**Information Sheet/Consent Form**

**We recommend that you use the following format to assist you in preparing the information sheet/consent form. Some steps stated below may not be relevant to your study. Please select those which are applicable to your study**

I am (state name of principal investigator), attached to the (state institute). My current designation is (state the designation). I would like to invite you to take part in the research study titled (state the title of the project here) conducted by (state the name of the investigator/s) at (state the site of the study here).

**1. Purpose of the study**

The purpose of this research is (state the expected purpose of the research here).

**2. Voluntary participation**

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

**3. Duration, procedures of the study and participant’s responsibilities**

The procedure/s to be carried out is/are (state the procedure/s of the research and how the participant has to take part in the study).

You will need to undergo the following visits and procedures (state the expected duration of participation, including the number and duration of visits to the research site and what happens at each visit).

**4. Potential benefits**

Participation in this study may benefit you/others by (state all the actual and potential benefits).

**5. Risks, hazards and discomforts**

(Any potential or actual risks, hazards and discomforts should be clearly defined)

**6. Reimbursements**

You would be paid a sum of Rs. (state any payment to the participant indicating the amount, when it would be paid and any conditions attached to it).

**7. Confidentiality**

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

**8. Termination of study participation**

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

**9. Clarification**

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

(State a list of persons with contact details from whom the participant can ask questions and clarify any doubts and their contact details).

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Day/month/year

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participa

nt and should have no connection to the research team). Participants who are illiterate should

include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the

individual has had the opportunity to ask questions. I confirm that the individual has given

consent freely.

Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant

Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Day/month/year