**Participant Information Sheet and Informed Consent**

PROTOCOL CODE: USM/JEPeM/

**Assessment Form**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | | | |
| **Study Protocol Title:** | |  | | | |
| **Principal Investigator:** | |  | | | |
| **Study Protocol Submission Date:** | |  | | | |
|  | | **To be filled by the PI** | | | **To be filled by JEPeM-USM Reviewers** |
| **Essential Elements**  **(as applicable to the study)** | | Indicate if the ICF has the specified element | | Page and paragraph where element is found | **REVIEWER’S COMMENTS** |
| **YES** | **N/A** |  |  |
| List of all investigators involved | |  |  |  |  |
| Research title | |  |  |  |  |
| Statement that the participant involves research | |  |  |  |  |
| Introduce study scope | |  |  |  |  |
| Approximate number of participants | |  |  |  |  |
| Description of the study purpose | |  |  |  |  |
| Eligibility criteria to participate | |  |  |  |  |
| Study procedures and expectation | |  |  |  |  |
| Expected duration of participation | |  |  |  |  |
| Foreseeable or potential risks (including psychological, physical and emotional) | |  |  |  |  |
| Expected or absence of direct benefit to participants | |  |  |  |  |
| Community sensitivities and expected benefits to the community or to society, or contributions to scientific knowledge | |  |  |  |  |
| Statement that the JEPeM-USM Review Panel and regulatory authorities may review study data | |  |  |  |  |
| Assurance of confidentiality unless required by law | |  |  |  |  |
| Specimen/data handling including storage and destruction/disposal of specimen/data at the end of the study | |  |  |  |  |
| Statement of possible future use, affirming participant’s right to refuse future storage and use of collected specimen/data | |  |  |  |  |
| Plans to develop commercial products and whether the participant will receive monetary or other benefit from such development | |  |  |  |  |
| Statement describing feedback of study finding whether provided or not | |  |  |  |  |
| Information of person(s) to contact in the study team for further information | |  |  |  |  |
| Statement on the approval by and contact of the secretary of the JEPeM-USM | |  |  |  |  |
| Appropriate language versions | |  |  |  |  |
| **RECOMMENDATION** | | | | | |
| * ACCEPTABLE | | | | | |
| * MINOR MODIFICATIONS | | | | | |
| * MAJOR MODIFICATIONS | | | | | |
| * NOT ACCEPTABLE   **Reasons:** |  | | | | |

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