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**Faculty of Medicine, University of Colombo**  
**Application for Ethics Review**  
**Guidance Notes to Applicants on the Preparation of the Information Sheet**  
**and the Consent Form**

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We recommend that you use the following format to assist you in preparing the information sheet and the consent form. Some steps stated below may not be relevant to your project. Please select those which are applicable to your project.

You should make these documents available in all relevant languages. Do not simply duplicate the sample documents given below. Use them as a guide to prepare the documents to be used in your study.

Once the project is approved by the Ethics Review Committee, you may add the following statement to your information sheet. “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”.

## 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). 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).

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).

**4. Potential benefits**

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

**5. Risks, hazards and discomforts**

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

**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).

**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 / 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).

**CONSENT FORM**

(title of the research project)  
(version number, date)

**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 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

Participant's signature.....Date.....

Name (BLOCK CAPITALS).....

**To be completed by the investigator**

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).....