**Informed Consent Information Template [for IC Form or IC Verbal Script]**

**Instructions:** **Delete all instructions and guidance notes *[italicized text in brackets]* and the UREO letterhead** prior to submission of the ICF form/script for review or prior to use in the research. Adapt as appropriate according to the nature of your study and participants (e.g. translate language). Refer to Endnotes for more guidance on content and types of informed consent.] [[1]](#endnote-1)

Title of the Research Study:

Name of Sponsor / Funder / Grant-Provider *[if applicable]*:

Name of Principal Investigator (PI):

Contact Information of PI:

Name of Faculty Adviser *[required if PI is a student]*:

Contact Information of Faculty Adviser:

You are being invited to participate in a research study. Your participation is voluntary, which means you are free to choose whether or not to participate. If you decide not to participate there will be no penalty or negative consequence.

*[It is recommended to be specific to the context of the participant. For ex., if employed: Your decision to participate or not will not have any impact on your job status or evaluations; if student: Your decision to participate or not will not have any impact on your class/school standing or evaluations.]*

Before you make a decision you will need to know what the study is about, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. The researcher is going to talk with you about the study and/or give you this document to read [*or indicate other means by which the informed consent process will be conducted*].

[*if relevant or if recommended to add by UREC*: You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.]

Do not sign or agree to participate if you are unsure or have remaining questions. Please ask the researcher to explain anything unclear to you, including any words in this form. If you decide to participate, you will be asked to *[sign this form/indicate other action that would signify active consent of participant]* and a copy or record of your consent and the study information will be given to you. Keep this form as it has the contact information and answers to questions about the study.

**What is the purpose of the study?**

The purpose of the study is to learn more about      .

* *Indicate a simple, accurate explanation of the purpose the study. Do not use scientific or professional jargon. Be clear; do not confuse or mislead. If the study is being conducted for a class, thesis, or dissertation, it should be mentioned here*.

**Why am I being asked to participate in the study?**

You are being asked to join this study because      .

* *Explain why the participant is appropriate for recruitment to the study. People wonder why they have been chosen and may feel confused or concerned. If selection is random, then explain the process to the prospective participant.*

**What will I be asked to do?**

* *Provide a basic chronology of what the participant will do in a simple, non-technical language. If multiple sessions are required, explain what will happen at each time. Remember to clearly explain any experimental procedures.*
* *Explain the types of questions that the participants are likely to be asked in the survey, interview, or focus group. If the research involves obtaining personal (identifiable) and/or sensitive information, inform the participant.*

**How long will I be in the study?**

The study will take place over a period of       hours/days/weeks/months. [*if appropriate:* This means for the next      months we will ask you to spend     days a month participating in this study. ] The session will last approximately       hours.

* *Explain how much time the subject will need to commit in terms of hours, days, weeks, months and years.*

**Where will the study take place?**

You will be asked to come to      , located at       on       at       pm or am.

* *Explain where the participant will have to go to participate, or where the sessions will take place. Be specific about requirements to go to different sites for different aspects of the study such as testing, meetings, etc.*
* *Will any travel or transportation costs be reimbursed? Indicate whether or not this will be provided.*

**Are there any risks and what are they?**

* *The document or script should clearly state all possible or anticipated discomforts and risks regardless of severity. It should also state what measures have been implemented within the study to minimize the possibility of occurrence of such risks.*

**What are the benefits of participating in the study?**

* *Indicate benefits to the participant and/or community and/or society as a whole. Compensation for participation in the study is not considered a benefit.*

**What happens if I do not choose to join the research study?** **Can I stop or withdraw from the study even after it has started?**

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. [*if appropriate*: You will not lose any benefits or advantages that you are now receiving or will receive in the future.] Your [*as appropriate*: teacher, parent, therapist, doctor] will not be upset with your decision.

* *Simply and directly tell the subject there are no negative consequences should they choose not to participate. The purpose is to mitigate any feelings of obligation or coercion on the part of the subject.*

You can stop your participation in the research study and withdraw your data at any time even after it has started. There is no penalty or loss of benefits if you decide to do so.

If you no longer wish to be part of the research study, or if you want to withdraw your data so that the research will no longer use it,

* *Describe how subjects can withdraw themselves and/or their data from the study*

If you choose not to be in the study, the following are other *[treatment, class activity/requirement, etc.]* choices that you may want to consider in place of research participation:

* *If this applies, provide the pertinent information about the alternative activity*

**How will confidentiality be maintained and my privacy protected?** **What** **personal or identifiable data will you obtain? Who will have access to or see my data?**

* *Explain how confidentiality will be maintained in this study. Sample text is below. Be specific about how records will be secured to protect the identity of the subject. Explain how subjects will be pseudo-anonymized; e.g. will code numbers be used? The content of this section will vary according to the research design. There may be more protections depending on the nature of the research (e.g. for sensitive research).*
* *Note: If there are limits to confidentiality, i.e. if professional ethics and/or legal regulations require the researcher to report information without the participant’s consent, then this must also be clearly stated in the informed consent form. Sample text is below; revise according to your research protocol:*

The information you provide is confidential. Your full name will not appear on any of the questionnaires, and information identifying you will not appear in any report or publication of this research. Only the principal investigator *[indicate other personnel]* will know the identity associated with the information collected for this study, and they will not reveal it to anyone else.

