Guide for Creating an Informed Consent Form for Surveys, Interviews, and Focus Group Discussions

Adapted from the WHO Informed Consent Template with modifications
(http://www.who.int/rpc/research_ethics/informed_consent/en/)

Note to Researchers:

1. Please note that this is a guide developed by the UPLB Research Ethics Board 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 certificate of consent.

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. Typical Informed Consent Forms can range from 3-7 pages depending on the study.

4. You may provide the following information as numbered statements 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. The question in each section will help you to formulate the content.

[INSTITUTIONAL LETTERHEAD – optional]

SECTION 1: ABOUT THE RESEARCHER

Informed Consent Form for _____. ***[Identity of the particular group of individuals (e.g., clients, patients, community leaders, service providers) in the project for whom this consent is intended]***

[Name of Principal Investigator] _____
[Name of Organization] _____
[Name of Sponsor] _____
[Name of Project and Version] _____

PART I: INFORMATION SHEET

SECTION 2: ABOUT THE RESEARCH

INTRODUCTION

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

STUDY TITLE

The title could be the same as in the protocol or a simplified version understandable to a lay person. The titles must be consistent throughout the documentation.

Invitation paragraph: It must be clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary.

> *Example:*
> *We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.*

PURPOSE OF THE RESEARCH - (*What is the purpose of the study?)*

Provide a brief outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol. Consider local beliefs and knowledge when deciding how best to provide the information.

TYPE OF RESEARCH – *(What type of research am I participating in?)*

Briefly state the type of research 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.

SECTION 3: STUDY INVOLVEMENT

PARTICIPANT SELECTION – (*Why have I been invited?)*

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

- Explain specifically why the participant has been invited.
- State how many participants you are intending to involve and their characteristics.

VOLUNTARY PARTICIPATION – (*Do I have to take part?)*

- The answer is 'No': It should be clear that taking part is entirely voluntary.
- 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.

PROCEDURES

A. Provide a brief introduction to the format of the research study and in which part of the study he/she will be involved.
B. 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/she does not have to share any knowledge that he/she is not comfortable sharing.
- It is also important for the participant to know that he/she can still opt out of the study even after the FGD by requesting that his/her participation not be cited as 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/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/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/she may answer the questionnaire personally, or it can be read to him/her; answered aloud and written down by a member of the research team.
- Assure the participant that if he/she does not wish to answer any of the questions, this may be skipped and he/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/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 – (*What will happen to me if I decide to take part?)*

This section details what will be involved in your research study from a participant's point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn.

- How long the participant will be involved in the research; how often they will need to attend a research session; and how long visits will be.
- If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
- If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon.
- If you will be using tissue samples, state whether the tissue will be collected as part of clinical care. Are you requesting use of tissue surplus for diagnostic needs, or collecting additional samples?

What should I consider?

You should explain:

- Conditions which may exclude individuals from participation;
- Whether they can participate if they are involved in other research studies.

SECTION 4: RISKS AND BENEFITS

RISKS – (*Are there any possible disadvantages or risks from taking part?)*

Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs: risks and their relative likelihoods, as well as what you will do to mitigate these risks. For example:

Procedures:	***Risks:***
Blood samples	The possibility of bruising and/or fainting
Questionnaires or interview questions	May cause distress: give indication of kinds of questions you will be asking, and outline what would happen if a participant becomes upset.

- 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/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.

BENEFITS – *(What are the possible benefits of taking part?)*

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 from which there can be actual benefits.

- Sometimes participants can benefit directly. If this is so, be clear; if not, be equally clear that there is no benefit.
- Ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.

REIMBURSEMENTS – *(Will I be reimbursed for taking part?)*

- Make clear whether they will be compensated for their time, inconvenience for having to take medications or for having to donate blood or tissue samples. It is important

that potential participants understand how these payments might be influenced by the duration of their involvement in your study (whether pro rata) or by factors such as the completeness of diaries they provide.

- Make clear whether they and/or others who might accompany them will be reimbursed for their expenses such as: travel, meals, childcare. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.

SECTION 5: REFUSING AND ENDING IN THE RESEARCH

RIGHT TO REFUSE OR WITHDRAW – *(What will happen if I don't want to carry on with the study?)*

Make clear that:

- Participation is voluntary and participants may change their minds at a later stage.
- Withdrawal will not affect the care they receive from any relevant service (e.g. for patients)

What procedure is in place in case of withdrawal?

