Guidelines for the Informed Consent

An informed consent form must include the following:

1. Obtaining an Informed Consent is not simply obtaining a signature on a prescribed format rather, it is a process of sharing information and addressing questions and concerns of the participant.
2. It is based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research.
3. Participants must then give their consent to participate on an informed consent form developed specifically for the research project.
4. There are very few research situations where a participant's signature on informed consent is not required. However, permission from IRB is always required for waving off of the signature.
5. The informed consent form should be submitted in English as well as in local language(s).
6. The goal and objective of research in simple jargon-free language. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant.
7. Informed consent is a continuous process involving three main components – a) providing relevant information to potential participants, b) ensuring the competence of the individual, ensuring the information is easily comprehended by the participants and c) ensuring voluntariness.

Format of the Informed Consent Form is given on the following page.

[*Organization / Institute name and address*]

Informed Consent Form

[Project Title:]

1. [Introduction]

Greetings…. Self-introduction
Statement mentioning that it is research

2. [Purpose of Your Study]

- Clear the research objectives and outcome of the study
- [Respondent's Role]-Explain the procedure to participate in the interview/survey. Explanation of all the research tools employed. Reasons or methods for inclusion/exclusion of the particular group or individual(s) in the community or in any other settings, for participation in the survey should be briefed.
- Detailed description of the methodology
- [Time]- Approx. estimated time to complete the survey
    - *The interview will take approximately ------mins to complete.*

3. [Risks or Benefits]-

- Risks: [Describe any potential risks/discomfort/inconvenience associated with participation.]
    - *You may feel some inconvenience because of the time and effort to be a participant. In case of sensitive surveys, including questions on You may also find some questions that we ask to be upsetting or may feel embarrassed to answer them. You do not have to respond to any question that makes you uncomfortable and you may stop the interview at any time and nothing will happen.*

- Benefits: [Explain any potential benefits to participants or community.]
    - *There are no direct benefits to participating in the study, although you will help us understand what children like you want or need*

4. [Privacy/Confidentiality/Data Security]

- It is necessary to maintain the privacy and confidentiality of participants at all stages.
- The extent of privacy, anonymity, and confidentiality that will be provided to participants
    - *The information shared by you will be kept confidential and will not be shared with anyone, and will be used only for research purposes.*
    -

- [Data Sharing- Data collected will be completely anonymized/partially anonymized]
    - *The data will only be used for research and planning purposes without any personal identification.*

  Suppose in the case of Indirect Identifiers, you may give:
    - *All the information you provide will be strictly confidential, and your name will not appear on the questionnaire. Instead, your questionnaire will contain an identification number that is known only by the principal investigator of this study.*
    - *No one including your family members, friends, or other members of the community will ever know that you have not participated in the survey and no one will know what answers you gave since we do not collect information about your name etc.*

- [Information on any follow-ups of survey if any]
    - *The survey team may also re-contact you if it is necessary to complete the information in the survey.*

- [Voluntary nature of participation and Right not to participate and withdraw]
    - *Your participation is voluntary. You may refuse to participate or may discontinue your participation at any time during the survey. You can also choose not to answer any questions.*

- [Importance of the response/survey and future use of the information]
    - *Your responses are very important to us and the community, as these answers will represent many other people. This is an important study and I hope you will participate fully.*

5. [Contact information]

We will leave the necessary contact information with you. If you have any questions or concerns about this study, please contact on the address given below.

6. [Address questions of the Respondent regarding the survey if any]

- Do you have any questions?
    - *Should you have any question about the survey please feel free to ask me or contact the concerned authority.*

[Principal Investigator and Contact Information]

Principal Investigator: [Name, Affiliation, Office, Mobile, Email Address]

7. [Consent] Respondent's willingness to participate in the study

- *Do* you *agree to participate in this survey?*

[Verification of consent]

Tick the answer:

1. *Consent is given along with signature/ thumb impression*
2. *Consent is given but without signature/thumb impression*
3. *Consent Refused*

[Interviwer's Declaration]

I have informed the respondent about the project, risk and benefit and also confidentially risktaken consent from the respondent before the interview.

Interviewer's Name: _____ *Date:* ___ / ___ / ___