

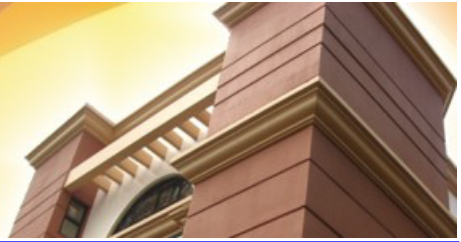


**UNIVERSITY OF SANTO TOMAS
THE GRADUATE SCHOOL**

THOMAS AQUINAS RESEARCH COMPLEX
ESPAÑA MANILA, PHILIPPINES

Ethics Review Committee

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



SELF-ASSESSMENT CHECKLIST FOR INFORMED CONSENT FORM

FORM 2

* ALL CAPS preferred for this field

* 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
Self-Assessment Checklist for Informed Consent
(kindly check the items that apply to your protocol)**

A. Assessment for Informed Consent	YES	NO	N/A
1. Informed Consent form (in English and Filipino or in a language understandable to the study participants).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Contains the following elements of an informed consent:			
2.1. The study's investigative nature.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.2. The number of the study participants in the trial.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.3. The purpose / objective of the study.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.4. The trial procedures treatments and probability for random assignment to each treatment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.5. The trial procedures to be done, including all invasive procedure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.6. The expected duration of a subject's involvement and number of follow-up visits.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.7. Potential or direct benefits (if any) from participation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.8. Alternative procedure(s) or course(s) of treatment that may be available.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.9. The risks, discomforts and inconveniences associated with the study, or when applicable to an embryo, fetus, or nursing infant.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.10. The provision for management of an adverse reaction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.11. The study participant's responsibilities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.12. A statement giving study participation is voluntary.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.13. A statement giving study participants the option to withdraw.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.14. That a study participant shall be given information that may be relevant to his/her willingness to continue participation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.15. A statement guaranteeing confidentiality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.16. Circumstances / reasons under which the subject's participation may be terminated	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.17. A statement or reimbursement of trial-related expenses of participants (if applicable)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.18. A statement guaranteeing medical care / indemnification for adverse events not subject to previous waiver.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2.19. Whom to contact in case of questions-on adverse event (telephone number of contacts included)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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: _____