Guidelines for Informed Consent Form

This informed consent form template may be adapted for specific studies. Its use is strongly recommended by the Yo San University Institutional Review Board (IRB). Refer to Chapter 2 of the IRB Handbook for additional information on the informed consent process. [Do not include this paragraph in your informed consent form.]

[Use age-appropriate language for children. Use consistent voice—either second-person (you) or third-person (participant(s) or subject(s)); avoid switching back and forth between 2d- and 3d-person.] (The OHRP recommends using 6th to 8th grade reading level for most adult subjects.)

Prospective Research Subject: Read this consent form carefully. Ask as many questions as you like before you decide whether you want to participate in this research study. You are free to ask questions at any time before, during, or after your participation in this research.

Project Title:
Principal Researcher:
Telephone:
E-mail:
Organization:  Yo San University
Location of Study:

Purpose of This Research Study
Include 3 to 5 sentences about the purpose of the research study written in non-technical or research language and at a reading level appropriate for the study population, beginning with: You are being asked to participate in a research study designed to….

Students should identify themselves as researchers and include in this section a statement that the research study will be conducted as part of their degree program [Indicate which degree] at Yo San University in Los Angeles, California.

Procedures
Describe procedures that will be used, beginning with:
You will be asked to…
• Identify and describe what participants will be asked to do. [Complete a survey or questionnaire, participate in an interview (face-to-face or telephone), combination, other]
• Define expected duration of subject’s participation. [Insert total hours subjects may expect to spend in the study; include time for follow-up interviews or reviews of transcripts]

Possible Risks
Describe known or possible risks.

Possible Benefits
Describe any benefits to the subject that may be reasonably expected. If the research will not be of direct benefit to the participant, explain possible benefits to others or to literature on topic.
Financial Considerations
Explain any financial compensation to subjects, or state:
You will not receive any financial compensation for your participation nor will you incur any costs as a result of your participation in this research.

Describe any costs to subjects, such as parking or meals, if any.

Treatment for Adverse Effects [Include ONLY if study involves more than minimal risk and requires full IRB review]
If the study involves greater than minimal risk, state:
If you are injured as a direct result of taking part in this research study, emergency care will be provided by [name] medical staff or by transporting you to your personal doctor or medical center. Neither the [researcher's name] nor Yo San University will provide you with long-term medical treatment or financial compensation except as may be provided through your employer's insurance programs or through whatever remedies are normally available by law.

Confidentiality
Describe the extent to which confidentiality of records identifying the subject will be maintained. For many studies, the following language may be appropriate:
Your identity in this study will be treated as confidential. Results of the study, including all collected data, may be published in my dissertation and in possible future journal articles and professional presentations, but your name or any identifiable references to you will not be included. However, any records or data obtained as a result of your participation in this study may be inspected by the persons conducting this study and/or Yo San University’s Institutional Review Board, provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. These records will be kept private in so far as permitted by law.

If contact with participants will be via e-mail, state:
Although e-mail is not totally secure, my computer has security software and no one else will have access to my computer and/or my e-mail account.

Describe steps that will be taken to protect confidentiality such as using number codes or pseudonyms for identifying data or subjects.

Explain that all study data will be retained for a minimum of three years as required by the IRB and then destroyed. [Verify the study records’ retention required for your professional association, such as the APA, and use that term instead of three years.]

Termination of Study
Informed consent forms should include the following statement or a similar statement in language appropriate to subjects:
You are free to choose whether to participate in this study. You may also choose to withdraw from the study or to decline to answer any questions at any time. You will not be penalized or lose any benefits to which you are otherwise entitled if you choose not to participate or choose to withdraw. You will be provided with any significant new findings developed during the course
of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study, please notify [name, telephone #] of your decision so that your participation can be terminated in an orderly fashion. Your participation in the study may be terminated by the investigator without your consent under the following circumstances: [Describe circumstances under which the researcher will terminate a subject’s participation such as failure to appear for an interview].

As applicable, include the following statement:
This study may need to be terminated without prior notice to, or consent of, participants in the event that…. [Describe circumstances such as loss of funding, illness, or other reason(s)]

Describe how data collected prior to a participant’s withdrawal from the study will be handled:
All data collected on, about, or by you will be destroyed and not used in the data analysis or writing of the findings if you choose to withdraw.

After the Study is Completed
If audio- or videotapes are used in the study, offer to give a copy of the audiotape, a transcript of the tape, or a copy of the videotape to each participant. Offer to provide a copy of the transcript of audiotapes to participants to review and make corrections or changes before it is analyzed. Offer to provide a summary of the results of your study to participants. [Make clear how you will provide the summary—mail, e-mail, post on Web site, etc.]

Resources
All informed consent forms should include the following statements:
Any questions you may have about this study will be answered by [Provide researcher’s and faculty advisor’s names, addresses, telephone #s, e-mail addresses].

Any questions you may have about your rights as a research subject will be answered by the IRB Coordinator, Yo San University, 310-577-3000, irb@yosan.edu

In case of a research-related emergency, call [Enter researcher and faculty advisor names, addresses, daytime telephone #s, evening, and overnight emergency telephone #s] and the IRB Coordinator at Yo San University at 1.310.577-3000. [Notify the IRB Coordinator within 48 hours of the event]

Subject and Researcher Authorization
Informed consent forms (to be signed by the subject or not) should include the following statement:
I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

For children, the consent form should include the following authorization statement:
I have read and understand this consent form, and I understand that I will receive a copy of this form. I voluntarily choose to participate in this research study.

The parent / guardian / legal representative consent form should include the following statement:
I have read and understand this consent form, and I voluntarily consent to my child’s
participation in this research study. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

[Depending on the study, additional signature line(s) may be needed for both parents, guardians, legal representatives, witness(es), and/or subject advocate(s).]

**Signatures**
Participant Name (printed): ________________________________
Participant Signature: ________________________________
Date: ________________________________

Principal Researcher’s Name (printed): ________________________________
Principal Researcher’s Signature: ________________________________
Date: ________________________________

Person obtaining consent, if other than principal investigator (printed):

Signature: ________________________________
Date: ________________________________
Abbreviated Written Informed Consent Form: [Not to be used with longer version informed consent form]

An abbreviated written informed consent form is a simple written statement that all elements of a comprehensive informed consent form have been provided to potential subjects in nonwritten form. The purpose is to document the granting of consent in projects where the researcher has made an oral presentation of informed consent elements to potential subjects. A witness not otherwise affiliated with the research should be present at every oral presentation. The witness signs and dates each form and the written script of the oral presentation. [Include a script to be read to participants with the abbreviated form]

If the abbreviated written informed consent form is used, an appropriate witness statement, such as the following, should be included above the witness signature and date lines in addition to signature lines for the participant and the researcher:

*My signature attests that I was present during the informed consent discussion of this research for the above named participant and that the information in the consent form and any other written information was accurately explained to, and apparently understood by the prospective participant, or his/her representative, and that the informed consent decision was made freely by the participant or the participant’s representative.*

Witness Name (printed): ________________________________________________

Witness Signature: ____________________________________________________

Date: __________________________________________________________________