Guide to Designing an Informed Consent Form

This guide is for research projects that use questionnaires/surveys, interviews, focus group discussions, and/or experiments/procedures that involve human participants.

Note to Researchers:

1. Please note that this is a guide developed to assist research proponents in the design of their informed consent forms (ICF). Researchers are encouraged to use this when creating their informed consent forms to best suit the design of their study. Use of alternative wording or format is allowed.

2. The informed consent form consists of two parts: the information sheet and the consent section. The information section of the ICF is to inform the research participants what data are being collected, the data collection procedures, and how the data will be used and protected. Please refer to the Data Privacy Act of the Philippines to know the rights of the research participants. The ICF should include statements on how these rights will be supported. (https://www.privacy.gov.ph/data-privacy-act/)

3. **Do not be concerned with the length of this guide.** It is long only because it contains **recommended texts and explanations** – You do not need to include these explanations in the informed consent forms that you develop and provide to participants in your research. Informed consent forms are typically 1-2 pages at most.

4. You may provide the following information as running paragraphs or under headings, as shown below.

5. Explanations in italics are for your information and should be deleted from the actual consent form. Material in brackets should be completed with relevant information.

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

[Title of Study]
Informed Consent Form

Name the group for whom this consent form is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, student leaders, local government officials - it is important that you identify which group this particular consent is for.

[Name of Principle Investigator]
[Name of Department/Office/Institution]
[Name of Sponsor/Source of Funding]
[Name of Research Project]

Inform participants that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at any time.

PURPOSE OF THE STUDY

You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what your participation will involve. Please read the following information carefully and feel free to ask the researcher if there is anything that is not clear or if you need more information.

The purpose of the study is to [*Briefly explain the research question <u>in layman's terms</u> which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. 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.*]

STUDY PROCEDURES

[*Provide a clear procedure of the participation in the research study. State what participants will be asked to do if they choose to participate. List all procedures, preferably in chronological order, which will be employed in the study.*

Explain the type of questions that the participants are likely to be asked in the focus group, interview, questionnaire, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment or discomfort, inform the participant of this. If the study involves experiments, the type of procedures that will be undertaken while they participate in the experiment should be clearly explained. If the participant might experience non-normative bodily sensations, inform them of this.]

DURATION

[*Include a statement about the time commitments of the research for the participant. This includes the length of time of the interview, FGD, survey questionnaire, or experiment. This should include the duration of their involvement in the follow-up, if relevant.*]

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you whether or not you decide to participate. If you decide to participate, you will be asked to sign this consent form. After you sign this consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be destroyed.

[*Indicate clearly that their participation is voluntary and they can choose to participate or not. They can also withdraw from the study at any time. State, only if it is applicable, that they will still receive all the services they usually do and will not receive any sanction if they decline participation. If the participant asks, they are entitled to review their remarks in individual interviews and erase a part or all of the recording or note.*]

RISKS

[*Explain and describe any risks that you anticipate or that are possible that may befall on the participant. The risks depend upon the nature of your study and their participation, and tailored to the specific issue and situation. Provide measures you are undertaking to minimize the foreseeable risks.*]

You may decline to answer any or all questions and you may withdraw your participation at any time if you choose.

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. Explain the kind of benefit the participant will receive, whether it is a token, gift certificate, expense reimbursement, education, new knowledge, etc. If there is no direct benefit to the participant, state this. For example: There will be no direct benefit to your participation in the study. However, we hope that the information from this study may…*]

CONFIDENTIALITY

Your responses in this research will be anonymous. Every effort will be made by the researcher to preserve your confidentiality, including the following:

[*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. Some measures taken to ensure confidentiality are listed below:*

1. *Assigning codes/psuedonyms for participants that will be used on all research notes and documents*
2. *Keeping notes, interview transcriptions, and any other personal identifiers in a locked cabinet that only the researchers will have access to*
3. *Softcopies of notes and research data with personal identifiers are password protected and has multi-factor authentication enabled for security.*
4. *Data with identifiers are kept only until 1 year after the duration of the research. After which, all hardcopies will be run through a cross cut shredder in University premises and all softcopies will be securely deleted.*
5. *Research results for publication will not include any personal identifiers of the research participant, unless explicit consent was given.*
6. *Research participant will be notified and a separate consent will be asked should any collected data be used beyond the scope of this consent.*

If the research is sensitive and/or involves participants who are highly vulnerable, explain any extra precautions you will take to ensure safety and anonymity. For focus groups, these provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.]

CONTACT INFORMATION

If you have any questions at any time about this study, or if you experience any non-normative sensations because of participation, or to exercise your data privacy rights, you may contact the researcher whose contact information is on the first page. If you have any questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Principal Investigator, please contact the Chair of the DLSU Research Ethics Review Committee at chairrerc@dlsu.edu.ph (632) 524-4611 local 513.

CONSENT

This section is mandatory

I have read the provided information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I understand that I will be given a copy of this form, and the researcher will keep another copy on file. I consent voluntarily to be a participant in this study.

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

This section is mandatory

Print Name of Impartial Witness_____
Signature of Impartial Witness _____
Date _____
Day/month/year

This section is mandatory

Print Name of Researcher_____
Signature of Researcher _____
Date _____
Day/month/year

If the participant is illiterate [1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____

Signature of witness _____

Date _____
Day/month/year

[1] A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).