LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

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CHECKLIST

STUDY PROTOCOL INFORMATION

		Submission Date	
LCP-IERB CODE		Sponsor Protocol Number	
Protocol Title			
Principal Investigator			
Sponsor			
Study Protocol Submission Date		Verified Complete by	

Documents to be submitted:

* ☐ Full Protocol
* ☐ Checklist Form (*LCPIERB Form* 2 (C) – 2018)
* ☐ Application Form for Protocol Review (*LCPIERB Form 2(B) – 2018)*
* ☐ Protocol Summary Sheet (*LCPIERB Form 2(D) – 2015)*
* ☐ Protocol Evaluation Form (*LCPIERB Form 2(E) – 2018)*
* ☐ Informed Consent Evaluation Form (*LCPIERB Form 2 (F) – 2015)*
* ☐ Protocol Document Review Form *(LCPIERB Form 2(G) – 2015)*
* ☐ Document Receipt Form (LCPIERB Form 2(A) – 2018)
* ☐ Budget
* ☐ Informed consent form in English (for studies with human participants)
* ☐ Informed consent form in local language (for studies with human participants)
* ☐ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
* ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)

☐ Informed consent form for Genetic Studies in English and Local language

☐ Data collection forms (including CRFs)

☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for Phase IV clinical trials)

☐ Recruitment advertisement, if applicable

☐ Other information or documents for participants (such as diaries, etc.)

* ☐ Curriculum Vitae of PI and study team members

* ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team, updated (at least within 3 years)

* ☐ Journal Reports and Literature Review (for fellows-in-training, residents-in- training, nurses and other allied personnel)

☐ Declaration of Conflict of Interest signed by the PI *(LCPIERB Form 2(B) – 2018: Application Form for Protocol Review)*

☐ Ethical considerations: description/ statement of compliance with ethical principle *(LCPIERB Form 2(B) – 2018: Application Form for Protocol Review)*

☐ LCPIERB Form 2(H) – 2018: Checklist for clinical trial outside LCP by LCP PI (must be accomplished by LCP PI applying for review and will conduct research at another site

☐ LCPIERB Form 2(I) – 2018: Checklist for clinical trial outside LCP by non-LCP PI (must be accomplished by non- LCP PI applying for review and will conduct research at another site

☐ Contracts and/or Approval of relevant offices (Written review Agreement/Authorization and Acknowledgement of Review) with LCP (LCPIERB Form 2(B) – 2018: Application Form for Protocol Review)

☐ Technical Review Board approval signed and dated, if applicable

Principal Investigator's Signature		Date	

Note:

1. Cover page of the file folder must contain the following information:
   - Protocol Title
   - Protocol No.
   - Sponsor
   - Principal investigator
   - Site Name
2. Follow the below sequence starting from the second page to succeeding pages:
   - TRB Approval signed and dated, if applicable
   - LCP-IERB above Documents
   - Table of Contents
   - Study Protocol
3. All documents submitted should be labeled or tabbed, and signed by PI as indicated; submit to LCPIERB Secretariat at room 4013, 4th floor Lung Center of the Philippines, Quezon Avenue Extension, Quezon City.
4. Submit study protocol and related documents in data a file folder or in PVC binders for clinical trials. For fellows-in-training, residents-in-training, nurses and allied personnel, use folders with binder.
5. All items with * must be submitted by fellows and residents-in-training, students, nurses and other allied health personnel.