**Date of Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PROTOCOL INFORMATION**

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| **BUREC Code.:**  (To be assigned by REC) |  |
| **Protocol Title:** |  |
| **Researcher/s:** |  |
| **Submission Date:** |  |

**Instructions:**

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| **Researcher:** | Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. |
| **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 “RECOMMENDATIONS” and signing in space provided for the primary reviewer. |

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| **ASSESSMENT POINTS** | **To be filled out by the Researcher** | | | | **REVIEWER COMMENTS** |
| **Indicate the protocol contains the specified assessment point** | | **Where it is found?** | |
| 1. **SCIENTIFIC DESIGN** | **YES** | **N/A** | **Page**  **No.** | **Paragraph**  **No.** |  |
| * 1. **Objectives**   *Review of viability of expected output* |  |  |  |  |  |
| * 1. **Literature review**   *Review of results of previous animal/human studies showing known risk and benefits of intervention, including known adverse drug effects, in case of drug trials* |  |  |  |  |  |
| * 1. **Research design**   *Review of appropriateness of design in view of objectives* |  |  |  |  |  |
| * 1. **Sampling design**   *Review of appropriateness of sampling methods and techniques* |  |  |  |  |  |
| * 1. **Sample size**   *Review of computation of sample size* |  |  |  |  |  |
| * 1. **Statistical analysis plan (SAP)**   *Review of appropriateness of statistical methods to be used and how participant data will be summarized* |  |  |  |  |  |
| * 1. **Data analysis plan**   *Review of appropriateness of statistical and non-statistical methods of data analysis* |  |  |  |  |  |
| * 1. **Inclusion criteria**   *Review of precision of criteria both scientific merit and safety concerns; and 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. **Researcher/s qualifications**   *Review of CV and relevant certifications to ascertain capability to manage study related risk* |  |  |  |  |  |
| * 1. **Suitability of site**   *Review of adequacy of qualified staff and infrastructures* |  |  |  |  |  |
| * 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 the privacy and confidentiality of participant information as indicated in the 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* |  |  |  |  |  |
| * 1. **Recruitment**   *Review of manner of recruitment including appropriateness of identified recruiting parties* |  |  |  |  |  |
| * 1. **Assent**   *Review of feasibility of obtaining assent vis à vis in competence to consent; Review of applicability of the assent age brackets in children:*  *0-under 7: No assent*  *7-under 12: Verbal Assent*  *12-under 15: Simplified Assent Form*  *15-under 18: Co-sign informed consent form with parents* |  |  |  |  |  |
| * 1. **Risk**   *Review of level of risk and measures to mitigate these risk (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 multicounty/multi-institutional studies,* *including intellectual property* *rights, publication rights,* *information and responsibility* *sharing, transparency, and* *capacity building* |  |  |  |  |  |

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| **RECOMMENDATIONS:** | | | |
| Approval  Exempt from Review | Minor revisions required | Major revisions required | Disapproval  Reasons for disapproval: |
| [Type here] | | | |

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| **PRIMARY REVIEWER:** |  | Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |