

ETHICS REVIEW BOARD
College of Social Sciences and Philosophy
University of the Philippines Diliman

CSSP-ERB STUDY PROTOCOL ASSESSMENT FORM

STUDY PROTOCOL INFORMATION

CSSP-ERB Code:	
Study Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date:	<DD/MM/YYYY>

INSTRUCTIONS

To the Principal Investigator: 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 Primary Reviewer: Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." Finalize your review by indicating your conclusions under "RECOMMENDED ACTION" and signing in space provided for the primary reviewer.

	To be filled out by the PI			To be filled out by the Primary Reviewer	
ASSESSMENT POINTS	Indicate if the study protocol contains the specified assessment point		Page and paragraph where it is found	**REVIEWER COMMENTS**	**REVIEWER RECOMMENDATIONS**
1. SCIENTIFIC DESIGN	**YES**	**N/A**			
1.1. Social value *Review of relevance of the study to an existing social or health problem such that the results are expected to bring about a better understanding of related issues, or contribute to the promotion of well-being of individuals, their families and communities (NEGHHR 2017)*					
1.2. Objectives *Review of viability of expected output*					
1.3. Literature review *Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials*					
1.4. Research design *Review of appropriateness of design in view of objectives*					
1.5. Sampling design *Review of appropriateness of sampling methods and techniques*					
1.6. Sample size *Review of justification of sample size*					
1.7. Data analysis plan *Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized*					
1.8. Inclusion criteria					

Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection					
1.9. Exclusion criteria *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*					
1.10. Withdrawal criteria *Review of criteria precision both for scientific merit and safety concerns*					
2. CONDUCT OF STUDY					
2.1. Data collection plan *Review of appropriateness of data collection, including description of personal data to be collected.* *For studies involving use of database, review of database management and role of personal data collector, as well as authority of investigator to access database (NEGHHR 2017)*					
2.2. Specimen handling *Review of specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and destruction for biobanked samples (as applicable) (NEGHHR 2017)*					
2.3. PI qualifications *Review of CV and relevant certifications to ascertain capability to manage study related risks*					
2.4. Suitability of site *Review of adequacy of qualified staff and infrastructures*					
2.5. Duration of participant involvement *Review of length/extent of human participant involvement in the study*					
3. ETHICAL CONSIDERATIONS					
3.1. Transparency and Conflict of interest *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site (NEGHHR 2017)*					
3.2. Privacy, confidentiality, and data protection plan *Review of measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators) (NEGHHR 2017);*					

Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use (NEGHHR 2017; Data Privacy Act of 2012)					
3.3. Informed consent process *Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances (NEGHHR 2017)*					
3.4. Waiver of informed consent *Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risk to participants, collection of data, and mechanisms to ensure confidentiality and anonymity (NEGHHR 2017)*					
3.5. Justification for the involvement of vulnerable groups *Review of involvement of vulnerable study populations and impact on informed consent. Vulnerable groups include the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants (NEGHHR 2017)*					
3.6. Justification for involving minors (less than 18 years old) *Review of involvement of minors and impact on informed consent. Research involving minors must always be assessed in the context of the protocol and the participants*					
3.7. Assent *Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:* *0-under 7: No assent* *7-under 12: Verbal Assent* *12-under15: Simplified Assent Form* *15-under18:Co-sign informed consent form with parents* *(NEGHHR 2017)*					
3.8. Consent for continued participation *For research involving children and adolescents, review of process for obtaining consent if the participant reaches legal age during the research. (CIOMS 2016)*					

3.9. Recruitment *Review of manner of recruitment including appropriateness of identified recruiting parties*					
3.10. Risks *Review of level of risk and measures to mitigate these risks (including physical ,psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable); Review of course of action in case of breach of data (as applicable)*					
3.11. Benefits *Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant*					
3.12. Safety monitoring plan *Review of appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants (NEGHHR 2017)*					
3.13. Post-trial access *Review of provision of clinical trials for post-trial access (as applicable)*					
3.14. Incentives or compensation *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses.*					
3.15. Compensation for study-related injuries/harm *Review of amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials (as applicable)*					
3.16. Community considerations *Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study*					
3.17. Collaborative study terms of reference *Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building*					

3.18. Dissemination / data sharing plan/ statement *Review of appropriateness in sharing research results which may have significant implications on the well-being of the participants and the community and in relation to achieving social value (NEGHHR 2017)*					
3.19. Other issues					

RECOMMENDED ACTION:

- ☐ APPROVE
- ☐ FOR MODIFICATION
- ☐ DISAPPROVE
- ☐ PENDING, IF CLARIFICATIONS ARE REQUIRED OR ADDITIONAL DOCUMENTS ARE NEEDED BEFORE A DECISION CAN BE MADE.

ADDITIONAL REMARKS:

PRIMARY REVIEWER	Signature	
Date: <DD/MM/YYYY>	Name	<Title, Name, Surname>
	Panel	<Name of Panel>