RESEARCH ETHICS OFFICE

INFORMED CONSENT ASSESSMENT FORM
2ND SUBMISSION
for graduate/undergraduate student research

Note to the Research Project/thesis/dissertation Leader:
Please indicate in the space provided below your revisions following the comments and recommendations from your reviewers. Please indicate the line number and page where this information can be found.

Note to the Reviewer:
*Please review the informed consent form according to the indicated essential elements. Kindly ensure that **vulnerability**, **recruitment process**, and **process of obtaining informed consent** are assessed in the context of the research protocol and the participant. Kindly finalize your review by indicating your recommendation for this research proposal/protocol.*

			To be accomplished by REO staff:	
			REO Package Number:	
To be accomplished by research project leader:			Submission date:	
Project title				
Study site				
Name of Research project leader			**Course and Year**	
	Email:		**Mobile number:**	

Name of Research Project Adviser		**Email**		**Mobile number**	

ESSENTIAL ELEMENTS **If applicable, the Informed Consent form should provide the following statements, :**	**To be filled out by the Researcher:** ***(Indicate the Page and line number where the specified essential element is articulated. Write NA if not applicable.)***	**To be filled out by the Reviewer** ***(indicate here your comments and feedback to guide the researcher to achieve the required articulation)***
1. That the study involves research		
2. Describing the purpose of the study		
3. Study-related treatments		
4. Study procedures including all invasive procedures		
5. Responsibilities of the participant		
6. Expected duration of participation in the study		
7. Approximate number of participants in the study		
8. Study aspects that are experimental		
9. Foreseeable risks to participant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure		
10. Risks from allowable use of placebo (as		

applicable)		
11. Reasonably expected benefits; or absence of direct benefit to participants, as applicable		
12. Expected benefits to the community or to society, or contributions to scientific knowledge		
13. Description of post-study access to the study product or intervention that have been proven safe and effective		
14. Alternative procedures or treatment available to participant		
15. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount		
16. Compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries		
17. Anticipated expenses, if any, to the participant in the course of the study		
18. Statement that participation is voluntary and may be withdrawn anytime without penalty or loss of benefit to which the participant is entitled		
19. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study		
20. Statement that the records identifying the participant will be kept confidential and will not		

be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality		
21. Description of data protection plan and details about storage (including who has access to the study-related documents, how long identifying data will be stored, and manner of storage) *(NEGHHR 2017)*		
22. Possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study		
23. Statement that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation		
Data privacy issues (24-29) in compliance with the Data Privacy Act of 2012		
24. If applicable, describing the conduct of survey, focus group discussion, interview e.g. voice recorded, video recorded, etc.		
25. Describing that consent for participation is time-bound		
26. Describing the data subject's right to be informed that his/her personal data will be collected and processed		

27. Describing the data subject's right to object or withhold consent to processing in case of changes or any amendment to the information supplied		
28. Describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure)		
29. Compensation or insurance or treatment entitlements of the participant in case of study-related injury		
30. Statement describing access of participant to the result of the study including details on what data will be shared and available, duration, and access criteria for data sharing		
31. Foreseeable circumstances and reasons under which participation in the study may be terminated		
32. Sponsor, institutional affiliation of the investigators, and nature and sources of funds		
33. Whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider		
34. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury		
35. that the XU Research Ethics Committee (XU REC) has approved the study, and may be reached through the following contact for		

information regarding rights of study participants, including grievances and complaints: Xavier Ateneo Research Ethics Office 2/F Lucas Hall Xavier University – Ateneo de Cagayan Corrales Avenue 9000 Cagayan de Oro City Email: reo@xu.edu.ph Tel: +63 88 853 9800 local 1967		
36. Comprehensibility of language used		
37. Other comments not addressed by items 1-36.		

Submitted by:	Name and signature	Date
Research Project/Thesis/Dissertation Leader:		
Research Project/ Thesis/Dissertation Adviser		
Evaluated by: Department Resident Ethics Evaluator		

To be filled out by the Reviewer:		
REVIEWER:		

Recommended action

- ☐ **APPROVE** (the application is satisfactory and needs no amendment or correction)
- ☐ **MINOR MODIFICATIONS** (the application is essentially ethically sound; however, the principal investigator needs to make some minor amendments before it can be approved)
- ☐ **MAJOR MODIFICATIONS** (the application is essentially ethically sound; however, the principal investigator needs to make some minor revisions before it can be approved)
- ☐ **DISAPPROVE** (the application is unethical and does not comply with the ethical requirement for research proposals)

Justification for recommendation