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 |  |