Study Protocol Assessment Form

STUDY PROTOCOL INFORMATION

UPCHE REC Code:[1] (to be filled by the REC staff)	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date: (to be filled by the REC staff)	

INSTRUCTIONS

To the Principal Investigator: Please indicate in the space provided below whether or not the specified assessment point is addressed in your study protocol by ticking on the appropriate box. To facilitate the evaluation of the assessment point, indicate in the gray column the page 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. If an item is deemed not applicable, please indicate N/A.

To be filled out by the P.I.		To be filled out by the Primary Reviewer	
ASSESSMENT POINTS (Indicate if the study protocol contains the specified assessment point)	Page where it is found	**REVIEWER COMMENTS**	**RECOMMENDATIONS**
1. SCIENTIFIC DESIGN			
1.1. Social Value *Review of the contribution of the research 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 the well-being of individuals, their families, and communities.* ☐Yes ☐No ☐N/A			
1.2. Objectives *Review of viability of expected output* ☐Yes ☐No ☐N/A			
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* ☐Yes ☐No ☐N/A			
1.4. Research design			

[1] To be issued upon initial processing by UPCHE REC

Review of appropriateness of design in view of objectives ☐Yes ☐No ☐N/A			
1.5. Sampling design *Review of appropriateness of sampling methods and techniques* ☐Yes ☐No ☐N/A			
1.6. Study Procedure *Review of appropriateness and feasibility of data collection method* ☐Yes ☐No ☐N/A			
1.7. Operational Definition of Variables *Review of operational definition of dependent, independent, and confounding variables* ☐Yes ☐No ☐N/A			
1.8. Sample size *Review of computation of sample size* ☐Yes ☐No ☐N/A			
1.9. Data analysis plan *Review of appropriateness of statistical and non-statistical methods of data analysis* ☐Yes ☐No ☐N/A			
1.10. Inclusion criteria *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection* ☐Yes ☐No ☐N/A			
1.11. Exclusion criteria *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion*			
1.12. Withdrawal criteria *Review of criteria precision both for scientific merit and safety concerns* ☐Yes ☐No ☐N/A			
2. CONDUCT OF STUDY			
2.1. Specimen handling *Review of specimen storage, access, disposal, and terms of use* ☐Yes ☐No ☐N/A			
2.2. PI qualifications *Review of CV and relevant certifications (including Conflict of Interest declaration) to ascertain capability to manage study related risks* ☐Yes ☐No ☐N/A			

2.3. Suitability of site *Review of adequacy of qualified staff and infrastructures* ☐Yes ☐No ☐N/A			
2.4. Duration *Review of length/extent of human participant involvement in the study* ☐Yes ☐No ☐N/A			
3. ETHICAL CONSIDERATIONS			
3.1. Conflict of interest *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site* ☐Yes ☐No ☐N/A			
3.2. Privacy and confidentiality *Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans* ☐Yes ☐No ☐N/A			
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* ☐Yes ☐No ☐N/A			
3.4. Vulnerability *Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, 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* ☐Yes ☐No ☐N/A			
3.5. Recruitment *Review of manner of recruitment including appropriateness of identified recruiting parties* ☐Yes ☐No ☐N/A			
3.6. 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 required; Parent/Guardian Consent/Permission Form required* *7 – under 12: Verbal Assent Form and Parent/Guardian Consent/Permission Form required* *12 – under 15: Simplified Assent Form and Parent/Guardian Consent/Permission Form required* *15 – under 18: Co-sign Informed Consent Form with parents* ☐Yes ☐No ☐N/A			
3.7. 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). State risk assessment as follows:* *Negligible risk – presents no more than an inconvenience to the human participants (e.g., filling up a form, meal recall)* *Minimal risk – probability and magnitude of harm or discomfort (e.g., induced anxiety) are not greater, in and of themselves, than those ordinarily encountered in daily life or routine physical, psychological, or educational examination* *Moderate risk – probability and magnitude of harm or discomfort is beyond minimal risk but not posing serious risk, and there are stringent mitigating measures to well manage the risks* *High risk – probability of serious harm so apparent needs serious review if approved at all (more than moderate, considerable)* ☐Yes ☐No ☐N/A			
3.8. 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 ☐Yes ☐No ☐N/A			
3.9. Incentives or compensation *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses* ☐Yes ☐No ☐N/A			
3.10. 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* ☐Yes ☐No ☐N/A			
3.11. 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* ☐Yes ☐No ☐N/A			

TYPE OF REVIEW:

☐ Expedited ☐ Full Review

COMMENT(S)

RECOMMENDATION(S) (Note: Please see sections with comments/recommendations for the required modifications)

RECOMMENDED ACTION:

☐ APPROVAL
☐ MINOR MODIFICATIONS*
☐ MAJOR MODIFICATIONS**

☐ DISAPPROVAL

The criteria for Major and Minor Modifications are as follows:

**Minor modification – recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g., incomplete documentation, informed consent elements, unsatisfactory informed consent format), administrative corrections like typo or grammar errors, minor changes on items not related to the procedure to be done*

***Major Modification – recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research; examples: major revisions in protocol design or method or ICF, inclusion/exclusion criteria, safety issues, data privacy issues*

REVIEWER	Signature	
Date:	Name	
	Position	Scientist Member/Non-Scientist Member