SELF-ASSESSMENT CHECKLIST FOR INFORMED CONSENT FORM (FORM 32)

** ALL CAPS preffered 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

☐ Masteral ☐ Independent

* Supervisor's Name:

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).	○	○	○
2. Contains the following elements of an informed consent:			
2.1. The study's investigative nature.	○	○	○
2.2. The number of the study participants in the trial.	○	○	○
2.3. The purpose / objective of the study.	○	○	○
2.4. The trial procedures treatments and probability for random assignment to each treatment.	○	○	○
2.5. The trial procedures to be done, including all invasive procedure	○	○	○
2.6. The expected duration of a subject's involvment and number of follow-up visits.	○	○	○
2.7. Potential or direct benefits (if any) from participation.	○	○	○
2.8. Alternative procedure(s) or course(s) of treatment that may be available.	○	○	○
2.9. The risks, discomforts and inconveniences associated with the study, or when applicable to an embryo, fetus, or nursing infant.	○	○	○
2.10. The provision for management of an adverse reaction	○	○	○
2.11. The study participant's responsibilities	○	○	○
2.12. A statement giving study participation is voluntary.	○	○	○
2.13. A statement giving study participants the option to withdraw.	○	○	○
2.14. That a study participant shall be given information that may be relevant to his/her willingness to continue participation.	○	○	○
2.15. A statement guaranteeing confidentiality	○	○	○
2.16. Circumstances / reasons under which the subject's participation may be terminated	○	○	○
2.17. A statement or reimbursement of trial-related expenses of participants (if applicable)	○	○	○
2.18. A statement guaranteeing medical care / indemnification for adverse events not subject to previous waiver.	○	○	○
2.19. Whom to contact in case of questions-on adverse event (telephone number of contacts included)	○	○	○

B. SUMMARY OF COMMENTS

☐ Approval/Favorable opinion

☐ Modifications required prior to approval

☐ Dissapproval/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: _____

Print Form