



## Ethics Review Committee

Faculty of Medicine, Wayamba University of Sri Lanka

### Sample Participant Information Sheet and the Consent Form

#### **Please note,**

- Participant information sheet and the consent form should be two separate documents.
- This document is only to assist you in preparing the information sheet and the consent form. Some parts of this document may not be relevant to your project. Please select those which are applicable to your project.
- Please do not reproduce the sample documents given below. Use them as a guide and prepare the documents that are applicable to your study.
- These documents should be produced in relevant languages depending on the population you are carrying out the study.

## **INFORMATION SHEET**

(Title of the research project)

(Version number, Date)

I am ..... (state name of principal investigator), attached to the ..... (state institute). My current designation is ..... (state the designation). Hereby I am inviting 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. By doing so you will not lose any medical care/ treatments or lose any privileges to which you are otherwise entitled. If you decide not to participate or withdraw from the study you can do that at any stage of the study.

### **3. Participant Selection**

Give a clarification why you chose this person as a participant in this research.

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

By consenting to be a participant you will be subjected to ..... (state what types of actions that will be taken with regard to participant, during the study period. Any sites they may have to visit, number of visits and duration of the follow-up etc.))

### **5. Potential benefits**

By participation in this study you may obtain following benefits..... (state all the actual and potential benefits).

### **6. Risks, hazards and discomforts**

By participating in this study, you will not be subjected to risk or hazards/you will be subjected to following potential difficulties, risks or hazards. (Use appropriate phrase)

### **7. Reimbursements**

You will not receive any payments for participating in this study./ You will be paid a sum of Rs. ....(For participation/ as traveling expenses etc.).

## **8. Confidentiality.**

We guarantee the confidentiality of all study records. Only anonymous data will be published and no information through which you may be identified will be released. Published data will never contain any information traceable to you, without your express permission. Data without identification information may be shared with other researchers as some journals expect the authors to make their data available to other researchers.

## **9. Sharing the Results**

(If there are plans for sharing the findings with the participants, details about it 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 any questions to ask about conduct of the study or need any clarifications please contact any of the following members of the investigating team.  
(State a list of persons with contact details).

**CONSENT FORM**

..... (Title of the research project) .....

Version number ..... date.....

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

**(Please keep a copy patient information sheet for yourself)**

- 1. Did you read the information sheet? YES/NO
- 2. Were you able to discuss about the study and clarify doubts? YES/NO
- 3. Did you have satisfactory answers to your questions? YES/NO
- 4. Are you satisfied with the information you received? YES/NO
- 5. Who explained details of the study to you? .....
- 6. Are you aware that you can withdraw from the study at any time, without giving reasons and without affecting your future medical care? YES/NO
- 7. Your medical and personal information, relating to your participation in this study may be available to all individuals involved in the study. However, all personal details will be treated as **strictly Confidential**. Do you give your permission for all individuals involved in the study 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

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).....