Guidance Note:

Informed Consent Form Template

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

Title of the Research Study:

Principal Investigator: (name and contact information)

Faculty Adviser *[required if PI is a student]*: (name and contact information)

[*Optional Introductory Statement:* *depending on the characteristics of the respondents, you may or may not begin with this Introduction. This may be appropriate for respondents who are unfamiliar with the need or rationale for a signed informed consent form.]*

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide not to participate there will be no penalty or negative consequence. Before you make a decision you will need to know the purpose of the study, 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 give you this document to read. [*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.]

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form as it has the contact information and answers to questions about the study. If you like, this form can be read to you.

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

The purpose of the study is to learn more about      .

* *Write a simple, accurate explanation of the purpose the study and the specific condition/s that are under study. 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 and justify why the participant is appropriate for recruitment to the study. Specify the requirements for participation to clearly illustrate why him/her, and not somebody else, is being asked to participate. If selection is random, then explain the process to the prospective participant.*

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

* *Provide a 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 identify any experimental procedures.*

**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.*

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

* *The document 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?**

Your participation could help us understand      . In the future, this may help other people to      .

* *If there are direct benefits to the participant, indicate those here. 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 or 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 in the research study,

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

*[If applicable; e.g. if there is an alternative to participation in a research study to fulfill some requirement, or if the study involves an experimental treatment -]*

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:

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

**How will confidentiality be maintained and my privacy protected?** **Who will have access to my data?**

* *Explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the subject. Explain how subjects will be de-identified; e.g. will code numbers be used? The content of this section will vary according to the research design. There may be cause for more or less protections depending on the nature of the research. The language should be altered when necessary.*
* *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, for research greater than minimal risk]* What happens if I am injured/experience distress/harm from being in 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*
* *Participant’s responsibilities (if any) relating to research-related harm/injuries*

*[Note: if there is sponsor/funder-specific injury language, add it here. For industry-sponsored research, the sponsor must pay for research-related injury unless otherwise negotiated with the institution.]*

**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 compensation (\*payments/stipend), if participants are being compensated for their time and travel.*
* *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 (632) 426-4001 local 4030 for any question, concern, or complaint about your rights as a research subject.

When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Signature of Participant:

Printed Name of Participant:

Date:

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: consent from authorized/legal guardian required

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

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

   15-17: sign assent form or co-sign informed consent form with authorized/legal guardian

   The requirement of documented informed consent may be waived in either of the following cases:

   The only record linking the participant to the research would be the informed consent document and the principal risk to the participants would be the potential harm resulting from breach of confidentiality; or

   The research presents no more than minimal risk and does not involve procedures for which written consent is normally required outside of the research context [↑](#endnote-ref-1)