- Are there any safety implications? Will participants be followed up and a final visit arranged?
- Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?
- If the study intends to retain tissue or data for future research, specify the effect of withdrawal on future use.

Examples:

If you withdraw from the study, we will destroy all your identifiable samples, but will use the data collected up to your withdrawal. (This is an example of how a participant's rights are 'limited') Or;

If you withdraw from the study, unless you state otherwise, any blood or tissue samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed at any time during or after the study. Or;

Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.

SECTION 6: SECURING AND SHARING RESEARCH INFORMATION

CONFIDENTIALITY – *(Will my taking part in the study be kept confidential?)*

- Explain arrangements made to ensure that information is kept secure. For example, where participant's identifiable data will be stored, what security arrangement is in place, and what will happen to the data once the study ends.
- If you are intending to approach participants in the future please consider adding information into a separate section "Participation in future research".
- Explain in what form you will hold information. For example:
  - Will participants be identified by study code only?
  - Will you destroy all direct identifiers and store only data from which participants cannot be identified?
  - Limits on anonymity should be made clear to participants. Since complete anonymity is difficult to achieve, it is more in keeping with data protection regulation to refer to data as 'de-identified'. Note that if you anonymize in this way during the study, it will not be possible for participants to withdraw their data. They should be informed of this here and/or in the section discussing withdrawal.
- ***Include the following text:*** Responsible members of the UPLB or UPLB REB may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

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 that the group participants shall be encouraged to respect confidentiality, but that this cannot be guaranteed.

Other consideration:

- If your study will involve video/audio-recording, outline what will happen to these recordings in the longer term; and, if transcribed, whether the recordings will be destroyed.

What will happen to the samples I give?

- State how they will be used in the research (where they will be transferred or held, what analysis will take place) and in what form.
- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.
- If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

What will happen to my data?

- State how the data would be protected or stored.

SHARING THE RESULTS – (What will happen to the results of this study? Alternatively: What happens at the end of the study?)

- Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they will be (for instance, with images of faces) it will be necessary to obtain specific consent for this.
- You should inform potential participants of your intentions with respect to:
  - Publishing research findings;
  - Presenting your findings at conferences;
    - Feeding back findings to participants themselves. Will you provide them with a summary, or add in a link to a website from which they could get the information, or ask them to contact you?
- Indicate whether the study is part of an educational project, such as fulfilment of requirements for masteral or doctoral degree. For example: Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

SECTION 7: CONTACT INFORMATION

WHO TO CONTACT – (What if there is a problem, any concern, any complaint?)

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

PART II: CERTIFICATE OF CONSENT

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent.

This section is mandatory

I, [participant name] _____, agree to participate in the research project titled [project title] _____, conducted by [researcher(s) name] _____ who has (have) discussed the research project with me.

I have received, read and kept a copy of the information letter/plain language statement. I have had the opportunity to ask questions about this research and I have received satisfactory answers. I understand the general purposes, risks and methods of this research.

I consent to participate in the research project and the following has been explained to me:

- **the research may not be of direct benefit to me**
- **my participation is completely voluntary**
- **my right to withdraw from the study at any time without any implications to me**
- **the risks including any possible inconvenience, discomfort or harm as a consequence of my participation in the research project**
- **the steps that have been taken to minimize/mitigate any possible risks**
- **what I am expected and required to do**
- **whom I should contact for any complaints with the research or the conduct of the research**
- **I am able to request a copy of the research findings and reports**
- **security and confidentiality of my personal information.**

Print Name of Participant: _____
Signature of Participant: _____
Date: **[MM/DD/YYYY]**

If Illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

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_____ **Thumb print of participant:**
Signature of witness _____
Date: [MM/DD/YYYY]

STATEMENT BY THE RESEARCHER OR PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

_____

Print Name of Researcher or person taking the consent

_____

Signature of Researcher or person taking the consent

_____

Date: <MM/DD/YYYY>

References:

IRB-HSBS General Informed Consent Template (2018). Retrieved from https://research-compliance.umich.edu/informed-consent-guidelines

National Ethical Guidelines for Health and Health-Related Research (2017). *Informed Consent Form Template for Surveys, Interviews, and Focus Group Discussions* (pp. 228-233). Retrieved from https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=98:neghhr-2017

Participant Information Sheets. University of Oxford. Retrieved from https://researchsupport.admin.ox.ac.uk/files/templateparticipantinformationsheetdocx

Sample Informed Consent Form for Research Participant. Retrieved from https://www.education.act.gov.au/__data/assets/word_doc/0004/441715/2013-04-17-Consent-Form-template-ETD.doc

Informed Consent Form Template

Note to Researchers:

1. This is a template developed by the UPLB Research Ethics Board to assist research participants in the writing of their informed consent form (ICF). It is highly recommended that researchers are to use this template for consistency.

