**STUDY PROTOCOL ASSESSMENT FORM**

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| **URERB Protocol Code:**(to be filled out by URERB Secretariat) |  |
| **Study Protocol Title:**(to be filled out by the Researcher/PI) |  |
| **Researcher/Principal Investigator:**(to be filled out by the Researcher/PI) |  |
| **Study Protocol Submission Date:**(to be filled out by URERB Secretariat) |  |
| **Review Classification**(to be filled out by the Chair) |  **Full Review Expedited Review** |

**INSTRUCTIONS**

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| To the Researcher/Principal Investigator: |  | 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. |
| 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 writing your comments on the space provided under “REVIEWER COMMENTS.”Finalize your review by indicating your conclusions under “RECOMMENDED ACTION” and affix your signature on the space provided for the primary reviewer. |
| **ASSESSMENT POINTS with Guide Questions** | **To be filled out by the Researcher** | **REVIEWER COMMENTS** |
| Indicate if the study protocol contains the specified assessment point | Page and paragraph where it is found |
| 1. **SCIENTIFIC DESIGN**
 | **YES** | **NO** | **N/A** |  |  |
| * 1. **Background/Rationale**

*Does it describe why the research needs to be done and its potential relevance?* |  |  |  |  |  |
| * 1. **Objectives**

*Is/are the objective/s reasonable?* |  |  |  |  |  |
| * 1. **Research Design**

*Is the choice of study design appropriate and clearly explained?* |  |  |  |  |  |
| * 1. **Research Instrument**

*Is the research instrument suitable/valid/ reliable? (see also attached instrument)* |  |  |  |  |  |
| * 1. **Population and Sampling**
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| 1. **Target Population**

*Are the source and number of participants reasonable and justifiable?* |  |  |  |  |  |
| 1. **Sampling Design**

*Are the sampling methods and techniques appropriate?* |  |  |  |  |  |
| 1. **Inclusion criteria**

*Are the attributes of subjects that are essential for their selection to participate clearly defined?* |  |  |  |  |  |
| 1. **Exclusion criteria**

*Are the attributes of subjects that require their exclusion stated clearly?* |  |  |  |  |  |
| * 1. **Data Gathering Procedure**
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| * 1. **Duration**

*Is the length of human participant involvement reasonable?* |  |  |  |  |  |
| * 1. **Data Collection, Use and Storage**
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| * *Are the methods for collecting data clearly described?*
 |  |  |  |  |  |
| * *Is there an adequate plan for the destruction of records at the end of the retention period?*
 |  |  |  |  |  |
| * *Is the plan for secure storage of data explained?*
 |  |  |  |  |  |
| 1. **ETHICAL CONSIDERATIONS** (please refer to the section on ethical considerations in the research protocol)
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| * 1. **Conflict of interest**

*Is the management of conflict arising from financial, familial, or proprietary considerations of the researcher, funding agency, study site or the study participants indicated?* |  |  |  |  |  |
| * 1. **Vulnerability**
 |
| * *Does it involve individuals who belong to vulnerable groups?*
 |  |  |  |  |  |
| * *If yes, are appropriate mechanisms in place to protect individuals in vulnerable groups?*
 |  |  |  |  |  |
| * 1. **Informed consent process**
 |
| * *Does it indicate who may solicit/give consent? especially in case of minors and those who are not legally competent to give consent?*
 |  |  |  |  |  |
| * *Does it indicate how and when it will be done?*
 |  |  |  |  |  |
| * 1. **Privacy and confidentiality**

*Are measures to protect privacy and confidentiality of participant information clearly stated?* |  |  |  |  |  |
| * 1. **Risks**
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| * *Are there probable risks to the human participants in the study?*
 |  |  |  |  |  |
| * *If yes, are there measures indicated to mitigate/minimize the risks?*
 |  |  |  |  |  |
| * 1. **Benefits**

*Are there potential direct benefit to participants or non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the research will be received by the participant?* |  |  |  |  |  |
| * 1. **Voluntariness/Withdrawal**

*Does it indicate mechanisms for voluntary participation and withdrawal of participants?* |  |  |  |  |  |
| * 1. **Assent**

*Is obtaining assent applicable?**Assent age brackets in children:**< 7 yrs old – consider dissent**7 – 12 yrs old – verbal assent* *12 – 15 yrs old – sign simplified version of ICD (assent document)**> 15 yrs old – sign regular version of ICD**In all cases – legal guardians must sign permission/informed consent* |  |  |  |  |  |
| * 1. **Incentives or compensation**

*Is there a clear provision of any amount and method of compensations, financial incentives, or reimbursement of study-related expenses?* |  |  |  |  |  |
| * 1. **Community considerations**

*Is the impact of the research beneficial to the community where the research conducted?* |  |  |  |  |  |
| 1. **RESEARCHER/PI QUALIFICATIONS** (please refer to the attached curriculum vitae)
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| *Is/are the researcher/s or investigator/s adequately trained and/or do they have sufficient experience?* |  |  |  |  |  |
| **RECOMMENDED ACTION** |
| * APPROVAL
 |
| * MINOR MODIFICATIONS
 |
| * MAJOR MODIFICATIONS
 |
| * DISAPPROVAL
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| **JUSTIFICATION FOR THE RECOMMENDATION****Mandatory Issues to be Addressed** (you may indicate the item number that needs to be addressed)**Suggestions for Improvement** (you may indicate the page/s that needs to be improved) |

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| **REVIEWER** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature over Printed NameDate\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |