INSTITUTIONAL ETHICS COMMITTEE, NDCH

Guidelines to Be Followed While Designing Participant Information Sheet

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 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.
    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 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’

h. The harms of being involved in the study: Example
    i. It 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
            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