Information Sheet

INSTRUCTIONS

Please use the templates below (pages 2 & 4) to assist you in preparing the information sheet and consent form. Do not duplicate the sample information sheet. Some paragraphs may not be relevant to your study. Please select those which are applicable to your study. Use the template as a guide to prepare the Information Sheet to be used in your study, paying particular attention to the wording when the information is directed at parents and guardians of minors less than 18 years of age, who will constitute the study population.

The consent form template may be used in its entirety for most studies needing consent from adults. However, in the case of proxy consent, the sentences will need to be suitably re-worded. An extra statement is needed if tissue samples are to be stored

It is a good idea if provision is made for sufficiently mature children to give their assent, in addition to the parental consent. In this case, there needs to be a separate form for the child's assent in addition to the form for parental proxy consent with a suitable heading.

You should make the forms available in English, Sinhala and Tamil. However, you may limit to English and one of the other languages, or English alone, if you can justify the exclusion of any language/s on the basis of the language competence of the study population.

All forms – as well as all other documents submitted for review – should contain page numbers as well as the version number and date in the page header.

Information Sheet

<Heading: State the title of the research project here>

I am <state name of principal investigator>, attached to the <state institute>. My current designation is <state the designation>. I would like to invite you to take part in the research study titled <state the title of the project here> conducted by <state the name of the investigator/s> at <state the site of the study here>.

1. Purpose of the study

The purpose of this research is <state the expected purpose of the research here>.

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant's responsibilities

The procedure/s to be carried out is/are <state the procedure/s of the research and how the participant has to take part in the study>. < If material is to be taken for study, such as blood or tissue samples for histology or DNA analysis etc, this must be stated explicitly, with quantities if relevant (e.g. ml of blood) >. < If tissue/DNA is to be stored for later study, this must be explicitly stated and consent must be taken (a) to store samples and (b) for their use in future studies: for research in similar conditions/diseases or for research in any studies >.

You will need to undergo the following visits and procedures <state the expected duration of participation, including the number and duration of visits to the research site (if any) and what happens at each visit>.

4. Potential benefits

Participation in this study may benefit you/others by <state all the actual and potential benefits – to the participant, if any or to others>.

5. Risks, hazards and discomforts

<Any potential or actual risks, hazards and discomforts should be clearly stated>

6. Reimbursements

You would be paid a sum of Rs. <state any payment to the participant indicating the amount, when it would be paid and any conditions attached to it; or state that there will be no payments>.

7. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way

that you could be identified in any way in any public presentation or publication without your express permission.

8. Termination of study participation

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

9. Clarification

If you have questions about any of the tests or procedures, or require additional information, please feel free to ask any of the persons listed below.

<Give a list of persons (investigators) from whom the participant can ask questions and clarify any doubts and their contact details such as mobile phone numbers (land line numbers are not acceptable)>.

The contact details of the REC, including the phone number and email address, should also be included.

Signed

……<Your name>

Principal Investigator

……<Signature>

……..<Contact details>