PROTOCOL CODE: USM/JEPeM/

USM/

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| **STUDY PROTOCOL ASSESSMENT FORM** | | | | | |
| **Study Protocol Title:** | | |  | | |
| **Principal Investigator:** | | |  | | |
| **Study Protocol Submission Date:** | | |  | | |
| **Undergraduate application exempted** | **To be filled by the PI** | | | | **To be filled by Reviewer** |
| **Indicate if the study protocol contains the specified assessment point** | | | | **Page** | **REVIEWER’S COMMENTS** |
|  | **YES** | **N/A** | |  |  |
| **Justification for study and literature review**  *Summarize the available knowledge and important knowledge gap to justify the scientific merit of the study proposed* |  |  | |  |  |
| **Objectives**  *General and specific objectives* |  |  | |  |  |
| **Research design** |  |  | |  |  |
| **Sample size estimation** |  |  | |  |  |
| **Sampling method** |  |  | |  |  |
| **Inclusion and exclusion criteria** |  |  | |  |  |
| **Vulnerability of the subject/participant**  *How it is handled* |  |  | |  |  |
| **Recruitment of subject/participant & informed consent seeking**  *Method of inviting participants eg: Advertisement* |  |  | |  |  |
| **Assent form requirement**  ***Under 7 years old: No assent. Complete Parental Consent.***  ***7-under 12 years old: Verbal Assent***  ***12-under 15 years old: Assent Form***  ***15-under 18 years old: Co-sign informed consent form with parents*** |  |  | |  |  |
| **Study location** |  |  | |  |  |
| **Research instrument** |  |  | |  |  |
| **Data collection method**  ***What to be done to the subjects/participants, possible risk & benefit*** |  |  | |  |  |
| **Duration of participant involvement** |  |  | |  |  |
| **Proposed data analysis** |  |  | |  |  |
| **Declaration of conflict of interest** |  |  | |  |  |
| **Handling privacy & confidentiality issue** |  |  | |  |  |
| **Community sensitivities & benefits** |  |  | |  |  |
| **Incentives/honorarium/ compensation** |  |  | |  |  |
| **Collaborative study terms of reference e.g. Intellectual property, etc.** |  |  | |  |  |

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| **RECOMMENDATION** | |
| * **APPROVED** | |
| * **MINOR MODIFICATIONS; PI not to be invited** * **MINOR MODIFICATIONS; PI to be invited** | |
| * **MAJOR MODIFICATIONS** | |
| * **DISAPPROVED** |  |
| **JUSTIFICATION FOR RECOMMENDATION** | |

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| --- | --- | --- | --- |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: |  | Name |  |
| **SECRETARY** |  | Signature |  |
| Date: |  | Name |  |