ETHICAL CONSIDERATION ASSESSMENT FORM

As mandated by the 2017 National Ethical Guidelines (page 28, section D, paragraph 2), UV-IRB should consider both the scientific and ethical aspects of the proposed research even when the REC is distinct from the technical review committee. For student researches, PI and advisers are advised to ensure that the technical and scientific soundness are in place, and that the recommendations of the technical review committee and consultants are considered and integrated in the protocol. It is further advised, that the Research Protocol Assessment Forms issued by UV-IRB are considered during the crafting and evaluation of the proposal.

Instructions:

To the Proponent: Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol to facilitate the evaluation of the assessment point. Indicate the page and paragraph where this information can be found.

To the Reviewer: Kindly evaluate how the assessment points outlined below have been appropriately addressed by the researcher protocol as applicable. Please confirm the submitted information by putting your comments in the space provided under "OBSERVATION" and "REFERENCE". Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and sign the space provided by the reviewer.

Reference Number: _____

Protocol Title: Click here to enter text.

Authors: Click here to enter text.
Adviser: Click here to enter text.
Panel Members: Click here to enter text.

Corner Colon & Jakosalem Streets, Cebu City 6000, Philippines *Telephone: +63 (32) 416.8607; Email: uvirb2017@gmail.com*

ETHICAL CONSIDERATION ASSESSMENT FORM

TO BE FILLED-OUT BY THE PRINCIPAL INVESTIGATOR OR PROPONENT: Indicate if the protocol contains the specified point → **ASSESSMENT POINTS**	**YES**	**NO**	**N/A**	Page & paragraph where it is found	**OBSERVATION** *(TO BE FILLED-OUT BY THE REVIEWER)*	**REFERENCE** *(TO BE FILLED-OUT BY THE REVIEWER)*
SOCIAL VALUE						
Is there Social Value? Is there relevance to an existing social or health problem?	○	○	○	pp		
Is the significance of the study clearly described in a separate section of the protocol with accurate and updated description of the current status, and how it will arrive at a solution?	○	○	○	pp		
Is there a dissemination plan of the study result?	○	○	○	pp		
JUSTICE						
Is distributive justice observed?	○	○	○	pp		
Is there equitable distribution of benefits and burdens?	●	○	○	pp		
Is there fair selection in the choice of population, sampling and assignments?	○	○	○	pp		
Is there provision of appropriate care regardless of their economic status, gender, race or creed?	●	○	○	pp		
Is there just compensation for harms brought about by participation in the research?	○	○	○	pp		
Are there provisions for research participants to be reimbursed for lost earnings, travel costs, inconvenience, and other expenses incurred when taking part in a study?	○	○	○	pp		
Is undue inducement avoided?	○	○	○	pp		
TRANSPARENCY						
TRANSPARENCY and DISCLOSURE No. 36 to 40 page 32 of the National Ethical Guidelines	●	○	○	pp		
PROTECTION OF HUMAN RIGHTS						
Are appropriate procedures identified to safeguard the rights of study participants?	●	○	○	pp		
Will the study be reviewed by an IRB/ERB?	●	○	○	pp		
Was the study designed to minimize risks and	●	○	○	pp		

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maximize benefits to participants?						
RISK–BENEFIT RATIO DETERMINATION						
Is there an access to potentially beneficial intervention that might otherwise be unavailable to them?	◉	○	○	pp		
Is the information they provide may help others with similar problems or conditions?	◉	○	○	pp		
Can it increase their knowledge about themselves or condition, either through opportunity for introspection self-reflection or through direct interaction with researchers	◉	○	○	pp		
Are there direct monetary or material gains through stipend or other incentives?	◉	○	○	pp		
Are there non-material compensation to participant (health education or other creative benefits)	◉	○	○	pp		
Were participants subjected to any physical harm, discomfort, or psychological distress? Did the researchers take appropriate steps to remove, prevent, or minimize harm?	◉	○	○	pp		
Are there social risks, such as the risk of stigma, adverse effects on personal relationship, loss of status, loss of privacy, and loss of time?	◉	○	○	pp		
Is there monetary (e.g. for transportation, child care, time lost from work)	◉	○	○	pp		
Did the benefits to participants outweigh any potential risk or actual discomfort they experienced? Did the benefits to society outweigh the cost to participants?	◉	○	○	pp		
INFORMED CONSENT/ IMPLIED CONSENT/ PROCESS CONSENT/ ASSENT						
Is there an integration of the 15 elements in your Inform consent, implied consent and process consent? (Polit & Beck, 2012)	◉	○	○	pp		
Is there an assent for minors? Review of applicability of the assent age brackets in children:	◉	○	○	pp		

