RESEARCH ETHICS OFFICE

STUDY PROTOCOL ASSESSMENT FORM
3RD SUBMISSION
for graduate/undergraduate student research

Note to the Research Project/thesis/dissertation Leader:
*Please indicate whether or not the specified recommendation is addressed by your research protocol. Indicate changes that were not part of the initial or previous evaluation. Please indicate the specific **line number(s)** and **page(s)** where these can be found in your paper. Revisions should be underlined and in bold-face. This form also serves as the evaluation form for the reviewers assigned to your paper.*

Note to the Reviewer:
Please accomplish the review of the paper according to the assessment points indicated. Kindly finalize your review by indicating your recommendation for this study protocol.

			To be accomplished by REO staff:		
			REO Package Number:		
To be accomplished by research project leader:			Submission date:		
Project title					
Study site					
Name of Research project leader			**Course and Year**		
	Email:		**Mobile number:**		

Name of Research Project Adviser		**Email**		**Mobile number**	

ASSESSMENT POINTS	**To be filled out by the Researcher:** ***(Indicate the Page and line number where the specified assessment point is articulated. Write NA if not applicable.)***	**To be filled out by the Reviewer** ***(indicate here your comments and feedback to guide the researcher to achieve the required articulation)***
1. Scientific design		
1.1. Objectives Contains a statement of the objectives		
1.2. Literature review If applicable, contain a review of results of previous human/animal studies showing known risks and benefits of intervention/ innovation, as they may be, when human participants or animals are involved in the research		
1.3. Research design Contains an articulation of the research design and the justification for the appropriateness of the design in view of the objectives		
1.4. Sampling design Contains an articulation of the sampling design and justification of the appropriateness of sampling methods and techniques		

1.5. Sample size Contains an articulation of the sample size and the justification of the sample size		
1.6. Data analysis plan Contains an articulation of the statistical and non-statistical methods to be used and how participant data will be summarized and a justification for the appropriateness of data analysis plan		
1.7. Inclusion criteria Contains an articulation of the inclusion criteria, criteria precision, and equitable selection, both for scientific merit and safety concerns		
1.8. Exclusion criteria Contains an articulation of the exclusion criteria and its justification of exclusion, both for scientific merit and safety concerns		
1.9. Withdrawal criteria Contains an articulation of the criteria precision of withdrawing participants, both for scientific merit and safety concerns		
2. Conduct of study		
2.1. Data collection plan Contains an articulation of the data collection and the justification for its appropriateness, including a description of personal data to be collected. For studies involving use of database, a statement of database management and role of personal data collector, as well as authority of investigator to access database should be included. (NEGHHR		

2017)		
2.2. Specimen handling Contain an articulation of the 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. (NEGHHR 2017)		
2.3. Principal investigator qualifications Contains the CV and relevant certifications to ascertain capability to manage study related risks		
2.4. Suitability of site Contains an articulation of the adequacy of qualified staff and infrastructures		
2.5. Duration of participant involvement Contains the articulation of the length/extent of human participant involvement in the study		
3. Ethical considerations		
3.1. Transparency and Conflict of interest Contains the articulation of the management of conflict arising from financial, familial, or proprietary considerations of the project leader, sponsor, or the study site (NEGHHR 2017)		
3.2 Privacy, confidentiality, and data protection plan Contains the articulation of the 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 o 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 Contains the articulation of the 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 Contains the articulation of the 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)		
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3.4. Waiver of informed consent Contains the articulation of the 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 Contains the articulation of the justification for the involvement of vulnerable study populations and impact on informed consent (see 3.3). 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) Contains the articulation for the justification for the involvement of minors and impact on informed consent (see 3.3). Research involving minors must always be assessed in the context		

of the protocol and the participants		
3.7. Assent Contains the articulation of the feasibility of obtaining assent vis à vis incompetence to consent; where the applicability of the assent age brackets in children are the following: 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, contains the articulation for the process of obtaining consent if the participant reaches legal age during the research (CIOMS 2016)		
3.9. Recruitment Contains the articulation of the manner of recruitment including appropriateness of identified recruiting parties		
3.10. Risks Contains the articulation of the level of risk and measures to mitigate these risks (including physical, psychological, social, economic), including plans for adverse event management; if applicable, contains the articulation for the 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 Contains the articulation of the 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 Contains the articulation of the safety monitoring plan and the 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 Contains the articulation of the provision of clinical trials for post-trial access		
3.14. Incentives or compensation Contains the articulation of the amount and method of compensations, financial incentives, or reimbursement of study-related expenses		
3.15. Compensation for study- related injuries Contains the articulation of the amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials.		

3.16. Community considerations Contains the articulation of the 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 Contains the articulation of the 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 Contains the articulation of the data sharing plan and the 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 Contains the articulation of issues not subsumed in the issues covered by items 3.1 to 3.18		

Submitted by:	Name and signature	Date
Research Project/Thesis/Dissertation Leader:		
Research Project/ Thesis/Dissertation Adviser		
Evaluated by: Department Resident Ethics Evaluator		

To be filled out by the Reviewer:		
REVIEWER:		

Recommended action

- ☐ **APPROVE** (the application is satisfactory and needs no amendment or correction)
- ☐ **MINOR MODIFICATIONS** (the application is essentially ethically sound; however, the principal investigator needs to make some minor amendments before it can be approved)
- ☐ **MAJOR MODIFICATIONS** (the application is essentially ethically sound; however, the principal investigator needs to make some minor revisions before it can be approved)
- ☐ **DISAPPROVE** (the application is unethical and does not comply with the ethical requirement for research proposals)

Justification for recommendation