



**UNIVERSITY OF SANTO TOMAS
THE GRADUATE SCHOOL**

THOMAS AQUINAS RESEARCH COMPLEX
ESPAÑA MANILA, PHILIPPINES

Ethics Review Committee

(Adapted with Permission from the UP-NIH Ethics Review Board)

(FORM 33)

* ALL CAPS preferred for this field

REVIEWER'S ASSESSMENT FORM

* PROJECT TITLE/RESEARCH STUDY

* PROPONENT (SURNAME)

(FIRSTNAME)

(MIDDLENAME)

* CONTACT NUMBER OF PRIMARY INVESTIGATOR

* ADVISER

* INSTITUTION/AFFILIATION:

Research Classification

Undergraduate

Doctoral

Clinical Trial

* Supervisor's Name:

Masteral

Independent

**For the Principal Investigator
Reviewer's Assessment Form**
(kindly check the items that apply to your protocol)

For the Reviewer/s
(kindly include your review comments)

For the Proponent (Student)
(kindly include the page number for every "yes")

A. The protocol/research study contains the following:	YES	NO	N/A
1. Background of the Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Significance of Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Rationale of Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Literature Review			
a. Results of animal/human studies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Known risks of procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Known benefits of procedure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Known adverse effects of drugs/procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Objectives of Study			
a. Primary objective	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Secondary objectives.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Statement of Risks of the Project			
a. To study participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. To community	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Possible adverse events (AE)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Statement of benefits of the project			
a. To study participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. To community	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Recruitment of participants			
a. Recruitment procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Inclusion/Exclusion criteria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Methods			
a. Type of study design	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Setting for project	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Duration of project	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Procedures to be done	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Informed consent/Elements of Informed Consent			
a. Participation information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Informed Consent of Participant/s	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Voluntarism of Participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Consent of legal guardian/s <i>(if needed)</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Two witnesses <i>(if needed)</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Conflict of interest			
a. Full disclosure of potential sources of conflict of interest involving any of the authors or the granting agency.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Anonymity, privacy and confidentiality of health information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Full disclosure of publication rights	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Amount and method of reimbursement of trial-related expenses of the study participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

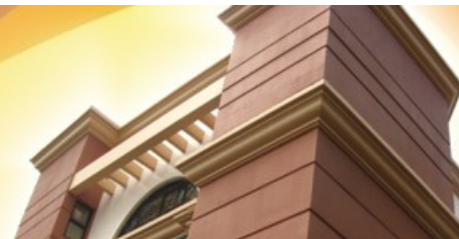


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REVIEWER'S ASSESSMENT FORM

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13. Vulnerable subjects involved in the study

a. A description of who may solicit consent, how, and when it will be done	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
b. A description of who may give consent (involving minors and not legally competent to give consent)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
c. Full disclosure of publication rights	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
d. Involvement of sensitive topics (sexual activity, illegal or political behaviour, mental health, gender or ethnic status, drug use).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

14. Risks

a. Provisions for management of adverse reactions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
b. Interim analysis and provisional or mandatory cessation guidelines in case harmful effect are demonstrated during the study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
c. Non-material compensation to participant/s such as health education or other creative benefits, where no clear, direct benefit from the project will be received by the said participant/s	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
d. Guarantee of medical care/indemnification of study participant/s in case of trial-related injuries, which shall not be subject to previous Waiver	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
e. Involving the collection, use and storage of human tissues/specimens and genetic information (blood, urine, saliva, DNA, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
f. Level of risks				
1) Low	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2) Medium	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3) High	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

15. Curriculum vitae of investigators

a. Complete name, titles, institutional affiliations of principal investigator	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
b. Name of co-workers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
c. Job description of co-workers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
d. Responsibilities of each worker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
e. Contract with sponsor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

16. Project sponsor/s

a. Complete name	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
b. Address	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
c. Name of contact person/s	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
d. Telephone number of contact person/s	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
e. Statement of sponsor's interest /co-authorship	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

17. List of references

18. Budget

B. SUMMARY OF COMMENTS

- Approval/Favorable opinion
- Modifications required prior to approval
- Disapproval/Negative opinion

Date:
Reason/s for disapproval

(Member, USTGS Ethical Review Committee)
Signature over printed name)

Date: _____

C. FINAL ACTION

- APPROVED
- DISAPPROVED

(Chairperson, USTGS Ethical Review Committee)
Signature over printed name)

Date: _____