Template (IEC can ask to incorporate additional information depending upon the study characteristics)

Participant Information Sheet

(SUBMITTED IN BOTH ENGLISH AND HINDI)

Title of study:
Funding Agency:
Study Centre:
Principal Investigator (*Name, affiliation, Email, phone*):

What is this study?

[IN PLAIN LANGUAGE, m*ention about your study background (disease/health condition/diagnostic test/medicine/, whichever is applicable), your objective, study design, what you will do to collect data, and how data will fulfill your study objective(s)*]

What is the meaning of participation?

[Explain to participant, what will be done to the participant in terms of data collection procedures like questionnaire administration, diagnostic test (all steps of testing)/drugs (type, approved or not (if yes, approved by??), route, dose etc.)?
Mention also separately, if his/her biological sample will be used for future analysis, if so, you are requesting his/her consent at same time. If you conduct future analysis, how report will be communicated]

What are the risks of participation?

[Explain, what will be potential risk to the participant in data collection process like discomfort to certain questions, pain during sample collection, taste of some drug, side effect of some drug (mild, moderate, and severe) with probability of occurrence.]

What are the benefits of participation?

[Explain, personal benefit to participant like reimbursement, cash incentive, likely treatment if diagnosed etc.]

Do I have to be in the study?

[Explain, why it is important for the participant to be in study? How collected data will help in terms of generating knowledge?.]

What about confidentiality?

[Explain, how you will maintain his/her confidentiality about data during and after data collection?]

Informed Consent Form

(SUBMITTED IN BOTH ENGLISH AND HINDI)

I---------- (full name), S/o Sh----------

I have read/understood the information about this study, that was told to me. I have been explained all the consequences.

- I understand that the responses and records concerning my participation are to be used only for the purpose of this research project.
- I have read the previous page(s) of the participant information sheet (PIS) and the personal responsible for data collection has explained the details of the study.
- I understand that I am free to ask additional questions.
- I understand that my participation in this study is voluntary.
- I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

Signature/thumb impression of Participant

Date:

Witness

1.

2.

Name and Signature of Investigator/Research Staff:

Date: