CSSP-ERB RVW Form 02

CSSP-ERB Assessment Forms

Part 1 - 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**			
a. 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)					
b. Objectives *Review of viability of expected output*					
c. 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*					
d. Research design *Review of appropriateness of design in view of objectives*					
e. Sampling design *Review of appropriateness of sampling methods and techniques*					
f. Sample size *Review of justification of sample size*					

g. Data analysis plan *Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized*					
h. Inclusion criteria *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection*					
i. Exclusion criteria *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*					
j. Withdrawal criteria *Review of criteria precision both for scientific merit and safety concerns*					
2) CONDUCT OF STUDY					
a. 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)					
b. 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)*					
c. PI qualifications *Review of CV and relevant certifications to ascertain capability to manage study related risks*					
d. Suitability of site *Review of adequacy of qualified staff and infrastructures*					
e. Duration of participant involvement *Review of length/extent of human participant involvement in the study*					

3) ETHICAL CONSIDERATIONS					
a. 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)*					
b. 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)*					
c. 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)*					
d. 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)					
e. 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)*					
f. 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*					
g. 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)*					
h. 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)*					
i. Recruitment *Review of manner of recruitment including appropriateness of identified recruiting parties*					
j. 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)					
k. 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*					
l. 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)*					
m. Post-trial access *Review of provision of clinical trials for*					

post-trial access (as applicable)					
n. Incentives or compensation *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses.*					
o. 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)*					
p. 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*					
q. 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					
r. 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)*					
s. Other issues					

RECOMMENDED ACTION:

Note: If **for modification**, indicate if minor or major modification by putting a check next to the appropriate choice. Also, highlight the justification for the recommended action from the choices provided.

___ APPROVE

___ PROVISIONAL APPROVAL

Specify: (e.g., NCIP Clearance)

_____

___ FOR MODIFICATION	___ Minor Modification *Justification:* ___ Incomplete Documentation ___ Incomplete ICF/PIS Elements ___ Unsatisfactory IC Format ___ Others: _____ ___ Major Modification *Justification:* ___ Change of Study Objectives ___ Change in the Recruitment Process ___ Revision of exclusion/inclusion Criteria ___ Change of Data Collection Method ___ Change in the process of mitigation of risk/harm to participants and the integrity of the research ___ Others: _____
___ DISAPPROVE	

ADDITIONAL REMARKS:

PRIMARY REVIEWER	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>
	Panel	<Name of Panel>

Part 2 - Informed Consent Assessment Form

ETHICS REVIEW BOARD
College of Social Sciences and Philosophy
University of the Philippines Diliman
csspethicsboard.upd@up.edu.ph

STUDY PROTOCOL INFORMATION

CSSP-ERB Code:	
Study Protocol 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 element is addressed by the informed consent form (ICF). 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 elements outlined below have been appropriately addressed by the informed consent form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS." In your comments, ensure that **vulnerability, recruitment process, and process of obtaining informed** consent are always assessed in the context of the study protocol and the participant. 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**	
Essential Elements (as applicable to the study)	Indicate if the ICF has the specified element	Page and paragraph where element is	**REVIEWER COMMENTS**	**REVIEWER RECOMMEND-ATIONS**

			found		
	YES	**N/A**			
4) Statement that the study involves research					
5) Statement describing the purpose of the study					
6) Study-related treatments and probability for random assignment					
7) Study procedures including all invasive procedures					
8) Responsibilities of the participant					
9) Expected duration of participation in the study					
10) Approximate number of participants in the study					
11) Study aspects that are experimental					
12) Foreseeable risks to participant/embryo/ fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; and integrating risks as detailed in the investigator's brochure					
13) Risks from allowable use of placebo (as applicable)					

14) Reasonably expected benefits; or absence of direct benefit to participants, as applicable					
15) Expected benefits to the community or to society, or contributions to scientific knowledge					
16) Description of post-study access to the study product or intervention that have been proven safe and effective					
17) Alternative procedures, interventions, or treatment available to participant					
18) 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					
19) 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					
20) Anticipated expenses, if any, to the participant in the course of the study					
21) Statement that participation is voluntary and may be					

withdrawn anytime without penalty or loss of benefit to which the participant is entitled					
22) For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study					
23) Statement that the study monitor(s), auditor(s), the CSSP-ERB Ethics Review Panel, and regulatory authorities will be granted direct access to participant's medical records for purposes **ONLY** of verification of clinical trial procedures and data					
24) 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					

25) 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)*					
26) Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant					
27) 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					
28) Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or					

have the materials destroyed					
29) Plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development					
30) 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 (28-33) in compliance with the Data Privacy Act of 2012					
31) Statement describing that consent for participation is time-bound					
32) Statement describing the data subject's right to be informed that his/her personal data will be collected and processed					
33) Statement describing the data subject's right to object or withhold consent to processing in case of changes or any amendment to the information supplied					

34) Statement 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)					
35) Compensation or insurance or treatment entitlements of the participant in case of study-related injury					
36) 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					
37) Foreseeable circumstances and reasons under which participation in the study may be terminated					
38) Sponsor, institutional affiliation of the investigators, and nature and sources of funds					
39) Statement whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider					
40) 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					
41) Statement that the CSSP-ERB Ethics Review Panel (specify) has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: **Name of CSSP-ERB Panel Chair** **Address:** **Email:** csspethicsboard.upd@up.edu.ph **Tel:**					
42) Comprehensibility of language used					
43) Other comments not addressed by items 1-34					

RECOMMENDED ACTION:

Note: If **for modification**, indicate if minor or major modification by putting a check next to the appropriate choice. Also, highlight the justification for the recommended action from the choices provided.

___ APPROVE

___ PROVISIONAL APPROVAL

Specify: (e.g., NCIP Clearance)

___ FOR MODIFICATION	___ Minor Modification *Justification:* ___ Incomplete Documentation ___ Incomplete ICF/PIS Elements ___ Unsatisfactory IC Format ___ Others: _____ ___ Major Modification *Justification:* ___ Change of Study Objectives ___ Change in the Recruitment Process ___ Revision of exclusion/inclusion Criteria ___ Change of Data Collection Method ___ Change in the process of mitigation of risk/harm to participants and the integrity of the research ___ Others: _____
___ DISAPPROVE	

ADDITIONAL REMARKS:

PRIMARY REVIEWER	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>
	Panel	<Name of Panel>