

POST-APPROVAL SUBMISSIONS

1. Progress Report

- The Principal Investigator (PI) shall submit a Progress Report every six (6) months from the date of IRB approval, at least one (1) month prior to the due date.
- **Required Documents:**
 - Cover Letter addressed to the PELI-IRB Chair
 - Accomplished Form 13 – Progress Report (PDF and editable Word format)
- **Submission Mode:**
 - Submit all documents and attachments in both hard copy and electronic copy

2. Continuing Review Application

- Must be submitted at least one (1) month prior to the expiration of ethical clearance.
- **Required Documents:**
 - Cover Letter addressed to the PELI-IRB Chair
 - Accomplished Form 19 – Continuing Review Application (PDF and editable Word format)
 - Accomplished Form 4.5 – Declaration of Conflict of Interest (for PI and Sub-Investigators)
 - Updated credentials of PI and Sub-Investigators
 - Summary list of previously approved submissions (e.g., amendments, deviations, SAEs)
 - Protocol synopsis and latest approved Informed Consent Form (ICF), as applicable
 - CVs of newly delegated personnel, if any
- **Submission Mode:**
 - Submit all documents and attachments in both hard copy and electronic copy

3. Protocol Amendment

- **Required Documents:**
 - Cover Letter addressed to the PELI-IRB Chair
 - Accomplished Form 12 – Protocol Amendment Form (PDF and editable Word format)
 - Clean and tracked changes versions of amended documents
 - Description of amendment(s), affected protocol section(s), and justification
- **Submission Mode:**
 - Submit all documents and attachments in both hard copy and electronic copy

4. Final Report

- **Required Documents:**
 - Cover Letter addressed to the PELI-IRB Chair
 - Accomplished Form 14 – Final Report (PDF and editable Word format)
- **Submission Mode:**
 - Submit all documents and attachments in both hard copy and electronic copy

5. Deviation / Early Protocol Termination / Notification / SAE

- **Required Documents:**
 - Cover Letter addressed to the PELI-IRB Chair
 - Appropriate accomplished PELI-IRB form (PDF and editable Word format):
 - Form 14 – Deviation / Non-Compliance Report
 - Form 18 – Early Protocol Termination
 - Form 11 – Serious Adverse Event (SAE) Report
 - Supporting documents, as applicable
- **Submission Mode:**
 - Submit all documents and attachments in both hard copy and electronic copy