CHECKLIST FOR REVIEWERS ON INFORMED CONSENT DOCUMENT

|  |  |
| --- | --- |
| **Study Protocol Title** |  |
| **Principal Investigator** |  |
| **Date on which the Protocol is received by the Reviewer** |  |

|  |  |  |
| --- | --- | --- |
| **1** | **Essential Elements** | **Observation**  [Present/ Not Present/ Not Applicable] |
| 1 | Statement that the study involves research with complete and clear explanation of the purpose of the research |  |
| 2 | Expected duration of the participant's participation |  |
| 3 | Description of the procedures to be followed, including all invasive procedures |  |
| 4 | Description of any reasonably foreseeable risks or discomforts to the participant |  |
| 5 | Description of any benefits to the participant or others reasonably expected from research. If no benefit is expected, the participant should be made aware of the fact. |  |
| 6 | Disclosure of the available specific appropriate alternative procedures or therapies to the participant. |  |
| 7 | Statement describing the extent to which the records and identity of the participant will be maintained confidential and who will have access to participant’s medical records |  |
| 8 | Trial treatment schedule(s) and the probability for random assignment to each treatment (in case of the randomized trials) |  |
| 9 | Compensation and/or treatment(s) applicable to the participant in the event of a trial-related injury and/ or AE and/ or SAE |  |
| 10 | An explanation about whom to contact for trial related queries, rights of the participant during the study and during the event of any AE and/ or SAE and/ or injury and/ or Death |  |
| 11 | The anticipated prorated payment, if any to the participant for participating in the trial, along with the participant's responsibilities during participation in the trial |  |
| 12 | Statement that participation is voluntary, that the participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the participant is otherwise entitled. |  |

|  |  |  |
| --- | --- | --- |
| 13 | Statement that there is a possibility of failure of IP to provide intended therapeutic effect |  |
| 14 | Statement that in case of placebo controlled trials, the placebo administered to the participants shall not have any therapeutic effect |  |
| **2** | **Additional elements, which may be required** |  |
| 1 | Statement of foreseeable circumstances under which the participant's participation may be terminated by the Investigator without the participant's consent |  |
| 2 | Additional costs to the participant that may result from participation in the study |  |
| 3 | The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant |  |
| 4 | Statement that the participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation |  |
| 5 | A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable |  |
| 6 | Approximate number of participants to be enrolled in the study |  |
| **3** | **Any other pertinent information** |  |

Signature with Date

Primary Reviewer: Yes/No