**University of Notre Dame**

**Guidelines for Informed Consent**

Informed consent is not a single event or just a form to be signed; it is an **educational process** that takes place between the investigator and the prospective subject. The basic elements of the consent **process** include:

* full disclosure of the nature of the research and the participant’s involvement,
* adequate comprehension on the part of the potential participant, and
* the participant’s voluntary choice to participate.

It is the investigator’s responsibility to document that the informed consent process has taken place, and an informed consent form is the standard for documenting the process for research projects involving human participants.

The consent form must be written in language that is easy for a potential participant to understand and assures that individual’s comprehension. Therefore, avoiding technical terms and complex sentences, even for the educated layperson, is very important.

When the participant population is not homogeneous, different consent documents may be required for different groups of people. If the research population will include participants under 18 years of age, then the IRB will expect investigators to use an assent form and a parental permission form instead. Similarly, research with cognitively or decisionally impaired individuals will require documented consent from another party—namely that person’s legally authorized representative.

The IRB also recognizes that there are instances when documenting written informed consent is not appropriate to a research project. A request should be made to the IRB for a waiver of informed consent with justification. Regardless of the method of documenting informed consent, however, the process of obtaining informed consent should always contain the same required components.

**Helpful guidelines for constructing an effective consent form:**

* A clear, concise explanation of the purposes of the research, including the name of the study.
* An explanation of what will be happening to the participant during the study, and an indication of the participant’s time commitment for each component.
* Description of the risks, side effects or discomforts of the study procedures are required. For social science and behavioral research, though risks usually do not extend beyond the possible loss of confidentiality and/or mild emotional distress, these should also be made clear to prospective participants.

If it appears that there are no real risks to participation, state, “We do not anticipate any risks to you participating other than those encountered in daily life.”
* Description of any potential benefits from participating.

These should be limited to direct benefits: information about better coping skills, awareness of available support or resources, or any other personal gain other than financial rewards. Thus, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant are NOT recognized as benefits. Also, gifts, extra credit for courses, and reimbursement for expenses are considered compensation.) If there are no direct benefits, simply indicate that there are none.
* A statement that the participant’s involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions that may make him/her feel uncomfortable, with no penalty to him/her, and no effect on the compensation earned before withdrawing, or their academic standing, record, or relationship with the University of Notre Dame.
* A statement that the participant is allowed to ask questions concerning the study, both before agreeing to be involved and during the course of the study.
* A description of how the participant’s confidentiality and information (data) will be protected.
* A description of what will be done with the data once the study is completed.
* An indication that recording devices, audio or visual, are being used (when applicable).

Be sure to describe what will be done with the any video or audio tapes upon the completion of the study (destroyed, erased, archived, etc.), and when (after transcription, 1 year, 3 years, etc.).

Also, provide a separate signature line on the consent form for the participant to agree to be video/audio taped or photographed, if the recording is optional for participation. For example:

Please sign below if you are willing to have this interview recorded on tape (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.

I am willing to have this interview recorded on tape:

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* An indication that the participant shall receive a copy of the signed and dated consent form.
* Conclude with a statement such as “You are making a decision whether or not to participate. Your signature indicates that you have read and understand the information presented above, that you have decided to participate, and that you consent to the procedures or treatment described above". Include an 18 year or older statement, if applicable.
* Include a statement, that participation in the research will not affect their relationship with the University of Notre Dame.
* Provide a space for signatures and the date of signature.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* The name(s) of the investigator(s) and contact information.
* An indication that the participant may contact the Institutional Review Board for (IRB) and Notre Dame Research Compliance, with any concerns or complaints. Include our email address (compliance@nd.edu), phone (574-631-1461).