|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Protocol Information** | | | | |
| SPUP REC Protocol Code | | | Submission Date | |
| Protocol Title | | | Study Site | |
| Name of Principal Investigator | | Sponsor/Contract Research Organization/Institution | | |
| Type of Review  Full Review | Expedited | | |  |

|  |  |  |
| --- | --- | --- |
| 1. **Assessment Points** | | |
|  |  | COMMENTS |
| 1. SOCIAL VALUE   *(Does the study have scientific or social value?)* | Yes  No  Unable to assess |  |
| 1. SCIENTIFIC SOUNDNESS | | |
| * 1. . Study Objectives   *(Is/are the proposal’s scientific question/s reasonable?)* | Yes  No  Unable to assess |  |
| * 1. . Literature Review   *(Does the protocol adequately present informational background as to the result of previous studies prior to human experimentation?)* | Yes  No  Unable to assess |  |
| * 1. . Research and Sampling design   *(Is the study design, sampling method and techniques appropriate?)* | Yes  No  Unable to assess |  |
| * 1. . Specimen/Data Collection, Processing, Storage   *(Are the procedures in collecting, processing, and storing data adequate?)* | Yes  No  Unable to assess |  |
| * 1. . Inclusion/Exclusion Criteria   *(Are the features of the target population appropriate?)* | Yes  No  Unable to assess |  |
| * 1. . Withdrawal Criteria   *(Is there a provision for withdrawal from the research?)* | Yes  No  Unable to assess |  |
| * 1. . Facilities/Infrastructure at Study Site   *(Are the research facilities adequate?)* | Yes  No  Unable to assess |  |
| * 1. . Investigator’s Qualification, Competence, and Experience   *(Is/are the investigator/s adequately trained and do they have sufficient experience?)* | Yes  No  Unable to assess |  |
| 1. ETHICAL SOUNDNESS | | |
| * 1. Privacy and Confidentiality Safeguards   *(Does the research ensure to protect privacy and confidentiality of participant information?)* | Yes  No  Unable to assess |  |
| * 1. Conflict of Interest   *(Does the research ensure mechanism of management of conflict arising from financial, familial, or proprietary considerations from PI, sponsor, or the study site?)* | Yes  No  Unable to assess |  |

|  |  |  |
| --- | --- | --- |
| * 1. Involvement of Human Participants   *(Does the research need to be carried out with human participants?)* | Yes  No  Unable to assess |  |
| * 1. Involvement of Vulnerable Populations   *(Does the study involve individuals who belong to vulnerable group?)* | Yes  No  Unable to assess |  |
| * 1. Participant Selection-voluntary, non-coercive recruitment   *(Are appropriate mechanisms in place to protect above individual in vulnerable group?)* | Yes  No  Unable to assess |  |
| * 1. Risk-Benefit Ratio   *(Does the protocol adequately address the risk/ benefit balance?)* | Yes  No  Unable to assess |  |
| * 1. Informed Consent Process   *(Is the informed consent procedure/ assent form adequately and culturally appropriate?)* | Yes  No  Unable to assess |  |
| * 1. Community Considerations   *(Does the study offer substantial and relevant contribution to local communities and address possible stigma or draining of local capacity?)* | Yes  No  Unable to assess |  |
| * 1. Collaborative Study Terms of Reference   *(Does the study present clear terms on IP rights, publication rights, information and responsibility sharing, transparency, and capacity building?)* | Yes  No  Unable to assess |  |

|  |  |
| --- | --- |
| **Recommendation** | **Justification for the Recommendation** |
| Approved  Minor Modifications Required  Major Modifications Required  Disapproved |  |

|  |
| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_  Reviewer’s Signature over Printed Name Review Date |