

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

CSSP-ERB INITIAL REVIEW SUBMISSION FORM

Please print in A4 size paper

SECTION I: APPLICANT INFORMATION		
1. Study Protocol Code:	CSSP-ERB Code:	
2. Study Title:		
3. Date of Submission:	<DD/MM/YYYY>	
4. Category of Investigator	☐ 4.1 Faculty ☐ 4.1.1 UPD ☐ 4.1.2 Other UP unit ☐ 4.1.3 Non-UP ☐ 4.2. Research, Extension, and Professional Staff (REPS) ☐ 4.2.1 UPD ☐ 4.2.2 Other UP unit ☐ 4.2.3 Non-UP ☐ 4.3 Undergraduate Student ☐ 4.3.1 UPD ☐ 4.3.2 Other UP unit ☐ 4.3.3 Non-UP ☐ 4.4 Graduate Student ☐ 4.4.1 UPD ☐ 4.4.2 Other UP unit ☐ 4.4.3 Non-UP ☐ 4.5 Others, please specify:	
5. Purpose of study	☐ 5.1 Academic requirement (Thesis, Dissertation, Training Requirement) (NOTE: Indicate name/s of adviser/s and describe roles of adviser/s in item 17 below) ☐ 5.2 Independent research work ☐ 5.3 Multi-institutional or multi-country collaboration ☐ 5.4 Others (indicate):	

6. Endorsing Unit/ Department/Institution	☐ 6.1 Anthropology ☐ 6.2 History ☐ 6.3 Geography ☐ 6.4 Linguistics ☐ 6.5 Philosophy ☐ 6.6 Political Science ☐ 6.7 Population Institute ☐ 6.8 Psychology ☐ 6.9 Sociology ☐ 6.10 Third World Studies Program ☐ 6.11 UPD (office or college and department): <office/college and department> ☐ 6.12 Non-UPD (Philippine institution): <name of institution> ☐ 6.13 Non-UPD (foreign institution): <name of institution>
7. Funding agency:	**NAME:**
	TYPE OF FUNDING AGENCY
	☐ 7.1 UPD or UPD unit ☐ 7.2 Investigator ☐ 7.3 PHL Government agency/office/entity ☐ 7.4 Multilateral Agency (UN agencies and other intergovernmental agencies) ☐ 7.5 Private company or Non-governmental organization (NGO) ☐ 7.6 Others (indicate):
8. Study Budget	NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet
9. Previous ethics approval or clearance issued by other sites	☐ 9.1 Name of Institutional Review Board or Ethics Review Committee: ☐ 9.2 Date of ethics approval: ☐ 9.3 Date of expiration of ethics approval: ☐ 9.4 Not applicable
10. Principal Investigator	<Title, Name, Surname>
11. Designation	
12. Address	<Institutional Address>
13. Telephone No.	
14. Mobile No.	
15. Email	
16. Other ongoing studies	☐ 16.1 Title: 16.1.1 CSSP-ERB Code:

	☐ 16.2 Title: 16.2.1 CSSP-ERB Code:
	☐ 16.3 Title: 16.3.1 CSSP-ERB Code:
	☐ 16.4 Title: 16.4.1 CSSP-ERB Code:
17. Other investigators with corresponding task description *(add additional rows as applicable)*	Co-Investigator: Email: Task description (*Refer to pg 47-54 of NEGHHR 2017 for roles of investigators*):
	Co-Investigator: Email: Task description *(Refer to pg 47-54 of NEGHHR 2017 for roles of investigators)*:
18. Submitted by:	<Title, Name, Surname>
	Study designation
19. Signature of PI	

20. Study Synopsis

Please write a synopsis of the study and indicate the page/s where this may be found in the full study protocol or in the annexes/appendices. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol.

21. Technical Synopsis	
a. Objectives/Expected output	*Please write the objectives of the study.*
b. Social value	*Please write a summary of the social value of the study.*
c. Literature review (and framework) rationalizing the design	*Please write a summary on the literature review (and framework) rationalizing the design.*
d. Research design	*Please write a summary regarding the research design.*
e. Sampling design, sample size and justification	*Please write the sampling design and sample size.*
f. Data analysis plan	*Please write a summary of the plan for data analysis including statistical basis for design, as applicable.*
g. Inclusion criteria, exclusion criteria, withdrawal criteria	*Please write the inclusion, exclusion and withdrawal criteria.*
h. Data collection and processing plan	*Please write a summary of the data collection and processing plan, including plans for data storage, duration of storage, and who has access to the stored data.*
i. Specimen collection and processing plan (as applicable)	*Please write a summary of the specimen collection and processing plan, including plans for specimen storage, duration of storage, access to the stored data, and details on biobank custodian and adherence to institutional guidelines for biobanking, and provision for sample and data removal and destruction for biobanked samples.*
j. Rationalization for choice of study site (Cross reference information with statements provided in the informed consent)	*Please indicate the specific study site/s and provide justification for the choice of site/s, including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable.* *Note that for multi-site protocols involving DOH hospitals, review is done by the Single Joint Review Ethics Board (SJREB). For further information on SJREB, you may visit DOH website accessible at https://www.doh.gov.ph/Single-Joint-Research-Ethics-Board-Forms.*

