



B I C O L U N I V E R S I T Y
College of Medicine
 Institutional Review Board



Telefax: (052) 742-0076

URL: <http://www.bicol-u.edu.ph/bucm/>

Email: bucm_irb@bicol_u.edu.ph

PROTOCOL EVALUATION FORM (FORM 2.3)

IRB Protocol No.		Date (D/M/Y):	
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Protocol Title:	
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Principal Investigators:	
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Department		Contact no./ Email	
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Co – investigator(s):		Contact no./ Email	
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Total No. of Participants:		No. of Study Sites:	
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Sponsor		Contact No/ Email	
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Duration of the Study:		Status:	<input type="checkbox"/> New	<input type="checkbox"/> Amended
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Reviewers:	
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Type of the Study	<input type="checkbox"/> Intervention <input type="checkbox"/> Document review <input type="checkbox"/> Social Survey	<input type="checkbox"/> Epidemiology <input type="checkbox"/> Individual based <input type="checkbox"/> Others, specify	<input type="checkbox"/> Observational study <input type="checkbox"/> Genetic <input type="checkbox"/>
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Review Status	<input type="checkbox"/> Full Board	<input type="checkbox"/> Expedited
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Description of the Study in brief: Mark whatever applies to the study.

<input type="checkbox"/> Randomized	<input type="checkbox"/> Drug	<input type="checkbox"/> Use of Genetic Materials
<input type="checkbox"/> Double blind	<input type="checkbox"/> Medical Device	<input type="checkbox"/> Multicenter study
<input type="checkbox"/> Single blind	<input type="checkbox"/> Vaccine	<input type="checkbox"/> Global protocol
<input type="checkbox"/> Open label	<input type="checkbox"/> Diagnostics	<input type="checkbox"/> Sponsor Initiated
<input type="checkbox"/> Observational	<input type="checkbox"/> Questionnaire	<input type="checkbox"/> Investigator Initiated



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A. PROTOCOL

DOCUMENT REVIEW

<p>1. Objectives of the Study <input type="checkbox"/> clear <input type="checkbox"/> unclear</p>	<p>What should be improved?</p>
<p>2. Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>3. Methodology: <input type="checkbox"/> clear <input type="checkbox"/> unclear</p>	<p>What should be improved?</p>
<p>4. Background Information and Data <input type="checkbox"/> sufficient <input type="checkbox"/> insufficient</p>	<p>Comment:</p>
<p>5. Risks and Benefits Assessment <input type="checkbox"/> acceptable <input type="checkbox"/> unacceptable</p>	<p>Comment:</p>
<p>6. Inclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate</p>	<p>Comment:</p>
<p>7. Exclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate</p>	<p>Comment:</p>
<p>8. Withdrawal Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate</p>	<p>Comment:</p>
<p>9. Involvement of Vulnerable Participants <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>10. Voluntary, Non-Coercive Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>11. Sufficient number of participants? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>12. Control Arms (placebo, if any) <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>13. Are the qualifications and experience of the participating investigators appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>14. Disclosure or Declaration of Potential Conflicts of Interest <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>15. Facilities and infrastructure of participating sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate</p>	<p>Comment:</p>
<p>16. Community Consultation <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>17. Involvement of local researchers and communities in the protocol preparation and implementation <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>



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- | | |
|---|----------|
| 18. Contribution to local capacity building
<input type="checkbox"/> Yes <input type="checkbox"/> No | Comment: |
| 19. Benefit to local communities
<input type="checkbox"/> Yes <input type="checkbox"/> No | Comment: |
| 20. Sharing of study results
<input type="checkbox"/> Yes <input type="checkbox"/> No | Comment: |
| 21. Are blood/tissue samples sent abroad?
<input type="checkbox"/> Yes <input type="checkbox"/> No | Comment: |

B. RECOMMENDATION

DECISION :	<input type="checkbox"/> Approval	<input type="checkbox"/> Minor Revision
	<input type="checkbox"/> Major Revision/ Resubmission	<input type="checkbox"/> Disapproval

Comments (Identify items for revision.)	
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Reviewer's Name		Date:	
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Signature :	
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