**Informed Consent forms**

**Instructions**

Informed consent form should have two parts

Part 1: information sheet

Part 11: certificate of consent

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.

**Part 1: Information Sheet**

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

Introduction

I……………. (Name of the PI) attached to…………..(state Institute) as…….. (designation) would like to invite you to take part in the….(title of the research) conducted by ……. (names of investigator/s) at (site of study)

1. Purpose of study

Explain the purpose of study (in simple / lay terms)

* 1. b. Type of research intervention
  2. c. Participation selection
  3. d. Voluntary participation
  4. e. Procedure and protocol
  5. f. If it is a clinical trial - provide information on the trial drug (name). Which phase of the trial. Why you compare or test this new drug. Explain known information /experience of the trial drug
  6. g. If any samples (blood/sputum/biopsy ….) taken
  7. h. Duration

Explain what type of intervention that will be undertaken

State why this participant has been chosen for this research

Clearly indicate that each individual can choose to participate or not to participate

Describe or explain the procedure that will be followed on a step by step. Explain what you expected them to do. Write “we would like to ask you to …….”. Explain what is routine and what is experimental

Explain when/how many times/any preparations needed/what will be done with them/how long they will be stored/ how these are discarded/do they be sent abroad.

Indicate a statement about the time commitment (research duration and follow up)

* 1. i. Risks
  2. j. Benefits

Explain any possible /anticipated risks. If any problem occurs what will be the action

Mention actual benefits. (not what they are entitled due to participate in the research)

Mention is it individual or community benefit

* 1. k. Reimbursement
  2. l. Confidentiality
  3. m. Sharing of results
  4. n. Right to refuse or withdraw
  5. o. Whom to contact

State clearly what you will provide for their participation. Ex travel cost/money for wages lost

Explain how the research team will maintain the confidentiality of data

Mention plan of sharing results

Mention that participation is voluntary and has right to withdraw/refuse at any stage without explaining why? It will not affect the individual’s right to get proper / routine / treatment / care

Contact numbers of PI and other investigators. Mention who gave approval for this and the contact number of that ERC

**Part 11: Consent Form**

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

To be completed:

**a. By the participant**

The participant should complete the whole of this sheet himself/herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO

2. Have you had an opportunity to discuss this study and ask any questions? YES/NO

3. Have you had satisfactory answers to all your questions? YES/NO

4. Have you received enough information about the study? YES/NO

5. Who explained the study to you? …………………………………………………………

6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO

7. Sections of your medical notes, including those held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records? YES/NO

8. Have you had sufficient time to come to your decision? YES/NO

9. Do you agree to take part in this study? YES/NO

< If tissue samples are to be stored for later studies, insert an additional section here as no. 10. Asking for agreement

(a) to store tissue;

(b) to use stored material for future research

(i) into the same condition as present research,

(ii) research into any condition. >

Participant’s signature…………………………..…………Date…………………….

Name (BLOCK CAPITALS)…………………………………………………………

**b. By the investigator**

I have explained the study to the above participant and he/she has indicated willingness to take part.

Signature of investigator……………………....…………..Date……………………….

Name (BLOCK CAPITALS)…………………………………………………………