**Study Protocol Assessment Form for Ethical Review**

STUDY PROTOCOL INFORMATION

**IRB Protocol No:**

**Date:**

**Study Protocol Title**:

**Study Protocol Number**:

**Principal Investigator**:

**Sub**-**Investigator/s:**

**Total # of Participants:**

**No. of study sites:**

**Sponsor:**

**Duration of the Study:**

**Status: \_\_\_\_New \_\_\_\_\_Amended**

**Reviewer:**

**Review Status: \_\_\_\_\_\_Full Board \_\_\_\_\_\_Expedited**

INSTRUCTIONS

**PRINCIPAL INVESTIGATOR:** Please put a check in the space provided below if the evaluation point is addressed by the study protocol. Please specify the page and paragraph where the information can be found to facilitate the assessment.

**REVIEWER:** Please assess how the evaluation points have been properly addressed by the study protocol by placing your comments in the space provided below. Finalize your review by ticking one of the boxes under “Suggested Action” and signing in space provided for the reviewer.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **To be filled out by the PI** | | |  |
| **ASSESSMENT POINTS** | Indicate if the study protocol contains the specified assessment point | | Page and paragraph where it is found | **REVIEWER COMMENTS** |
| 1. **SCIENTIFIC DESIGN** | **YES** | **N/A** |  |  |
| * 1. **Objectives**   *Review of viability of expected output* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **Inclusion criteria**   *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection* |  |  |  |  |
| * 1. **Exclusion criteria**   *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion* |  |  |  |  |
| * 1. **Withdrawal criteria**   *Review of criteria precision both for scientific merit and safety concerns* |  |  |  |  |
| 1. **CONDUCT OF STUDY** |  |  |  |  |
| * 1. **Specimen handling**   *Review of specimen storage, access, disposal, and terms of use* |  |  |  |  |
| * 1. **PI qualifications**   *Review of CV and relevant certifications to ascertain capability to manage study related risks* |  |  |  |  |
| * 1. **Suitability of site**   *Review of adequacy of qualified staff and infrastructures as attached in the delegation log and MOA/CTA agreement with site* |  |  |  |  |
| * 1. **Duration**   *Review of length/extent of human participant involvement in the study* |  |  |  |  |
| 1. **ETHICAL CONSIDERATIONS** |  |  |  |  |
| * 1. **Conflict of interest**   *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **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. Vulnerability must always be assessed in the context of the protocol and the participants.* |  |  |  |  |
| * 1. **Recruitment**   *Review of manner of recruitment including appropriateness of identified recruiting parties* |  |  |  |  |
| * 1. **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*  *7-under 12: Verbal Assent*  *12-under15: Simplified Assent Form*  *15-under18:Co-sign informed consent form with parents* |  |  |  |  |
| * 1. **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)* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **Incentives or compensation**   *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **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* |  |  |  |  |
| * 1. **Other issues**   *Review of issues not subsumed in the issues covered by assessment points above* |  |  |  |  |

**SUGGESTED ACTION**

* APPROVAL
* MINOR REVISIONS
* MAJOR REVISIONS
* DISAPPROVAL
* PENDING, MAJOR CLARIFICATIONS REQUIRED BEFORE DECISIONS CAN BE MADE

**JUSTIFICATION FOR RECOMMENDED ACTION**

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REVIEWER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_