GUIDELINES AND TEMPLATE FOR AN ADULT INFORMED CONSENT FORM

Please keep in mind that the typical standard is to write informed consent at no higher than an eighth grade reading level. It should be written in the second person (the first person can be considered coercive). Avoid scientific terms or jargon and keep it concise to increase readability. The elements below should be included, and this document can serve as a template for informed consent:

Consent Form

Title of this Research Study

List the title in this section as it appears on the IRB Approval Request Form.

Invitation

Inform the participant that this is a research study and invite them to participate:

> Example:
> You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

What is the reason for doing this research study?

This section should briefly state the purpose of the study. This information should be provided in simple language without scientific terms.

What will be done during this research study?

Briefly describe the procedures using the order in which they will occur and include how long the study will take. If data collection involves audio or videotaping, participants must be advised of this.

What are the possible risks of being in this research study?

If there are no known risks:

> Example:
> There are no known risks to you from being in this research study.

If there is a potential for risk:

> Example:
> The following risk(s) may be involved in participation in this research *(describe the risks, starting with the most likely to occur)*.

What are the possible benefits to you?

If there is some direct benefit for participation, describe it here, including any incentives, compensation, or course credit.

If there is no reasonable direct benefit to participation:

> Example:
> You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
Describe any possible benefits to society (such as advancement of knowledge in the area being studied).

What will participation in this research study cost you?

State any financial obligations that will result from participation.

If there are no financial obligations:

> Example:
> There is no cost to you to be in this research study.

How will information about you be protected?

If data is collected such that it is anonymous (only if names or other identifying information has <u>not</u> been collected during the study):

> Example:
> All data collected in this study is anonymous. This means that no names or identifying information will be recorded during the study. There is no way to connect your identify with any of your responses.

If data is collected such that it is not anonymous:

> Example:
> Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.
> *(Explain procedures for assuring data privacy and confidentiality, such as use of numbered identifiers, locked files, restricted access, destruction of the data after a specific time period, how long audio or video tapes will be kept and how they will be disposed of, etc.)*
> The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

What will happen if you decide not to be in this study or if you decide to stop participation during the study?

Include the following language in all informed consent documents:

> Participation in this study is completely voluntary. If you choose to participate, you may stop participation at any time without penalty and without losing any benefits that are a part of this study.

What should you do if you have questions or concerns about this research study?

For studies that involve no or minimal risk:

> If you have any questions or concerns during or after this study, you may contact:
> *(Give the Principal Investigator's name and contact information. If the P.I. is a student, the faculty advisor's name and contact information must also be provided.)*

For studies that involve greater than minimal risk, you must include an explanation as to whether any compensation or treatments are available, and if so, what they consist of and where more information can be obtained.

> Example (if there will be no compensation for services or treatment):
> If you have a problem or experience harm as a direct result of being in this study, you should immediately contact:
> *(Give the Principal Investigator's name and contact information. <u>If the P.I. is a student, the faculty advisor's name and contact information should be provided instead</u>.)*
> If necessary, you can be provided with referral information for appropriate services or treatment. However, you will not receive any compensation for services or treatment.

Who can you contact if you have questions about your rights as a participant?

Use the following language::

You can speak to the researcher or you can contact the Our Lady of the Lake Institutional Review Board at 434-6711, ext. 2489 or grahl@lake.ollusa.edu.

Documentation of Informed Consent

Use the following language:

Your signature on this form indicates that you understand the information provided to you about participation in this research study and that you freely agree to participate. You will be given a signed copy of this consent form to keep, and the researcher will also keep a signed copy.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Researcher's Printed Name

_____ _____
Researcher's Signature Date

IRB Approval Notice

Use the following language:

This research study has been reviewed and approved by the OLLU Institutional Review Board. For questions about participant's rights during or after the study, contact the Chair of the IRB at 210-434-6711, ext. 2489 or grahl@lake.ollusa.edu.