|  |  |  |
| --- | --- | --- |
|  | **Ethics Review Committee**  **Postgraduate Institute of Medicine**  **University of Colombo**  **Sample Information Sheet** |  |

**<Title of the project>**

I/We <name of principal investigator/s>, a <Designation> attached to <institute/s of affiliation> would like to invite you to take part in a research project titled <Non-technical Title> conducted by <Names of Investigators> at <Study Site>

1. **Purpose**

The objective/s of the study in 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 < 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 < duration of each visit and number of visits> over the course of a total of about < expected duration of participation>.
2. You will need to <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 < 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. < if 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. **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. **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. **Clarifications**

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

<The names and contact information of investigator/s>

<postal address, email address, telephone numbers>

If you have any clarification, concerns, or complaints related to this research project, you may contact the Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo.

ERC Office Address: Ethics Review Committee, Postgraduate Institute of Medicine, University of Colombo, 160, Prof. Nandadasa Kodagoda Mawatha, Colombo 07.

Telephone: 0112-689266 (between 9am and 4pm on working days)

Email: [erc@pgim.cmb.ac.lk](mailto:erc@pgim.cmb.ac.lk)