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| **FORM 2.3 PROTOCOL EVALUATION** |

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| --- | --- |
| WVSU-URERC Protocol Number |  |
| Sponsor Protocol Number\* |  |
| Study Protocol Title\* |  |
| Date of Submission |  |
| Principal Investigator/ Researcher\* |  |
| Institution/Department\* |  |
| Contact Number\* |  |
| Sponsor\* |  |

*\*To be filled out by Principal Investigator/Researcher*

*The following sections are for WVSU-URERC use only:*

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| Type of Review |  |  | Full Board |  | Expedited |  | Exempt |

|  | *To be filled out by the Primary Reviewers* | | | | |
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| **ASSESSMENT POINTS** | *Pls check the appropriate box* | | | | **REVIEWER COMMENTS & RECOMMENDATIONS** |
| 1. **SOCIAL VALUE** | **YES** | | **NO** |  |  |
| *Review of relevance of the study 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 well-being of individuals, their families and communities* |  | |  |  |  |
| 1. **SCIENTIFIC DESIGN** | **CLEAR** | | **UNCLEAR** |  |  |
| * 1. ***Objectives***   *Specific, measurable, achievable, relevant, and time-bound* |  | |  |  |  |
| * 1. ***Literature Review*** | **SUFFICIENT** | | **INSUFFICIENT** |  |  |
| *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. ***Research Design*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
| *Review of appropriateness of design in view of objectives (i.e., includes Conceptual/Theoretical Framework)* |  | |  |  |  |
| * 1. ***Sampling Design*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
| *Review of appropriateness of sampling methods and techniques* |  | |  |  |  |
| * 1. ***Sample size & site recruitment or accrual ceiling***   *Review of justification of sample size* | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
|  | |  |  |  |
| * 1. ***Control Arms*** *(placebo, if any)* | **YES** | | **NO** | **N/A** |  |
|  | |  |  |  |
| * 1. ***Data Analysis Plan*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
| *Review of appropriateness of statistical and non-statistical methods to be used and how participant data will be summarized* |  | |  |  |  |
| * 1. ***Inclusion Criteria*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection* |  | |  |  |  |
| * 1. ***Exclusion Criteria*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion* |  | |  |  |  |
| * 1. ***Withdrawal Criteria*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of criteria precision both for scientific merit and safety concerns* |  | |  |  |  |
| 1. **CONDUCT OF STUDY** | | | |  |  |
| * 1. ***Data Collection Plan*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of appropriateness of data collection, including description of personal data to be collected. For studies involving use of database, review of database management and role of personal data collector, as well as authority of investigator to access database.* |  | |  |  |  |
| * 1. ***Biological Sampling*** | **YES** | | **NO** |  |  |
| * + 1. ***Specimen Handling***   *Review of specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and destruction for bio banked samples* | **CLEAR** | | **UNCLEAR** | **N/A** |  |
|  | |  |  |
| * + 1. ***Are blood/tissue samples sent abroad?*** | **YES** | | **NO** | **N/A** |  |
|  | |  |  |  |
| * 1. ***PI/Researcher Qualifications*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
| *Qualifications**and**experience of the participating investigators and research team. Review of CV and relevant certifications to ascertain capability to manage study related risks* |  | |  |  |  |
| * 1. ***Suitability of Site***   *Review of adequacy of facilities and infrastructures* | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
|  | |  |  |  |
| * 1. ***Duration of Participant Involvement*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of length/extent of human participant involvement in the study* |  | |  |  |  |
| 1. **ETHICAL CONSIDERATIONS** | | | | |  |
| * 1. ***Transparency and Conflict of interest*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site* |  | |  |  |  |
| * 1. ***Privacy, Confidentiality, and Data Protection Plan*** | **CLEAR** | | **UNCLEAR** |  |  |
| *Review of measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators)*  *Review of appropriateness of processing personal data, storage of data, access, disposal, and terms of use* |  | |  |  |  |
| * 1. ***Informed Consent Process*** | **CLEAR** | | **UNCLEAR** | **N/A** |  |
