



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

Quezon Avenue Extension, Quezon City, Philippines 1100

4th Flr. Room 4013 Tel Nos. 9246101 local 568

E-mail : lcpierb@gmail.com. Website : erc@lcp.gov.ph

PROTOCOL DOCUMENT REVIEW FORM

Submission Date	
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LCP-IERB CODE		Sponsor Protocol Number	
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Protocol Title	
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	Name	Mobile / Phone Number
Principal Investigator		
Sponsor		

INSTRUCTIONS:	Please evaluate how the elements outlined below have been appropriately addressed by the study protocol, as applicable, and by confirming the submitted information and putting your comments in the space provided under "COMMENTS." Finalize your review by indicating your decision, recommendations and signing in the space provided for the primary reviewer.	
1	Objectives of the Study <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	Comments:
2	Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
3	Methodology: <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	Comments:
4	Background Information and Data <input type="checkbox"/> Sufficient <input type="checkbox"/> Insufficient	Comments:
5	Risks and Benefits Assessment <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
6	Inclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comments:

7	Exclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comments:
8	Withdrawal Criteria <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
9	Involvement of Vulnerable Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
10	Voluntary, Non-Coercive Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
11	Sufficient number of participants? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
12	Control Arms (placebo, if any) <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
13	Are the qualifications and experience of the participating investigators appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
14	Disclosure or Declaration of Potential Conflicts of Interest <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
15	Facilities and infrastructure of participating sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comments:
16	Community Consultation <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
17	Involvement of local researchers and communities in the protocol preparation and implementation <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
18	Contribution to local capacity building <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
19	Benefit to local communities <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
20	Sharing of study results <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
21	Are blood/tissue samples sent abroad? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
22	Will Pharmacogenetic study be done? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:

Decision	<input type="checkbox"/> Approval <input type="checkbox"/> Minor Revision <input type="checkbox"/> Major Revision / Resubmission <input type="checkbox"/> Disapproval
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Recommendations: (Identify items for revision)	
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Primary Reviewer	Signature	Date