INFORMED CONSENT (ENGLISH VERSION)

Title of the Study	
Name of Principal Investigator	
Name of Organization	
Date Submitted	

This informed consent form has two parts: (1) Information Details (information about the study and the details of participation), and (2) Certificate of Consent (certification that the participants were given the information about the study). The informed consent form will be translated to Filipino version. Each participant will be given copies after the researcher discussed all pertinent information.

PART I: INFORMATION SHEET

INTRODUCTION

Briefly introduce the proponent and concerned organization, emphasize that this is an invitation to participate in a study/research and that he or she can take time to reflect on whether he or she want to participate or not. Assure the participant that he or she does not understand some of the words or concepts, that these will be explained and that he or she can ask questions at any time.

PURPOSE OF THE RESEARCH

Explain the research question in ordinary, non-technical terms. Use local and simplified words rather than scientific terms and professional jargon. Consider local beliefs and knowledge when deciding how best to provide the information.

TYPE OF RESEARCH INTERVENTION

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

PARTICIPANT SELECTION

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

VOLUNTARY PARTICIPATION

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

PROCEDURES

Provide a brief introduction to the format of the research study and in which part of the study he or she will be involved.

Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussions which may be sensitive or potentially cause embarrassment, inform the participant of this.

In focus group discussions:

Give the location of the FGD, describe the FGD process, inform the participant that there will be 7-8 other persons with similar experiences, that the discussion will be guided by a moderator who is trained to do so, whether the discussion will be recorded, how confidentiality will be kept and how long the records will be stored. Give the participant an idea on what topics will be taken up, that questions the participant has about the study may also be raised and discussed and that he or she does not have to share any knowledge that he or she is not comfortable sharing. It is also important for the participant to know that he or she can still opt out of the study even after the FGD by requesting that his or her participation not be cited part of the data.

For interviews:

Inform the participant about the location of the interview (or a preferred location of the participant) and identity of the interviewer. Assure the participant that he or she does not wish to answer any of the questions during the interview, the interviewer will move on to the next question; that no one else but the interviewer will be present unless he or she would like someone else to be there. Describe how the interview will be recorded and kept confidential. Explain how long the study records will be kept and subsequently destroyed.

For questionnaire surveys:

Describe how the survey will be distributed and collected. Inform the participant that he or she may answer the questionnaire personally, or it can be read to him or her; answered aloud and written down by a member of the research team. Assure the participant that if he or she does not wish to answer any of the questions, this may be skipped and he or she can proceed to the next question. The information recorded is confidential, name is not included on the forms, only a number will identify him or her, and no one else except [name of person(s) with access to the information] will have access to the results of the survey.)

DURATION

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

RISKS

Explain and describe any risks that can be anticipated or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

If the discussion is on sensitive and personal issues (e.g., reproductive and sexual health, personal habits, etc.) or confidential in nature, then there is a risk of embarrassment, discomfort or fear. Assure the participant that he or she does not have to answer any question or take part in the discussion, interview, or survey if he or she feels the question(s) are too personal or if talking about them makes him or her uncomfortable.

BENEFITS

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

REIMBURSEMENTS

State clearly that the participants will not receive payments beyond reimbursements for expenses incurred as a result of their participation.

CONFIDENTIALITY

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized.

If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(The following applies to focus groups)

Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant the group participants shall be encouraged to respect confidentiality, but that this cannot be guaranteed.

SHARING THE RESULTS

If there is a plan and a timeline for the sharing of information, include the details. The participant may also be informed that the research findings will be shared more broadly, for example, through publications and conferences.

RIGHT TO REFUSE OR WITHDRAW

Reiterate that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom one is seeking consent. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

WHO TO CONTACT

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local REC that has approved the proposal.

PART II: CERTIFICATE OF CONSENT

I have read the entire information sheet (or have been read to me) and I voluntarily agree to participate in the study. I had enough time to ask further questions about the possible benefits and consequences of joining in the study and all had been answered to my satisfaction. I also understand that I may ask additional questions at any time. Further, I understand that I have the right to withdraw at any moment in this survey without justifying my decision to do so and without affecting my medical care.

Respondent Code Number:

Name of Participant Signature of Participant Date of Signature

Name of Witness Signature of Witness Date of Signature

I certify that I have completely explained to the above individual the nature and purpose of the survey, potential benefits and disagreeable discomforts in participating. Also, I have answered all the participant's questions and concerns and have witnessed the above signature.

Name of Investigator Signature of Investigator Date of Signature