**(Title of the research project)**

**(Version number, date)**

**INFORMATION SHEET**

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 on (state the brief non technical title of the project here) conducted by (state the name of the investigator/s) at (state the site of the study here and sponsor if relevant).

1. **Purpose of the study**

The purpose of this research is (state the expected purpose of the research in simple non technical terms).

1. **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.

1. **Duration, procedures of the study and participant’s responsibilities**

This study will be conducted over a period of (state anticipated duration of study). If you volunteer to participate in this study, we will ask you to do the following:

1. We will ask you to (take part /visit the clinic) for (include duration of each visit and number of visits) over the course of a total of about (state expected duration of participation).
2. You will need to (state the procedure/s of the research including what happens at each visit in simple terms and how the participant has to take part in the study)
3. **Potential benefits**

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

1. **Risks, hazards and discomforts**

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

1. **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 you will not be paid any sum of money for participating in this study

1. **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.

1. **Termination of study participation**

You may stop participating 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.

1. **Clarifications**

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 person/s with contact details from whom the participant can ask questions and clarify any doubts and their contact details. Contact Details should be appropriate to the nature of the study).

**This project has been approved by the Ethics Review Committee, Faculty of Medicine, University of Colombo. You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112695300 extension 240 (between 9am and 4pm) or by sending an email to** **info.ethics@med.cmb.ac.lk**

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**CONSENT FORM**

**Part A - To be filled by the participant**

The participant should complete the whole of this sheet 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. Information 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

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

Name (BLOCK CAPITALS):

………………………………………………………………………………………………………………………………………………………

**Part B - To be filled by the investigator**

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

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

Name (BLOCK CAPITALS):

………………………………………………………………………………………………………………………………………………………