

INFORMED CONSENT FORM (for age 18 years and above)

ORC is collecting information for the purpose of evaluating your application for Ethical Review. By signing this form, you are certifying that all information provided are true and correct and likewise authorizing this office to process your information. The accomplished form will be kept in a secured place and will be disposed of after submission of the proposal.

The Informed Consent Form should be printed on official University letterhead and should be signed in 2 copies: 1 for the participant and 1 for the researcher to keep on file.

Part 1: ESSENTIAL INFORMATION IN THE PARTICIPANT INFORMATION SHEET (PIS)

The PIS should be a clear document that provides the necessary information while being easily understood by those for whom it has been written (**age-appropriate**).

1. Details of the research study should include the following:
 - a) Title of research project
 - b) Principal investigator and co-investigators
 - c) College / Department / Office / Institution
 - d) Funding source, if any
2. Invitation to participate and selection of participants
3. Purpose of the research study (State the purpose of the research in layman's term. Use local and simplified words, rather than scientific terms and professional jargon, and consider local beliefs and knowledge.)
4. Study procedure and duration
 - a) Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organize this section and increase readability. Define and explain scientific terms or professional jargon. Use language appropriate to the population.
 - b) If applicable, specify the time commitments of the research for the participant including length of time for participation in each procedure or activity, the length of time of the interview, FGD, survey, questionnaire, or experiment, the total length of time for participation, frequency of procedures and location of the procedures to be done.
 - c) If subjects will be audio-, video-, or digitally recorded, describe the procedure to be used.
 - d) If any study procedures are experimental, clearly identify which ones.
5. Voluntary participation and withdrawal
6. Removal for research and termination of research, when relevant

7. Potential risks and discomfort (Describe any reasonable foreseeable physical, physiological, social, legal, or financial risks or harms that might result from participating in this study and explain how these will be minimized.)
8. Direct benefits (Describe any potential benefits to the subject. If the subject will not directly benefit from the study, clearly state the fact.)
9. Compensation, reimbursement and cost to participants, when relevant
10. Data Privacy and Confidentiality (Explain how the researcher will maintain privacy of participants and confidentiality of data with respect to both information about the participants and information that the participant shares. This explanation includes the following items:
 - Purpose of collecting and processing personal information
 - Any data sharing agreement, disclosures or transfer of personal data to a third party (if applicable)
 - Assurance of non-disclosure if the research team will engage the services of a third party (e.g. a statistician/data analyst/consultant for processing of personal data)
 - Security measures to be implemented for the protection of their data, so as to maintain the availability, integrity and confidentiality of their personal data, to protect such data from accidental or unlawful destruction, alteration and disclosure, and any other unlawful processing.
 - Information on the rights of the data subjects in the context of their participation in the research
11. Contact information to respond to the following:
 - a) Queries on the details of the research protocol
 - b) Related concerns and grievances
 - c) Management of research-related injuries
 - d) Issues related to human rights of participants

Part 2: CONSENT CERTIFICATE should include the following:

- a. Statement of consent for voluntary participation
- b. Statement of consent for audio-, video- or digital recording, when relevant
- c. Statement of consent for data sharing and re-use, when relevant
- d. Printed name, signatures and date signed by the participant
- e. Statement by the impartial witness, if participant is illiterate
- f. Printed name, signature and date signed by the impartial witness
- g. Statement by the researcher

h. Printed name, signatures and date signed by the researcher