Sample Participant Information Sheet (PIS) and the Informed Consent Form (ICF)

Notes to Applicants:

1. PIS and the ICF should be two separate documents.
2. This document is only a sample and therefore some parts may not be relevant to your project. Do not duplicate the sample documents. You may prepare your own PIS and ICF using this as a template.
3. PIS and ICF should be submitted in all relevant languages.
4. **If the research involves storage and future use of human biological material, an additional PIS and ICF are required. A template is provided.**

Insert: Title, Date and Version number

PARTICIPANT INFORMATION SHEET

(Title of the research project)

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 project 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 project is (state the expected purpose of the research here).

2. Voluntary participation

Your participation in this study is voluntary. You are free not to 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. Participant Selection

Indicate why you have chosen this person to participate in this research.

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

a) 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).
b) 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 and what happens at each visit).
c) Provide the following additional details if the study involves collection of biological material.
   - Type, quantity and the procedure of collection
   - Safety and invasiveness of the procedures for acquisition
   - Intended uses of the biological materials, including any commercial use
   - Measures employed to protect the privacy and to minimize risks to participants
   - Duration and location of storage, transport across borders and the process for disposal
   - Anticipated linkage of biological materials with information about the participant
   - The process for requesting withdrawal of human biological materials from the research

5. Potential benefits

Participation in this study may benefit you/others by (state all the actual and potential benefits).

6. Risks, hazards and discomforts

(Any potential or actual risks, hazards and discomforts should be clearly defined)

7. 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).

8. Confidentiality.

Confidentiality of all records is guaranteed and no information by which you can be identified will be released and only anonymous data will be 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. Data without identification information may be shared with other researchers as many journals expect the authors to make their data available to other researchers

9. Sharing the Results

Plan for sharing the findings with the participants (if there are such plans) should be provided.

10. 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.

11. Clarification

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.
(State a list of persons with contact details from whom the participant can ask questions and clarify any doubts and their contact details).

12. If you have any complaints about unethical conduct related to this research, you may make a complaint to Ethics review committee, Faculty of Medicine, University of Kelaniya using information given below.

ERC Office Address: Ethics review committee, Faculty of Medicine, University of Kelaniya.
Telephone no: 0112961267
Email: ercmed@kln.ac.lk

Insert: Title, Date and Version number

INFORMED CONSENT FORM

(Title of the research project)

To be completed 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 have the right to not to participate in this study? YES/NO
7. 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
8. 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
9. Do you know that you are required to give a sample of (Specify the type of human biological material) for this study? YES/NO
10. Have you had sufficient time to come to your decision? YES/NO
11. Do you agree to take part in this study? YES/NO

Participant's signature……..…… Date…….

Name (BLOCK CAPITALS)……

To be completed by the investigator/ person obtaining consent

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

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

Name (BLOCK CAPITALS)…….