2. You can modify this document to suit the design of their study, i.e., some components may be added, deleted, or modified. The use of alternative wording or format is allowed.

3. Whatever modifications you make, please make sure that it is in plain language. According to the International Plain Language Federation, "a communication is in plain language if its wording, structure, and design are so clear that the intended audience can easily find what they need, understand what they find, and use that information."

4. The words/phrases in brackets followed by blanks are meant to guide the researcher on the information that needs to be provided. The final informed consent form should be devoid of bracketed words/phrases, blanks or underlined words/phrases.

INFORMED CONSENT FORM

INFORMATION SHEET

INTRODUCTION

I am [Name]_____, the principal investigator of the study titled [Title of Study] _____. I am a [student/staff designation or rank] _____ of the University of the Philippines Los Baños, College, Laguna and pursuing [Degree Program] _____ of the UPLB Graduate School or specifically under [Name of Unit/Department/College] _____. This study is funded/sponsored by [Agency/Sponsor] _____ and is being conducted as a [thesis/dissertation/special problem/research] project.

I would like to invite you to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information; and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask me.

PURPOSE OF THE RESEARCH

The purpose of this research is to [provide a brief, simple, non-technical/plain language description of the research] _____.

TYPE OF RESEARCH

This research is a [type of study – e.g. cross-sectional, longitudinal, descriptive, etc. or a study that will involve a vaccine, an interview, a questionnaire, or a series of finger pricks] _____ type of study that will be conducted for a period of [number of months or years] _____.

PARTICIPANT SELECTION

You are asked to take part in this study because [state the reason a person has been asked to participate] _____.

The study will involve _____ [number] participants who are _____ [mention selection criteria – e.g. women of child-bearing age, children or minors aged 7 to 17 years old, or residents of the local community, etc.]

VOLUNTARY PARTICIPATION

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time.

If you refuse to participate, it will not in any way cause a negative effect on _____ [you/your job/your position/your status/etc.]

PROCEDURES

As a participant, you will be asked to do/provide the following:

[List all research/experimental procedures in this section. The following should always be included, if applicable:]

- The location where research activities/procedures will take place
- Description of all research interactions/experimental activities or interventions
- Data collection procedures (questionnaire surveys, focus group discussions, interviews, audio-visual recording, observation, etc.)
- Identification of which procedures are standard and which are experimental.
- Randomization procedures
- Use of medical records

Participation in the [surveys, interviews, focus group discussions, etc.] _____ will take [specify the duration of the study and the total amount of time required for participation in the study] _____.

Alternative wording:

You will be asked to take one survey each week for a period of two months. Each survey is expected to take about one hour.

RISKS

This study may involve some risks that can be anticipated or that are possible. Specifically, the procedure that involves [description of the procedure – e.g. blood sample collection, or interview questions, etc.] _____ can cause possible harm or risk in the form of _____ [mention the risk involved – e.g. bruising at the site of injection, fainting, distress from embarrassing questions, etc.].

Take note:

Include the risks and/or discomforts of all study procedures. Include a brief general statement followed by a listing of all risks arranged and described according to their severity and the likelihood of their occurrence.

The researcher will try to minimize these risks by _____ [describe what you will do to protect participants against risks.]

For example, to minimize/mitigate psychological risks, we will provide you with counselling resources.

For the study that involves surveys/interviews/focus groups: to minimize/mitigate the risks, you do not have to answer any questions you do not want to answer or questions that you are not comfortable to answer.

BENEFITS

If no direct benefit:

You may not receive any personal benefits from participating in this study. However, others may benefit from the knowledge gained from this study.

If there is benefit:

You might benefit from participating in the study _____ [describe direct benefits]
Or;
The results from this study will be able to benefit the [participant/community/society, etc.] _____ in the form of _____ [mention only actual benefits, if any].

