the reason for the delay. Such submissions will automatically be scheduled for the following fortnightly meeting, provided they are otherwise complete.*

| Submission Received By                                | Meeting Considered                                          |
|-------------------------------------------------------|-------------------------------------------------------------|
| Thursday, 2:00 PM (or earlier), preceding the meeting | Next scheduled Tuesday meeting (fortnightly)                |
| After Thursday, 2:00 PM                               | Deferred automatically to the following fortnightly meeting |

Note: This cut-off applies to first-time submissions as well as resubmissions, amendments, and any documents requested by the Committee following a prior review. No exceptions will be made for late submissions; applicants are advised to plan submissions well ahead of the deadline to allow time for the Secretariat's completeness check.

## 8. Review Process

1. The Secretariat circulates the finalized agenda and application dossiers to Committee members at least 3 working days before the meeting, along with the meeting link/joining details where the meeting is being held online.
2. The Review Committee evaluates each application against applicable ethical and scientific guidelines.
3. The Committee may issue one of the following decisions: Approval, Conditional Approval (with required modifications), Deferral (pending further information), or Rejection.
4. Minutes of the meeting and the Committee's decision are finalized by the Secretariat within 1 working day of the meeting and circulated to Review Committee members for their confirmation, after which the finalized minutes are forwarded to the NBC Chairperson.

## 9. Communication of Decision

The Secretariat communicates the Committee's decision to the applicant in writing within 05 working days of the meeting. Where conditional approval or deferral is issued, the letter will specify the required modifications or additional information and the resubmission deadline.

## **10. Resubmission of Deferred or Conditionally Approved Applications**

Applicants responding to a Committee decision must submit the revised documents, along with a point-by-point response to Committee comments, subject to the same submission deadline described in Section 7 (i.e., received by 2:00 PM on the Thursday preceding the next relevant Tuesday meeting).

## **11. Record Keeping**

The Secretariat maintains a log of all applications, submission and acknowledgment dates, meeting schedules, and Committee decisions, retained in accordance with the NBC's document retention policy.

## **12. Enquiries**

Applicants may direct queries regarding submission requirements or deadlines to the NBC Secretariat.

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