PART 1 - CONTENT FOR CONSENT FORM

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English/ Regional language, which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigator

PART 2 - CONTENT FOR PARTICIPANT CONSENT FORM

Participant's name: **Address:**

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the investigating team. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the Participant:_____ Date: _____

Signature of the Witness: _____ Date: _____

Signature of the Investigator:_____ Date: _____

Note: Consent form part 2, should be appropriately worded for adults and children (less than 18 years) e.g. If the participant is less than 18 years of age, instead of 'my participation', 'my child's/ward's participation' needs to be replaced.