REIMBURSEMENTS

As a participant, you will not be given any payment for being a part of the study. However, expenses incurred as a result of your participation will be reimbursed. [Specify the amount/price-range that they can only reimburse for expenses incurred]

COMPENSATION (If applicable)

You will receive [type and total amount of compensation] for your participation in the study. **[**Describe also how compensation will be distributed if the participant withdraws from the research before the end of the study]

RIGHT TO REFUSE OR WITHDRAW

Your participation in this study is voluntary and you may cancel this consent at any time and without any reason. If you do so, your participation in the study will end and the study staff will stop collecting information from you.

If you withdraw from the study _____ [specify what procedure is in place in case of withdrawal. For example, we will destroy all your identifiable samples, but will use the data collected up to your withdrawal].

CONFIDENTIALITY

Any personal information that you will provide including the data that will be obtained as part of your involvement in the study will be kept private and confidential. Written records will be kept in a cabinet with lock and can be accessed only by the principal investigator and/or the research team which includes _____ [mention the persons who will have access to the records]. Your identity will also be anonymized and coded and only the persons mentioned above will have access to the codes.

To ensure that the research is complying with applicable regulations, responsible members of the UPLB or UPLB REB may be given access to data for monitoring and/or audit of the study

(The following applies to focus groups)

Information shared in the focus group will be treated with privacy and confidentiality but it also becomes known to other participants in the focus group . Although we cannot guarantee the individual decisions of each participant to not disclose any sensitive personal information, all participants are reminded before and after the group discussion of their responsibility to respect privacy and protect the confidentiality of the research activities.

***(Other consideration*)**

If your study will involve video/audio-recording, outline what will happen to these recordings in the longer term; and, if transcribed, whether the recordings will be destroyed.

(What will happen to the samples given?)

- State how they will be used in the research (where they will be transferred or held, what analysis will take place) and in what form.
- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.
- If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

(What will happen to the data collected?)

State how the data would be protected or stored.

SHARING THE RESULTS

This study is part of the requirements for a _____ [identify your masteral or doctoral degree] at the Graduate School of the University of the Philippines Los Baños.

(Feeding back findings)

You will be informed of the results (if applicable) through _____ [provide details – e.g. through a summary, link to a website, or contact of the personal investigator, etc.) not later than _____ [state the number of weeks/months for the planned return of results] after the collection of sample/data.

In addition, the results of this study could be published in an article or be presented in a conference, but would not include any information that would let others know who you are without your permission.

(If applicable only)

We may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

RESEARCH ETHICS APPROVAL

This study observes and upholds the 2022 National Ethical Guidelines for Research Involving Human Participants. The UPLB Research Ethics Board (Panel _____) has reviewed and approved the study protocol on _____ [state date of approval] (Cite Application ID).

WHO TO CONTACT

If you would like to::

- Obtain more information about the study;
- Ask a question about the study procedures;
- Report an illness, injury, or other problem;
- Leave the study before it is finished;
- Express a concern about the study;

Please contact the following:

The Researcher/Graduate Student	Chair, Guidance Committee	Chair, UPLB Research Ethics Board
Name Email Address Mobile Number	Name Email Address Mobile Number Office Address	Name Email Address Mobile Number Office Address

CERTIFICATE OF CONSENT

I, [participant name] _____, agree to participate in the research project titled [project title] _____, conducted by [researcher(s) name] _____ who has (have) discussed the research project with me.

I have received, read and kept a copy of the information letter/plain language statement. I have had the opportunity to ask questions about this research and I have received satisfactory answers. I understand the general purposes, risks and methods of this research.

I consent to participate in the research project and the following has been explained to me:

- **the research may not be of direct benefit to me**
- **my participation is completely voluntary**
- **my right to withdraw from the study at any time without any implications to me**
- **the risks including any possible inconvenience, discomfort or harm as a consequence of my participation in the research project**
- **the steps that have been taken to minimize/mitigate any possible risks**
- **what I am expected and required to do**
- **whom I should contact for any complaints with the research or the conduct of the research**
- **I am able to request a copy of the research findings and reports**
- **security and confidentiality of my personal information.**

Print Name of Participant: _____
Signature of Participant: _____
Date: **[MM/DD/YYYY]**

If Illiterate

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_____ **Thumb print of participant:**
Signature of witness _____
Date: [MM/DD/YYYY]

STATEMENT BY THE RESEARCHER OR PERSON TAKING CONSENT
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

_____
Print Name of Researcher or person taking the consent

_____
Signature of Researcher or person taking the consent

_____
Date: <MM/DD/YYYY>