k. Duration of human participant involvement	*Please indicate duration of research participation.*
l. Duration of data collection	*Please indicate duration of data collection.*
m. Duration of the study	*Please indicate the study duration in months.*
22. Ethical Considerations	*The section on ethical considerations should be stated in the study protocol.*
a. Protection of privacy and confidentiality of research information including data protection plan	*Please write a summary on the protection of privacy and confidentiality of research information including data protection plan.*
b. Informed consent process and recruitment procedures	*Please write a summary regarding process of recruitment and informed consent, including how potential participants will be identified and what information will be made available to the participants, who will obtain informed consent and how this will be done.*
c. Vulnerability of research participants	*Please write a summary regarding vulnerability of research participants to risks and harm, as applicable.*
d. Participation of special populations or vulnerable groups	☐ Children (under 18) ☐ Indigenous People ☐ Elderly ☐ People on welfare/social assistance ☐ Poor and unemployed ☐ Patients in emergency care ☐ Homeless persons ☐ Refugees or displaced persons ☐ Patients with incurable diseases ☐ Persons incapable of giving consent ☐ Prisoners or parolees ☐ Mental health patients ☐ Others (indicate): ☐ Not applicable
e. Involvement of children and adolescents	☐ Children aged less than 7 years old ☐ Children aged 7 years old to less than 12 years old ☐ Children aged 12 years old to less than 15 years old ☐ Children aged 15 years old to less than 18 years old ☐ Not applicable
f. Participant-related compensations/ reimbursements/ entitlements	*Please write plans on participant-related compensations/reimbursements/entitlements, including reasons or justifications for such.*
g. Risks or harm of the study	*Please identify possible risks or harm that the participant/community may encounter in the course of your study, including how you plan to mitigate or address these, including social risks and issues for safety.*
h. Benefits of the study	*Please write a summary regarding benefits of the study, including a statement justifying a favorable benefit-risk ratio.*

i. Community considerations	*Please write a statement regarding community considerations, as applicable.*
j. Dissemination/data sharing/transparency plan	*Please write a summary regarding plans on dissemination and data sharing/transparency.*
k. Terms of reference of collaborative study	*Please indicate terms of reference of collaborative study, as applicable, such as intellectual property agreements and similar concerns.*
l. Terms of available study-related insurance	*Please indicate the terms of available study-related insurance, as applicable.*

SECTION II: SCIENTIFIC/TECHNICAL REVIEW APPROVAL ENDORSEMENT

This section should be signed by the Chair/Head of the Scientific/Technical Review committee/office that reviewed the scientific soundness of the study and issued the appropriate approval. Alternatively, results of Scientific/Technical Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.

STUDY TITLE:		
Principal Investigator:	<Title, Name, Surname>	
I confirm that the (NAME OF SCIENTIFIC/TECHNICAL REVIEW COMMITTEE/OFFICE) has reviewed and approved the following study protocol-related information: objectives/expected output supported by literature review; overall research design; sampling design, sample size, Inclusion/exclusion/withdrawal criteria; data collection plan and specimen collection, processing, and storage as applicable; data analysis plan including statistical design/framework, as applicable.		
Issuing committee/office:		
Head of committee/office:	<Title, Name, Surname>	
Signature:		Date of Signature: <DD/MM/YYYY>

SECTION III: INSTITUTIONAL ENDORSEMENT

This section should be signed by the head of unit (administrative authority legally empowered to sign on behalf the unit such as Dean, Department Chair/Director, and the like) of the Principal Investigator. This section is required only for initial submission, ***provided there are no changes in study protocol information below.***

STUDY TITLE:		
Principal Investigator:	<Title, Name, Surname>	
I confirm that I have read this Application and that the research will be implemented under the oversight of this Unit/Department/Institution in accordance with the conditions of approval by the CSSP Ethics Review Board. I also confirm that the Principal Investigator has a regular appointment in this institution.		
Issuing unit/dept/inst:		
Head of unit:	<Title, Name, Surname>	
Signature:		Date of Signature: <DD/MM/YYYY>

SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW

This section should be completed by the signatory official who can sign on behalf of the institution that has oversight on the research site, ***IF the research site is OUTSIDE the scope of authority of CSSP****. If not applicable, put N/A in all fields. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.*** *In case regional IRB will opt not to review, attach letter of endorsement.*

STUDY TITLE:		
Principal Investigator:	<Title, Name, Surname>	
Research Site Personnel:	<Title, Name, Surname>	
Institutional Affiliation of Research Site Personnel:		
Signature		Date of Signature: <DD/MM/YYYY>
This is to certify that the **<NAME OF RESEARCH SITE>:** 1) Has no local Institutional Review Board/ Ethics Review Committee; and		

2) Authorizes and acknowledges the CSSP Ethics Review Board (CSSP-ERB) to perform the ethical review of the abovementioned study protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits.

Responsibilities of the Site:

1) Monitoring of the site - continuing review, SAEs
2) Communicate reportable events to the CSSP-ERB
3) Attend CSSP-ERB meetings, if applicable

Name of Research Site		
Address of Research Site		
Signatory Official	<Title, Name, Surname>	
Position of Official		
Signature		Date of Signature: <DD/MM/YYYY>

SECTION V: DECLARATION OF CONFLICT OF INTEREST

This section should be signed by the Principal Investigator indicating disclosure of financial interest and arrangements.

STUDY TITLE:	
FUNDING AGENCY/SPONSOR:	

Check the applicable box/boxes of the declaration of conflict of interest, including the nature of significant conflict of interest, as applicable.

☐ I declare that I have significant conflict of interests that are required to be disclosed as follows:

- ☐ Significant financial interests.
- ☐ Any financial arrangements entered into between the sponsor for the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

  (Attach details of investigator's disclosable financial arrangements and interests, including the description of steps to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.)
- ☐ Any proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing)
- ☐ Any significant personal/family interest (up to 4th civil degree by consanguinity or affinity) with the sponsor or the results of the study.
- ☐ Other possible conflict of interest:

☐ I declare that I do not have any significant conflict of interest in conducting the study, as listed above.

Principal Investigator:	<Title, Name, Surname>	
Institution:	<Name of Institution>	
Signature:		Date of Signature: <DD/MM/YYYY>