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• 0-under 7: No assent; • 7-under 12: Verbal Assent; • 12-under15: Simplified Assent Form; • 15-under18: Co-sign informed consent form with parents						
Is there a written form for verbal consents/assents?	○	●	○	pp		
Is there a discussion regarding the comprehension of informed consent?	●	○	○	pp		
Is there a discussion regarding the documentation of informed/Process/Implied Consent and Assents?	●	○	○	pp		
Is there a discussion regarding authorization to access private information?	●	○	○	pp		
Is there deception? If there is, is it justifiable?	●	○	○	pp		
PRIVACY AND CONFIDENTIALITY						
Is there a confidentiality procedure as indicated by data collection methods including data protection plans?	●	○	○	pp		
Is anonymity observed?	●	○	○	pp		
Is privacy respected?	●	○	○	pp		
Is DATA PRIVACY ACT of 2012 observed?	●	○	○	pp		
Is there a certificate of confidentiality?	●	○	○	pp		
Is DEIDENTIFICATION observed?	●	○	○	pp		
DEBRIEFING, COMMUNICATIONS AND REFERRALS						
Is there discussion on debriefing, communications, and referrals?	●	○	○	pp		
INCENTIVES OR COMPENSATION						
Is there justifiable amount and method of compensation, financial incentives or reimbursement of study-related expenses?	●	○	○	pp		

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CONFLICT OF INTEREST						
Is there management of conflict arising from financial familial or proprietary considerations of the PI, sponsor, or the study site?	○	●	○	pp		
RECRUITMENT						
Is there a discussion on a manner of recruitment including appropriateness of identified recruiting parties?	○	●	○	pp		
Was any type of coercion, intimidation or undue influence used to recruit participants? Did they have the right to refuse to participate or to withdraw without penalty?	●	○	○	pp		
VULNERABILITY ASSESSMENT						
Are study participants vulnerable?	●	○	○	pp		
• Children	○	●	○	pp		
• Mentally or emotionally disabled people	○	●	○	pp		
• Severely ill or physically disabled people	●	○	○	pp		
• Terminally ill	○	●	○	pp		
• Institutionalized people (Hospital, Facility, Homes, Hospice, Rehabilitation)	○	●	○	pp		
• Pregnant women	○	●	○	pp		
• Junior members of hierarchial groups	●	○	○	pp		
• Ethnic and racial minority groups	●	○	○	pp		
• Homeless	●	○	○	pp		
• Politically powerless	●	○	○	pp		
What extra protections are employed? No.19-22 pp. 28 of National Ethical Guidelines 2017	○	●	○	pp		

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BENEFICENCE

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COLLABORATIVE STUDY TERMS OF REFERENCE						
Is there an agreement including intellectual property rights, publication rights, information and responsibility sharing, transparency and capacity building?	○	◉	○	pp		
SPECIAL GUIDELINES						
CONSIDERATIONS based from the SPECIAL GUIDELINES as mandated by the NATIONAL ETHICAL GUIDELINES FOR HEALTH AND HEALTH-RELATED RESEARCH version 2017				pp		

RECOMMENDED ACTION	
☐ EXPEDITED ☐ FULL BOARD	☐ APPROVE ☐ MINOR MODIFICATIONS ☐ MAJOR MODIFICATIONS ☐ DISAPPROVE ☐ PENDING, IF MAJOR CLARIFICATION ARE REQUIRED BEFORE A DECISION CAN BE MADE
JUSTIFICATION FOR RECOMMENDED ACTION:	

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ETHICAL CONSIDERATION ASSESSMENT FORM

PRIMARY REVIEWER:	RESEARCH ADVISER:	RESEARCH INSTRUCTOR/COORDINATOR:
_____ (Print Name & Signature)	_____ (Print Name & Signature)	_____ (Print Name & Signature)

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