LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

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Checklist for Clinical Trial Outside LCP by LCP Personnel

Submission Date	

LCP-IERB CODE		Sponsor Protocol Number	

Protocol Title	

Name		Email	Mobile / Phone / Fax Number	Institution / Department
Principal Investigator				

Preferred means of contact	☐ Mobile ☐ Phone ☐ Fax

External Site Name	External Site Address	External Site Medical Director / Administrator	Phone / Fax Number

Study Sponsor / CRO	

INSTRUCTIONS: This form shall be filled-up by an LCP Principal Investigator applying for ethical clearance from the LCPIERB for a clinical trial that will be conducted outside the LCP premises. All fields should be filled out. If necessary, supporting documentation may be required.

A. Safety Requirements for Research Participants

Does the study site provide a 24-hour emergency room service?

_____ If YES, proceed to A-1 and do not fill out A-2
_____ If NO, proceed to A-2

A-1	Yes	No	Remarks
1. Does the study site emergency room have a fully loaded e-cart?	☐	☐	
2. Does the study site emergency room have a functioning defibrillator?	☐	☐	
A-2			
1. If there is no 24-hour emergency room service, where do you intend to refer your research participants in case of adverse events especially after office hours?			<Name of emergency facility>
2. Describe nature of your appointment in the hospital where patients will be referred for emergency care in case of an adverse event? (NOTE: Final LCPIERB approval also depends on the logistical feasibility in cases of adverse events to ensure safety of participants)			<description>
B. Administrative Questions	**Yes**	**No**	**Remarks**
1. Do you have an office space in the clinic that is conducive to the conduct of the clinical trial?	☐	☐	
2. Does the study site have a telephone line?	☐	☐	
3. Does the study site have a fax machine on 24 hours?	☐	☐	
4. Can the sponsor commit to pay for expenses for site visit by the LCPIERB (1 visit per year by two LCPIERB members and 1 Staff)?	☐	☐	
5. Are you and your clinic/hospital administrator willing to have a Certificate of Agreement (Authorization and Acknowledgment of Review) with LCP regarding the review of the study protocol and monitoring of the conduct of study by the LCPIERB?	☐	☐	
6. Where do you plan to recruit your research participants?	<name of site>		
7. How many participants with the condition of interest do you see per month in your clinic or hospital?	<quantity>		

Principal Investigator's Signature		Date	
Administrator of Study Site	 *Signature over printed name*	Date	