There are instances in which information concerning your interview/data would have to be released without your consent. This would happen if \_\_\_\_\_\_\_\_\_\_\_\_ *[e.g. you pose a serious danger to yourself or others, or if there is evidence to suggest child abuse or neglect.]*

***[if appropriate]* What happens if I am injured/experience distress/harm from being part of the study?**

* *Describe what care or treatment will be provided for research related harm/injury that directly results from participation in the research, and any limits to this care or treatment or other compensatory measures*
* *Provide contact information for research-related harm/injury*
* *Explain how treatment for research-related harm/injuries would be paid. If there is sponsor/funder-specific injury language, add it here.*
* *Participant’s responsibilities (if any) relating to research-related harm/injuries*

*Note: Exculpatory statements or any statements that appear to free the researcher or entity from malpractice, negligence, blame, fault, or guilt is not allowed in the consent process. The participant should not be made to waive any legal rights.*

**Will I have to pay for anything?**

* *Explain the how much it will cost to participate in the study (how much, to whom and why) or state that there are no costs associated with participating in the study.*
* *Include the costs associated with transportation to and from the study site, parking, lunch and other related expenses. State what study-related expenses are reimbursed.*

# Will I be paid for participating in this study?

* *Description of any monetary or other form of compensation (e.g. food pack, gift certificate), if participants are being compensated for their time, effort, and travel.*
* *Compensation has to be judicious and commensurate to the effort and time expended by the participant and not exploitative or coercive.*
* *If there is no compensation for participation in this study, state that here.*

# Who can I call for questions about the study or if I’m concerned about my rights as a research participant?

If you have questions or concerns regarding the study and your participation in it, contact the Principal Investigator listed on page 1 of this form.

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the University Research Ethics Office at the Ateneo de Manila University by calling mobile no 0945 2136758 or landline (632) 8426-4001 local 4030 for any question, concern, or complaint about your rights as a research subject.

**Certificate of Consent**

*[This section is mandatory and should be written in first person language. Fill in the blanks with the appropriate information.]*

I have been invited to participate in a study about      . In the study I am asked to      .

I have read the information about the study, or it has been read to me. I have had the opportunity to ask questions about it and they have been answered to my satisfaction.

I consent volutarily to be a participant in this study.

Signature of Participant:

Printed Name of Participant:

Date (month/day/year):

*[If the participant is unable to sign, or conditions justify that the participant not sign to protect their identity, then a literate witness must sign in behalf of the participant. This person should be selected by the participant and have no connection to the research team.]*

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.

Signature of Witness:

Printed Name of Witness:

Date (month/day/year):

**Statement by the researcher/person obtaining consent**

*[This section is mandatory.]*

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 document has been provided to the participant.

Signature of Researcher /person taking the consent:

Print Name of Researcher/person taking the consent:

Date (month/day/year):

Endnotes [Do not include as part of your ICF]

1. In obtaining informed consent, researchers should inform prospective participants about:

   1. the purpose of the research, expected duration, and procedures;
   2. why and how they were selected for recruitment in the study;
   3. their right to decline to participate and to withdraw from the research after participation has begun, and how to withdraw consent if they decide;
   4. any foreseeable consequences of declining or withdrawing;
   5. potential risks, discomforts, or adverse effects and other reasonably foreseeable factors that may be expected to influence their willingness to participate;
   6. any prospective research benefits, direct and indirect;
   7. confidentiality protections and limits of confidentiality (if there are);
   8. any incentives or compensation for participation; and
   9. whom to contact for questions about the research and research participants’ rights

   The elements of informed consent may be altered or waived if all the following conditions are met:

   1. the research involves no more than minimal risk
   2. the waiver or alteration will not adversely affect the rights and welfare of the participants
   3. the research cannot practicably be carried out without the waiver or alteration
   4. when appropriate, the participants will obtain the additional pertinent information after participation

   Assent guidelines for prospective participants who are minors:

   0-7 years old: active consent from authorized/legal guardian required

   8-11 years old: provide active verbal assent (can refuse participation even if consent of guardian is obtained); active consent from authorized/legal guardian required

   12-15: provide active verbal assent and/or sign simplified assent form (can refuse participation even if consent of guardian is obtained); active consent from authorized/legal guardian required

   15-17: provide active verbal assent and/or sign assent form (can refuse participation even if consent of guardian is obtained) or co-sign informed consent form with authorized/legal guardian; active consent from authorized/legal guardian required

   [↑](#endnote-ref-1)