**Building a Research Participant Information Sheet**

**Instructions for writing a Participant information sheet for a research protocol**

1. Ensure that the participant information sheet is addressed to the prospective participants of research and is therefore addressed as “you are invited, you will undergo.., you may experience.., you will receive compensation..” etc
2. Write in simple language which is easily understood by the participants (assume that the participant is an VIII standard student of a non-English medium school reading this document prepared in English)
3. Translate into regional language with the help of a translator and not an unverified free online translation.
4. Invite the prospective participant to enroll in the study and begin by clarifying that the study is research and not part of healthcare
5. Provide clear and complete information about the research including the following:

**a. The title of the study**

**b. The details of the investigators: Name, designation, department**

**c. The total number of participants and the total study sites**

**d. The purpose of the study in simple terms**

**e. Reason why the participant is being included in the study. Example:**

* + 1. If the study is on patients with malaria, state that he/she is included in the study because he/she is diagnosed of malaria
    2. If the study is a case control study on smokers and non-smokers, then state that the person is included in the study because he is a smoker or non-smoker

**f. Details on the screening procedure and the eligibility**

**g. Duration of the study and the duration for which the participant has to be involved in the study: Example**

1. If the study is going to be carried out for 2 years and the patient has to visit the hospital once for research and subsequently 6 monthly visits, then you may describe as “The duration of study is 2 years and you will be required to come once every month for six months”
2. If the study is going to be carried out for 2 years and the patient has to visit the hospital only once, then this may be described as “the duration of the study is 2 years and you will be required to visit only once.

**h. The participants’ responsibility and cooperation**

* + 1. Number of visits to the hospital with details
    2. Total number of blood draws, total volume of blood, number X-rays, etc
    3. Need for hospitalization
    4. Any specific regime/restrictions to be followed
    5. Maintenance of a diary
    6. Reporting of any symptoms or events to the PI

**i. Ensure voluntariness in the enrollment process by providing following details:**

* + 1. The choice that the subject has
    2. The voluntary nature of the enrolment
       1. He/she can refuse to participate
       2. He/she can accept/agree/consent to participate
       3. He/she can withdraw from the study
       4. Any such decision will not affect
          1. The treatment
          2. The care
          3. The legal rights
    3. That there is no force or influence to participate
    4. That he/she can take enough time to decide whether or not to participate
    5. That he/she can ask any doubts to the PI at any point of time

**j. Provide details on how the PI will assess the comprehension and understanding of the participant (whether the PI will use any formal comprehension assessment such as a multiple choice question constructed from the content of the PIS).**

**k. Details of the intervention/observation: Describe in detail the methodology of the intervention or observation or investigations or collection of samples or responding to questionnaire in simple language**

**i. Terminology:** Do not use medical terminology or jargon. Instead, use simple English words to describe the same.  Example

* + - 1. If the study requires Contrast CT: use the term “CT scan with an injection’
      2. If the study requires PCR for tuberculosis: use the phrase “ a blood test for detection of TB, which is called PCR”
      3. If the study requires an intervention like appendicectomy: use the phrase ‘operation on the abdomen (stomach) to remove a part of the intestine called appendix’
      4. If the study involves a medical regimen like HAART: use the phrase ‘ a group of drugs used in the treatment of HIV infection’

**ii. Procedures:** Describe the procedures

* + - 1. Eg. Ultrasound/X-Ray- who will do it, where, privacy, result sharing, precautions, possible complications, cost bearing, time needed, repeat testing, etc
      2. Eg. Surgical procedure- explain in simple terms, anesthesia, what will be done, possible complication, post-operative care
      3. Eg. Clinical tests: explain in simple terms, how the test will be done, time taken, any possible discomfort, etc,
      4. Eg. Reports of investigations- histopathology report, X ray report from medical records

**iii. Biological samples:** If the study requires collection of biological samples for the purpose of research- Provide details on

* + - 1. Whether collected as a part of research or treatment
      2. If collected as a part of research- what laboratory tests will be done for the purpose of this research
      3. How much, method of collection including number of times
      4. How long the biological fluid/tissue/sample will be stored
      5. Any prospects of use of blood/tissue samples in future research
      6. Whether the samples will be shared with other researchers,
      7. When and how the samples will be disposed.
      8. Provide details on what will happen to the data associated with the sample.

**iv. Questionnaire-**

* + - 1. Provide details on what information will be collected, and that personal identifiers will not be collected, and that if there are sensitive questions, how they will be delivered and details of any other information,
      2. Provide details on the time required to respond
      3. Option to refuse to answer sensitive questions
      4. How privacy and confidentiality will be maintained

l. **The benefits of the study: Example**

* + 1. To the participant
    2. To the society
    3. Scientific advancement

m. **The harms of being involved in the study: Example**

* + 1. If the study involves taking a sample of blood, then state that 5 ml of blood will be taken from your arm just like a routine blood test and this is not associated with any risk or complications, except that you will experience some pain during the procedure and for a few minutes after that. No treatment is required for the same
    2. If the study involves taking an X-ray, then state that an X-ray will be taken which is usually not associated with any complications
    3. If the study requires intake of some medications, then state the common side effects of the drugs, their frequency and severity and whether they require to be treated

n. **Provide details on whether compensation (reimbursement) will be offered or not:**

* + 1. For the time/wages lost
    2. For the tests/treatment

o. **Please provide details on whether compensation will be made or not, for any harms/adverse events related to the research:**

1. Management plan for adverse event
2. Details on who will bear the cost
3. Compensation for serious adverse event
4. Details of the nominee in case of payment of compensation

p. **Protection of the participant’s privacy and the data confidentiality**

* + 1. That the privacy of the participant will be ensured during the study
    2. That the data/ findings of the study will be kept confidential and will be accessible only to the research team members and will not be shared with third parties except authorized persons like auditors, Sponsors, EC members.
    3. That the data will be anonymized
    4. That photographs taken (if any), will be masked so as to protect the privacy of the participant
    5. That the results of the study may be presented in conference or published in scientific journals, and if so, will be done anonymously.

q. **Contact persons:**

* + 1. Details of a responsible person from the research team who will clarify the doubts of the participant. Details of the person to contact in case of adverse events/ problems
    2. Details of a responsible member of the ethics committee (preferably Member-Secretary) who will address the concerns on the rights of the research participant, in case he/she is not satisfied by the responses from the PI (phone number, email and contact address)

r. Provide details on whether or not there is any conflict of interest for any of the members of the research team.

s. A statement that one copy of the PIS and a signed copy of the ICF will be provided to the participant.