INSTITUTIONAL ETHICS COMMITTEE, NDCH

Guidelines to Be Followed While Designing Consent & Participant Information Form

(Non-regulatory Clinical / Academic trials)

Dear Principal Investigator,

To help you process your research protocol faster, we are providing some elements that we recommend should be there in the informed consent & participant information document. Before you submit the protocol for ethical clearance we strongly urge you to build a comprehensive informed consent and participant information document.

A well constructed informed consent & participant information document will ensure that:

1. The participant will be provided enough information (including study title & PI name)
2. This will be provided in a language that he/she understands
3. The participant will be given adequate time to understand the implications of consenting
4. Opportunity will be given to ask questions from the PI or a member of the study team
5. Some method of assessing the comprehension of the participant will be undertaken
6. Participant's consent is voluntary and free of coercion
7. Option to refuse is offered, without comprising patient rights
8. Option to voluntarily withdraw at any stage of the research, after initially agreeing without compromising rights
9. Participant will get to retain one copy of the consent form *OR* one copy of the participant information sheet
10. Maintaining privacy of the participant and confidentiality of the data
11. Permission to publish the data while protecting privacy and confidentiality
12. The PI or a study team member will be available for clarification with adequate contact details
13. There is a place on the form for signature, name and date for the participant and/or legally authorized representative and a study team member
14. There is a place on the form for name, date and signature of an independent witness, in case the participant is illiterate or unable to sign
15. Sample of the informed consent document is provided in a local language
16. If treatment is offered to the participants, then alternate methods of treatment available must be explained to the participants.