**Participant Information Sheet and Informed Consent**

PROTOCOL CODE: USM/JEPeM/

**Assessment Form**

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| --- |
|  |
| **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 |  |