	Recoletos Ethics Review Office (RERO) University of San Jose – Recoletos Main Campus Magallanes Street, Cebu City **RERO ASSESSMENT FORM** **Study with Human Participants**	**FORM 2D**

To the researcher: Fill out the necessary information needed in the following elements below. Attached to this form is the sample consent and/or assent form.

STUDY TITLE	
NAME OF PRINCIPAL INVESTIGATOR/ RESEARCHER	
Special Population/Vulnerable Group used as participants in the study (Refer to WHO and PHREB List)	☐ Children (under 18) ☐ Indegenous People ☐ Elderly ☐ People with Disability ☐ Homeless person ☐ Poor and Unemplyed ☐ Mentally Challenge Individual ☐ Others (Please Specify)
Number of Participants	
Procedure of data collection/ survey	☐ Experimental Procedure (Non-Invasive) ☐ Experimental Procedure (Invasive) ☐ Focused Group Discission (FGD) ☐ Personal Interview ☐ Self -Administered Questionnaire ☐ Researcher- Administred Questionnaire ☐ Telecommunication survey ☐ Online/ Internet Survey

	☐ Others (Please Specify)

A. Assessment Checklist of Informed Consent and Assent

	To be filled out by the Researcher		REVIEWER'S COMMENTS To be filled out by the Ethics Review Committee
Elements of Informed Consent	Check if the following elements are present in your informed consent form	Page and paragraph where the element is found	
1. Brief introduction of the research team	☐ Yes ☐ Not applicable		
2. Statement of invitation to be part of the research study	☐ Yes ☐ Not applicable		
3. Statement that introduce the title of the study and a brief description of the study.	☐ Yes ☐ Not applicable		
4. Statement that described the purpose of the study	☐ Yes ☐ Not applicable		
5. Statement that describes the participants and why they are chosen and being part of the study	☐ Yes ☐ Not applicable		
6. Statement about how many participants needed in the study	☐ Yes ☐ Not applicable		
7. Statement that described the procedures of collection of			

data	☐ Yes ☐ Not applicable		
8. Statement about the responsibility of the participants	☐ Yes ☐ Not applicable		
9. Statement that the participants are voluntary and can withdraw the participation anytime without penalty or loss of benefit	☐ Yes ☐ Not applicable		
10. Statement about the duration of the study and/or interview	☐ Yes ☐ Not applicable		
11. Statement that described the benefit of the participants being part of the study	☐ Yes ☐ Not applicable		
12. Statement if there are foreseeable risks to participants (eg. pain, discomfort, inconvenience)	☐ Yes ☐ Not applicable		
13. Statement that the study product or intervention is proven safe and effective	☐ Yes ☐ Not applicable		
14. Statement of alternative procedures or treatment available to participants if adverse event will happen.	☐ Yes ☐ Not applicable		
15. Statement of compensation and/or payments to the participant in the duration of the study. (eg. money, material goods)	☐ Yes ☐ Not applicable		
16. Statements that the researcher/ investigator is			

competent to handle the participants and or with the guidance of their adviser's and experts in the field.	☐ Yes ☐ Not applicable		
17. Statement that the study is monitored by the adviser, IRERB and other regulatory agency (ex. DSWD) to ensure safety of the participants and the researcher	☐ Yes ☐ Not applicable		
18. Statement of confidentiality of participants collected data and records. This will be kept confidential and will not be made available in public even when the results are published	☐ Yes ☐ Not applicable		
19. Statements of policy and confidentiality of the use of genetic information including tracing of familial lineages	☐ Yes ☐ Not applicable		
20. Statement of collection and use and confidentiality of participants personal and medical records and biological specimen (e.g. tissue and blood sample samples)	☐ Yes ☐ Not applicable		
21. Statement that declares the data privacy protection of participants	☐ Yes ☐ Not applicable		
22. Statement that describes extent and rights to access of the participants to the result of the study	☐ Yes ☐ Not applicable		
23. Statement that describes the termination of study if circumstances may arise that may affect the life of participants	☐ Yes ☐ Not applicable		
24. Statement that study is sponsored and/or has			

institutional affiliation and/or other sources of funds	☐ Yes ☐ Not applicable		
25. Statement regarding persons or institution to whom to contact in case of adverse event that would happen related to the study.	☐ Yes ☐ Not applicable		
26. Statement that describes the protocols that includes minors. Both the assent form of minors and consent form of Parents'/ guardian/ legal authorized representative must be signed	☐ Yes ☐ Not applicable		

B. Assessment checklist for ethical process of informed Consent/ Assent

	To be filled out by the Researcher		REVIEWER'S COMMENTS To be filled out by the Ethics Review Committee
Elements of Informed Consent Process	Check if the following elements are present in the process of informed consent form	Page and paragraph where the element is found	
1. The approved informed consent and assent form will be used during the conduct of the study			
2. If there are more than one language prepared for informed consent, are the participants were given to choose the preferred language			
3. Statement that the participants can ask questions or clarification regarding the informed consent			
4. Statement that the researcher/ investigator will explain the informed consent/ assent			

5. The informed consent will be signed by the participants before the conduct of the procedure			
6. Participants that are unable to read has a witness or legal authorized representative during the presentation and signing of informed consent			
7. The participants were not forced of influenced to sign the informed consent or assent			
8. The informed consent/ assent has a clause and/or provision that the participants understand the content of the form			

DECLARATION of the RESEARCHER/s

I/we certify that the information in this assessment form is true and correct to the best of my/our knowledge. Furthermore, I/we have read and understood the guidelines for the responsible conduct of research and abide all the procedures approved by the technical and ethics committee. I will not start my data collection until I receive and ethics clearance from the Recoletos Ethics Review Office.	
Signature over Printed Name of the Principal Investigator/ Researcher/ Team Leader:	Date Signed:
Signature over Printed Name of the research team members	
Signature over Printed Name of the Adviser (NOTE: For undergraduate and graduate students only)	

ETHICS REVIEW RECOMMENDATION

This section is to be filled out by the Ethics Review Committee

General Assessment

		REVIEWER'S COMMENTS To be filled out by the Ethics Review Committee
1. Elements needed in the informed consent based on the study are present and complete	☐ Yes ☐ Not applicable	
2. The statements are comprehensive and can be understood by the participants	☐ Yes ☐ Not applicable	
3. Language used in the informed consent is appropriate to the participants of the study.	☐ Yes ☐ Not applicable	

College Ethics Committee Decision

This section is for the College Research Ethics Review Committee

For Primary Reviewer:

This proposal has been reviewed based on the institutional guidelines in the ethical conduct of research. The primary reviewer reached the following decision:

- ☐ Approved without revision
- ☐ Approved with minor revision
- ☐ Approved with major revision
- ☐ Forward the proposal for review by the College/ Department
- ☐ Disapproved

Reviewed by:

_____
Signature over Printed Name / Date

For College/ Department Committee

This proposal has been reviewed based on the institutional guidelines in the ethical conduct of research. The College/ Department panel reached the following decision:

- ☐ Approved without revision
- ☐ Approved with minor revision
- ☐ Approved with major revision
- ☐ Forward the proposal for Full Board
- ☐ Disapproved

Reviewed by:

_____	_____
Signature over Printed Name / Date	Signature over Printed Name / Date
_____	_____
Signature over Printed Name / Date	Signature over Printed Name / Date

_____
Signature over Printed Name / Date

Note:
When the revision is complete, please send the revised copy together with this application to the Recoletos Ethics Review Office for the release of the Ethics Clearance.

Justification of Decision: