

INITIAL REVIEW

A. Protocol Initial Submission

1. Prepare Complete Submission Package

- Ensure all required documents and forms are complete.
- Follow the **Form 4.1 Checklist**.
- *Incomplete submissions will not be accepted and will be returned.*

2. Submit to IRB

- Submit the following:
 - Two (2) hard copies (for PELI-IRB)
 - One (1) receiving copy (for PI)
 - One (1) electronic copy
- The receiving copy will be stamped with the date received.

3. Acknowledgment and IRB Code

- A unique IRB Protocol Code will be assigned.
- Use this code in all future communications.

4. Technical Review

- The protocol undergoes technical review prior to ethical review.
- The PI may be required to clarify or revise methodology, study design, sampling, or analysis.

5. Ethical Review

- Upon technical approval, the protocol proceeds to:
 - Expedited Review, or
 - Full Board Review
- Additional clarifications may be requested.

6. IRB Decision

- The PI will receive one of the following:
 - Approval
 - Modification
 - Disapproval
 - Request for Clarification
- Decisions are communicated through official IRB correspondence.

7. Communication and Compliance

- Ensure timely responses to all queries and required revisions.
- *Delays in response may result in delays in approval.*

Required Documents for Initial Submission

- Cover Letter addressed to the PELI-IRB Chair
- **Form 4.1** – Application for Protocol Review
- **Form 4.2** – Protocol Evaluation Form (Technical Review)
- **Form 4.3** – Protocol Evaluation Form (Ethical Review)
- **Form 4.4** – Informed Consent Evaluation Form
- **Form 4.5** – Declaration of Conflict of Interest
- **Form 4.10** – Letter of Undertaking (for oversight, if applicable)

Forms 4.2, 4.3, and 4.4 must be submitted in both PDF and editable Word format for IRB review.

B. Protocol Resubmission

- All resubmissions shall be made using **Form 9 – Protocol Resubmission Form**.
- Resubmissions must be completed within **90 days** from the date of the decision letter.
- *Failure to comply within 90 days will result in inactivation and archiving of the protocol. Subsequent submissions will be treated as a new initial submission.*

Required Documents for Resubmission

1. Cover Letter (addressed to the PELI-IRB Chair)

Must include:

- Summary of revisions made
- Reference to IRB recommendations
- Specific page/section of changes

2. Revised Protocol Package

- Updated version number and date must be reflected
- Updated Study Protocol (clean and tracked versions)
- Updated Informed Consent Form (clean and tracked versions)
- Supporting documents, as applicable

3. Form 9 – Protocol Resubmission Form

- Submit in both PDF and editable Word format

Form 9 Completion Requirements:

- List each IRB recommendation
- Provide corresponding PI response/action taken
- Indicate exact location of revision (page/section)
- Ensure all comments are fully addressed with specific, aligned responses

Submission Mode:

- Submit all documents and attachments in both hard copy and electronic copy