

GUIDELINES FOR WRITING PARTICIPANT INFORMATION SHEET

Guidelines for writing Participant information sheet for a research protocol

1. Write in simple language which is easily understood by the participants (assume that the participant is equivalent to a VIII standard child)
2. Translate into regional language with the help of a translator and not Google translator
3. 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 purpose of the study in simple terms
 - d. Duration of the study and the duration for which the participant has to be involved in the study:

Example

- i. 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”
 - ii. If the study is going to be carried out for 3 years and the patient has to visit the hospital only once, then this may be described as “the duration of the study is 3 years and you will be required to visit only once.
- e. The reason why the participant is being included in the study

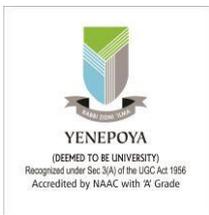
Example:

- i. If the study is on patients with malaria, state that he/she is included in the study because of malaria
- ii. 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. The benefits of the study:

Example

- i. To the participant
 - ii. To the society
 - iii. Scientific advancement
- g. Details of the intervention:
- i. Describe in detail the study protocol in simple language
 - ii. Do not use medical terminology or jargon. Instead, use simple English words to describe the same.



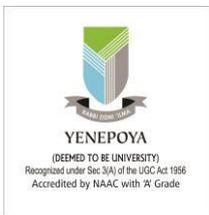
Example

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 appendectomy: 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’

h. The harms of being involved in the study

Example

- i. 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, expect that you will experience some pain during the procedure and for a few minutes after that. Not treatment is required for the same
 - ii. If the study involves taking an X-Ray, then state that an X Ray will be taken which is usually no associated with any complications, however, it is very rarely associated with complications like skin disorders or cancer
 - iii. 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
- i. Any prospects of use of blood samples in future research or whether the samples will be destroyed
- j. The participants’ responsibility and co-operation
- i. Number of visits to the hospital with details
 - ii. Need for hospitalization
 - iii. Any specific regime/restrictions to be followed
 - iv. Reporting of any symptoms or events to the PI
- k. The choice that the subject has
- i. The voluntary nature of the enrolment
 1. He/she can refuse to participate
 2. He/she can accept to participate
 3. He/she can withdraw from the study
 4. Any such decision will not affect
 - a. The treatment



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- b. The care
 - c. The legal rights
 - ii. That there is no force or influence to participate
 - iii. That he/she can take enough time to decide whether or not to participate
 - iv. That he/she can ask any doubts to the PI at any point of time
 - l. Compensation offered: with specifics
 - i. For the time lost
 - ii. For the tests/treatment
 - iii. For adverse events
 - m. Protection of the participant
 - i. That the privacy of the participant will be ensured during the study
 - ii. That the data/ findings of the study will be kept confidential
 - iii. That the data will be anonymized
 - iv. That the photographs taken if any, will be masked
 - v. protection of privacy of the participant
 - n. Details of the Person who will clarify doubts
 - o. Details of the person to contact in case of adverse events/ problems
- Has the compensation been addressed adequately(Member Secretary ,
Yenepoya ethics Committee, Phone Number and Address)