Template of Study Information Sheet and Consent Form

Study Information Sheet

(Name the group of individuals for whom this information sheet is written. In case your study is carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important tp provide group specific consent forms –ie you identify which group a particular consent is for although the study information sheet may be the same.)

This study information sheet is for ……. participating in the research titled- …….…….

Principal Investigator:
Supervisor:
Organization: Lady Irwin College, University of Delhi

Introduction
You are invited to participate in a research study conducted by----------. This study is funded by----------. Your participation in this study is voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether to participate or not. Please take as much time as you need to read the consent form. You are free to ask me any queries or if you do not understand anything. If you decide to participate, you will be asked to sign this form.

(For studies involving children…..Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.)

Purpose
In the present study, we wish to study ----------(explain in simple lay terms)

Type of Research Intervention
Briefly state the type of intervention if any that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves taking a blood sample, anthropometric measurements or simply being asked questions.

Participant selection
State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.
Voluntary Participation

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.
EgYour participation in the study is voluntary. You can choose to say *No and not participate in the study*You may withdraw at any time during the study.

Study Procedures
If you agree to participate, you will be asked to fill up a questionnaire/ be a part of focus group discussion/ undergo Body Measurements or blood tests (as the case may be).
Brief description of what is expected of the subject.
The procedures will be carried out at your home or at a place as per your convenience.

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant. Mention the time the participant will need to spend in each interaction.

Benefits
Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.
Eg Your participation would help us/community in ——————————.

Reimbursements
State clearly what you will provide the participants with as a result of their participation. eg expenses incurred as a result of participation in the research. These may include, for example, travel costs and money for wages lost due to visits to the study locale.
Or for eg.....You will not be provided with any payments to take part in the study. However your -------test results will be provided to you. Also, you can ask for free counselling (optional) during the course of the study.

Confidentiality
The information shared by you will be kept confidential. Your personal data and identity would not be revealed at any stage. You should also inform the participant that the research findings will be published in scientific journals and presented in conferences but the identity of the participants will not be disclosed .

Risks and Discomforts
If you feel uncomfortable talking about any topic or sharing any personal information, you will not be forced to answer any question that you do not wish to. The study does not involve any risk to your health or to your life....only in case the intervention is related to their health / disease risk

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw.Tailor this section to ensure that it fits for the group for whom you are seeking consent.

Who to Contact

If you have questions, concerns or complaints as a research participant, you may contact any of the following:..

give contact details of principal investigator and supervisor - phone and email id.

Consent form (for adult participants and parents of child participants)

I … … … … … … … … …., a resident of…… have read the information in the study information sheet / have had the study information sheet read out to me. I am over 18 years of age and, exercising my free power of choice, hereby willingly give my consent to participate in the study/ for my child to participate in the study . I certify that :

(1) I have fully understood the information provided about the study.
(2) My rights and responsibilities have been explained to me by the investigator.
(3) I have been informed that there are no known risks associated with this study and explained the possible benefits.
(4) I am aware of the fact that I/my childcan opt out of the study at any time without having to give any reason and this will not affect my access to ...(eg. facilities in school/health and nutrition services/....).
(5) I hereby give permission to the investigators to release the information obtained from me/ my childas result of participation in this study to the sponsors, regulatory authorities, and Government agencies.
(6) My/ my child's identity will be kept confidential when the data are published or presented in scientific meetings.
(7) I have been provided information about individuals whom I can contact to seek clarifications during the study period. I have also been provided a copy of the study information sheet and the consent document.

(If illiterate:*A literate witness must sign as witness to the thumb print consent by the person giving consent (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should have their thumb-print taken and this should be backed up by two witnesses who are not part of the study team .)*

_____ _____
Name of the participant *Date*

_____
Signature /Thumb impressionof the participant (if thumb impression then take signature of the witness and their addresss
Address- _____

_____
*Contact No-*_____ *Email id-* _____

Note: When the subject is a child parental consent for the child's participation in the study will be taken first - form will be referred to as Parental Consent. After parental consent, the assent is to be obtained from the child if the child is 7 years of age or beyond.. The child study information form should be separate, and should be in a language that the child can understand. If the child gives her/his assent the signature of the child is to be taken in the child assent form given below

Child's Assent

I have read this information (or had the information read to me). I know that my parents have agreed to my participation in the study.I have had my questions answered and know that I can ask questions later if I have any further queries.

I have understood the information provided to me regarding the study and I agree to take part in the study.

_____ _____

Name of the Participant *Date*

_____

Signature of the Participant

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

State the procedures that the participant has to undergo like participating in discussion/ filling a questionnaire/ having body measurements taken, etc.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of study information sheet has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____ Day/month/year