# STUDY PROTOCOL ASSESSMENT FORM

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| **PSURERC Code**  *(to be provided by the PSURERC Staff)* |  |
| **Study Protocol Title:** |  |
| **Principal Investigator/Lead Researcher:** |  |
| **Study Protocol Submission Date:** |  |

# STUDY PROTOCOL INFORMATION

**INSTRUCTIONS**

To the Investigator/Researcher: To facilitate the evaluation of the assessment point, please indicate the page and line number/s where the pertinent 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’S COMMENTS AND RECOMMENDATIONS.” Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and signing in the space provided for the primary reviewer.

| **ASSESSMENT POINTS** | Page and line numbers where the pertinent information can be found  (as applicable) | **REVIEWER’S COMMENTS AND RECOMMENDATIONS** |
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| **1. SCIENTIFIC DESIGN** | | |
| **1.1. Objectives**  *Review of the viability of the expected output* |  |  |
| **1.2. Literature review**  *Review of results of previous studies showing known risks and benefits, including known adverse effects* |  |  |
| **1.3. Research design**  *Review of the appropriateness of the design given the objectives.* |  |  |
| **1.4. Data collection procedure**  *Review of appropriateness of collection procedure. The data collection procedure should be specific and have complete details.* |  |  |
| **1.5. Data collection instruments**  *A review of the soundness of data collection instruments (questionnaire, interview guide, observation tools, etc.).* |  |  |
| **1.6. Locale of the study**  *Review of the appropriateness of the chosen locale of the study.* |  |  |
| **1.7. Sampling design and size**  *Review of the appropriateness of the method of sampling and techniques, and justification of sample size* |  |  |
| **1.8. Statistical analysis plan (SAP)**  *Review of appropriateness of statistical methods to be used and how participant data will be summarized* |  |  |
| **1.9. Data analysis plan**  *Review of the appropriateness of non-statistical methods of data analysis* |  |  |
| **1.10. Inclusion criteria**  *Review of the precision of criteria, both for scientific merit and safety concerns, and equitable selection* |  |  |
| **1.11. Exclusion criteria**  *Review of criteria precision, both for scientific merit and safety concerns, and justified exclusion* |  |  |
| **1.12.Withdrawal criteria**  *Review of the criteria precision for scientific merit and safety concerns* |  |  |
| **2. CONDUCT OF STUDY** | | |
| **2.1. Specimen handling**  *Review of specimen storage, access, disposal, and terms of use* |  |  |
| **2.2. Research/Investigation team qualifications**  *Review of CV and relevant certifications to ascertain the capability to manage risks* |  |  |
| **2.3. Suitability of site**  *Review of the adequacy of qualified staff, infrastructure, and physical setup* |  |  |
| **2.4. Duration**  *Review of the length/extent of human involvement in the study* |  |  |
| **3. ETHICAL CONSIDERATIONS** | | |
| **3.1. Conflict of interest**  *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, researchers, sponsor, or the study site* |  |  |
| **3.2. Privacy and confidentiality**  *Review of measures or guarantees to protect the privacy and confidentiality of participant information as indicated by data*  *collection methods including data protection plans* |  |  |
| **3.3. Informed consent process**  *Review 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* |  |  |
| **3.4. Vulnerability**  *Review of involvement of vulnerable 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 diseases, politically powerless people, or junior members of a hierarchical group.*  *Vulnerability must always be assessed in the context of the protocol and the*  *participants.* |  |  |
| **3.5. Recruitment**  *Review of manner of recruitment, selection, and invitation, and appropriateness of identified recruiting parties.* |  |  |
| **3.6. Assent and parental (LAR) consent**  *Review of the 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* |  |  |
| **3.7. Risks to participants**  *Review of the level of risk and measures to mitigate these risks (including physical, psychological, social, legal, and economic), and plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)* |  |  |
| **3.8. Risks to the researchers/investigators**  *Review of the level of risk and measures to mitigate these risks (including physical, psychological, social, legal, and economic).* |  |  |
| **3.9. Benefits**  *Review of potential direct or indirectt benefit to participants; the potential to yield generalizable knowledge about the participants’ condition/problem; non-material benefits to the participant (e.g., health education or other creative benefits).* |  |  |
| **3.10. Social value**  *Review of the significance of the study, its social value, and the benefits of the study to the society.* |  |  |
| **3.11. Dissemination plan**  *Review of the appropriateness of the dissemination activities about the findings of the study.* |  |  |
| **3.12. Incentives or compensation**  *Review of amount and method of compensation, financial incentives, or reimbursement of study-related expenses* |  |  |
| **3.13. Community**  **considerations**  *Review 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* |  |  |
| **3.14. 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* |  |  |

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| RECOMMENDED ACTION:  [ ] APPROVE  [ ] MINOR MODIFICATIONS  [ ] MAJOR MODIFICATIONS  [ ] DISAPPROVE  [ ] PENDING, MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE  JUSTIFICATION FOR RECOMMENDED ACTION: |
| **PRIMARY REVIEWER** Signature  Date: Name: |