



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

Quezon Avenue Extension, Quezon City, Philippines 1100
 Room 4013, 4th floor, LCP Main Building Tel Nos. 89246101 local 4047 / 4048
 E-mail : lcpierb@gmail.com, Website : www.lcp.gov.ph

FOR SUBMISSION OF POST-APPROVAL REVIEW APPLICATION PROTOCOL PACKAGE:

To ensure the systematic and organized facilitation of submitted documents, please follow the procedure of submission.

1. Submit Post-approval application through email, lcpierb@gmail.com
2. SUBJECT of the email should be: (LCP-IERB Code) - Amendment/Continuing Review/SAE/PD/Final Report Application
3. All documents shall be signed and dated as indicated.
4. Incomplete submission will not be accepted.
5. Hard copy package to be submitted within 1 week after online submission.

FOR AMENDMENT APPLICATION

1. Submit the AMENDMENT APPLICATION package through the LCP-IERB email at lcpierb@gmail.com and three (3) printed duplicate copies within 7 calendar days after the online submission.
2. **AMENDMENT APPLICATION package includes the following:**
 - a. Cover letter summarizing the content of the submission indicating in which page of the revised study protocol the respective revision may be found, and the documents attached to the submission.
 - b. Properly filled-out, signed and dated LCPIERB Form 3.2 – 2022: Amendment Application Form with the first column filled-out with List of Amendment/s and the second column with the reason/s of amendment, in MS Word **AND** PDF format.
 - c. The revised documents (Protocol/ICF and others) in MS Word **OR** PDF format with the modified part **underlined and bold-faced**. A footer should be included in all pages indicating both the DATE and VERSION NUMBER of the submitted study protocol/ICF.

FOR CONTINUING REVIEW APPLICATION / PROGRESS REPORT

1. Submit the CONTINUING REVIEW APPLICATION / PROGRESS REPORT package through the LCP-IERB email at lcpierb@gmail.com and three (3) printed duplicate copies within 7 calendar days after the online submission.
2. **CONTINUING REVIEW APPLICATION / PROGRESS REPORT package includes the following:**
 - a. Properly filled-out, signed and dated LCPIERB Form 3.3-2022: Continuing Review Application Form in MS Word **AND** PDF format.
 - b. Copy of (1) recently approved protocol and ICF, (2) recently approved amendments/revision since the last renewal (with the modified part **underlined and bold-faced**), and (3) each previously submitted Progress Report, in MS Word **OR** PDF format. A footer should be included in all pages indicating both the DATE and VERSION NUMBER of the submitted study protocol/ICF.

FOR SAE REPORT

1. Submit the SERIOUS ADVERSE EVENT REPORT (SAE) package through the LCP-IERB email at lcpierb@gmail.com and one (1) printed copy within 7 calendar days after the online submission.
2. **SAE Report package includes the following:**

- a. Properly filled-out, signed and dated LCPIERB Form 3.1-2022: Serious Adverse Event Report Form in MS Word **AND** PDF format.
- b. Attach standard SAE report form (CIOMS) to the LCP-IERB Form in PDF format

FOR PROTOCOL DEVIATION / NON-COMPLIANCE REPORT

1. Submit the Protocol Deviation / Non-Compliance Report package through the LCP-IERB email at lcpierb@gmail.com and one (1) printed copy within 7 calendar days after the online submission.
2. **Protocol Deviation / Non-Compliance Report package includes the following:**
 - a. Properly filled-out, signed and dated LCPIERB Form 3.4-2022: Study Protocol Non-Compliance Report Form in MS Word **AND** PDF format.
 - b. Copy of necessary documents to clarify and/or justify the non-compliance

FOR FINAL REPORT

1. Submit the FINAL REPORT package through the LCP-IERB email at lcpierb@gmail.com and three (3) printed copies within 7 calendar days after the online submission.
2. **FINAL REPORT package includes the following:**
 - a. Properly filled-out, signed and dated LCPIERB Form 3.8-2022: Final Report Form in MS Word **AND** PDF format.
 - b. Copy of (1) recently approved protocol and ICF in MS Word **OR** PDF format. A footer should be included in all pages indicating both the DATE and VERSION NUMBER of the submitted study protocol/ICF.
 - c. Copy of Final Paper / Result of the study
 - d. Documents to support the submission

Note for Hard copy Submission:

1. Hard copy submission in **3 duplicate copies**, within one week after the online submission on appointment basis. (Contact the secretariat at (02) 89246101 local 4047)
2. Follow the below sequence starting from the second page to succeeding pages:
 - ✓ LCPIERB Forms
 - ✓ Cover Letter (if applicable)
 - ✓ Other attachments
3. All documents submitted should be labeled, tabbed and signed by the PI as indicated (if the submission is consisting of more than 2 documents)
4. Submit study protocol and related documents in data file folder or in PVC binders for Clinical Trials.
5. Our office is located at RM 4013, IERB Office, 4th Floor, Lung Center of the Philippines, Quezon City.

REVIEW FEE

TYPE OF PROTOCOL		TYPE OF REVIEW	REVIEW FEE
Sponsor Initiated Protocol	Pharmaceutical Sponsored / Investigational New Drug	Full Board	50,000.00
		Expedited	30,000.00
		<u>Renewal</u>	<u>30,000.00</u>
		<u>Amendment</u>	<u>10,000.00</u>
	Government Funded Research (e.g., DOST, WHO etc.)	Full Board / Expedited	30,000.00
		<u>Renewal</u>	<u>15,000.00</u>
Principal Investigator Initiated Protocol	Protocols from Professional Researcher: ➤ Researcher from the academe ➤ Consultants affiliated to recognized local and international Organization	Full Board	10,000.00
		Expedited	5,000.00
		<u>Renewal</u>	<u>5,000.00</u>
	Protocols from trainees such as: <i>Trainees of the <u>home institution</u>:</i> <i>Trainees of the <u>other institution</u>:</i> ➤ Hospital Fellow / Resident ➤ Graduate School ➤ Undergraduate Students	No fees shall be charged	
		Full Board / Expedited 5,000.00	
		Undergraduate Students Full Board / Expedited 1,000.00	
		No review fee for renewal	

STATEMENT OF ACCOUNT

Submit the following information:

- Sponsor Code <If applicable>
- Principal Investigator:
- Sponsor:
- Bill to:
- Billing Address:

LCPIERB will review the protocol once payment of the review fee has been settled with the LCP cashier.
(Submit photocopy of OR to the LCP-IERB Secretariat)