| *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. ***Waiver of Informed Consent*** | **CLEAR** | | **UNCLEAR** | **N/A** |  |
| *Review of justification for waiver of informed consent or waiver of documentation of consent with considerations to potential risk to participants, collection of data, and mechanisms to ensure confidentiality and anonymity* |  | |  |  |  |
| * 1. ***Vulnerable Participants***   *Vulnerable groups include the minors, 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. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants* |  | |  |  |  |
| * + 1. ***Involvement of Vulnerable Participants*** | **YES** | | **NO** | **N/A** |  |
|  | |  |  |  |
| * + 1. ***Justification for the Involvement of Vulnerable Groups***   *Review of involvement of vulnerable study populations and impact on informed consent* | **CLEAR** | | **UNCLEAR** | **N/A** |  |
|  | |  |  |  |
| * + 1. ***Protection of vulnerable participants*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
|  | |  |  |  |
| * 1. ***Assent for Elderly*** | **YES** | | **NO** | **N/A** |  |
| *For adults who are not competent to consent (for example, elderly or adults with conditions that prevent appropriate consent), review feasibility of obtaining assent vis à vis incompetence to consent.* |  | |  |  |  |
| * 1. ***Assent for Minors*** | **YES** | | **NO** | **N/A** |  |
| *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. ***Recruitment*** | **CLEAR** | | **UNCLEAR** | **N/A** |  |
| *Review of manner of recruitment including appropriateness of identified recruiting parties*  *Voluntary, non-coercive recruitment* |  | |  |  |  |
| * 1. ***Risks*** |  | | | | |
| * + 1. ***Level of Risk***   *Negligible- No* *foreseeable risk of harm or discomfort and foreseeable risk not more than inconvenience, e.g. filling out forms, participating in a survey.*  *Minimal - Foreseeable risk is discomfort, e.g. related to measuring blood pressure, anxiety induced by the prospect of an interview.*  *More than minimal****:***  *Moderate -**Highly probable, may be prolonged and uncontrollable/unavoidable need close monitoring and safeguards.*  *High -**Probability of serious harm so apparent needs serious review if approved at all* | **NEGLIGIBLE** | **MINIMAL** | **MORE THAN MINIMAL** | |  |
|  |  |  | |  |
| * + 1. ***Risk Assessment*** | **CLEAR** | | **UNCLEAR** |  |  |
| *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); Review of course of action in case of breach of data (as applicable)* |  | |  |  |  |
| * 1. ***Benefit Assessment*** | **CLEAR** | | **UNCLEAR** |  |  |
| *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. ***Safety Monitoring Plan*** | **APPROPRIATE** | | **INAPPROPRIATE** |  |  |
| *Review of appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants* |  | |  |  |  |
| * 1. ***Post-trial Access*** | **YES** | | **NO** | **N/A** |  |
| *Review of provision of clinical trials for post-trial access* |  | |  |  |  |
| * 1. ***Compensation/ Reimbursement of Study related expenses*** | **APPROPRIATE** | | **INAPPROPRIATE** | **N/A** |  |
| *Review of amount and method of compensation/ reimbursement of study-related expenses.* |  | |  |  |  |
| * 1. ***Compensation for Study-related Injuries*** | **APPROPRIATE** | | **INAPPROPRIATE** | **N/A** |  |
| *Review of amount and method of compensations for study-related injuries, including treatment entitlements, or certificate of insurance for clinical trials.* |  | |  |  |  |
| * 1. ***Community Considerations*** | **CLEAR** | | **UNCLEAR** | **NONE** |  |
| *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*** | **CLEAR** | | **UNCLEAR** | **NONE** |  |
| *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. ***Dissemination of Results/Data Sharing Plan*** | **CLEAR** | | **UNCLEAR** | **N/A** |  |
| *Review of appropriateness in sharing research results which may have significant implications on the well-being of the participants and the community and in relation to achieving social value.* |  | |  |  |  |
| * 1. ***Are the provisions for the mitigation of risks in the ICF consistent with what is in the protocol?*** | **YES** | | **NO** | **N/A** |  |
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| **RECOMMENDATION** |  | Approval |  | Minor Revision/ Resubmission |
|  |  |  |  |
|  | Major Revision/ Resubmission |  | Disapproval |

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| **SUMMARY OF RECOMMENDATIONS** |  |

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| --- | --- | --- | --- |
| Reviewer’s  Name and Signature |  | Date |  |