

State University of New York at Delhi  
Institutional Review Board  
*Informed Consent Guidelines*  
*This document was adopted with permission from the University at Albany*

**What is Informed Consent?**

Informed consent is the term given to the communication process that allows individuals to make an informed choice about participation in a research study. This process is reflected in an informed consent document that contains specific, required information about the research study. The informed consent document serves as the formal authorization by an individual of his or her agreement to participate in the proposed research.

The human subjects in your project must participate willingly, having been adequately informed about the research. If the human subjects in your project are part of a vulnerable population (i.e. prisoners, cognitively impaired individuals, or minors), special protections are required. Contact the IRB Office for more information.

**Consent may be obtained by either of the following methods:**

1. A **written consent** document that includes the required elements of informed consent as outlined below. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
2. A **short form written consent** document, stating that the required elements of informed consent as outlined below have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. In addition, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

## **Guidelines for Preparing Written Consent**

**Please note: The following is an informed consent template, which contains all required elements of informed consent. Except where noted, written informed consent must contain all sections described in the template.**

The consent form should read easily (~ 8th grade level). Please note if it is intended to provide informed consent in a language other than English, please include a copy of the consent document or script in the specific language as well in English. Suggested text is included below for some required consent elements, however, the text should be revised to adequately describe your specific research project.

### **REQUIRED CONSENT ELEMENTS FOR ALL RESEARCH STUDIES:**

**1. Title of the research project**

Provide title.

**2. Names of the researchers**

Provide names, university affiliation, and degrees.

**3. Description of the research**

You must clearly identify your project at the beginning as research and discuss in lay terms the purpose.

**4. Description of human subject involvement**

Discuss in lay terms what will be required of the subject during his/her participation. Include a description of the research procedures and identification of any procedures that are experimental. You must provide a reasonable estimate of the duration of each session, number of sessions, and total duration of participation across the project.

**5. Risks & discomforts of participation**

Provide a detailed description, in lay terms, of the risks and discomforts of participating in the study. If applicable, provide information about other appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject. For studies that involve sensitive topics such as AIDS/HIV status, sexual behavior, illegal conduct, drug use or abuse or other potentially damaging information the risk of exposure should be identified and discussed.

**Suggested text if you do not anticipate any risks other than minimal discomfort from answering questions or surveys:**

*"We do not anticipate any risk in your participation other than you may become uncomfortable answering some of the questions."*

**6. Measures to be taken to minimize risks and discomforts:**

Please describe in lay terms any measures taken to minimize risk and discomfort of the subject during his/her participation in the research study.

**7. Expected benefits to subjects or to others:**

Provide information on the probability of direct benefits, if any. You must indicate clearly if no benefit is likely to the participant. Participant payment is not considered a benefit and should not be discussed in this section.

**Suggested text if no direct benefit is anticipated:**

*"Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained from this research."*

**8. Confidentiality of records/data**

Include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. Describe the steps you are taking to preserve confidentiality and specify if participants will be identified in any reports on the research. In addition, include a description of the eventual disposal of identifiable information, tapes, questionnaires, etc.

The researcher should specify if the research is anonymous. Anonymous means that there is no personal identifying information recorded on any research documentation, including consent forms and questionnaires. This includes any code that can reasonably link personal information to a specific participant. **In addition, the researcher must add a description of any legal duty to report abuse that might supersede these confidentiality promises. The researcher should specify in this section when a "Certificate of Confidentiality" has been obtained and briefly explain the protections that it offers the participants.**

**Required Text:**

*"All information obtained in this study is strictly confidential unless disclosure is required by law. In addition, the Institutional Review Board, the sponsor of the study (e.g. NIH, FDA, etc.) and University or government officials responsible for monitoring this study may inspect these records."*

**Required text for Internet Research:**

*"This project has been approved by the SUNY Delhi Institutional Review Board. Approval of this project only signifies that the procedures adequately protect the rights and welfare of the participants. Please note that absolute confidentiality cannot be guaranteed due to the limited protections of Internet access."*

**9. Research Involving More than Minimal Risk (include only if applicable):**

When more than minimal risk is anticipated you must include an explanation as to whether any compensation and/or treatments are available if injury occurs and if so, what they consist of or where further information may be obtained. This may include treatments such as referrals for counseling services, intervention services or hotline references.

**10. Audio/Video Recording of subjects (include only if applicable):**

Include a statement that audio and/or video-recording devices will be used, if applicable. You must also state what will be done with the recordings/pictures upon completion of the study (destroyed, erased, archived, kept for future studies, etc.). Caution interview participants before the interview begins to avoid mentioning the names of or identifying information about third parties. If identifying information is mentioned inadvertently, the taping should be stopped immediately, the identifying information erased, and the caution repeated before taping resumes. Please provide a separate line on the consent form for the subjects to agree to each audio/video session to be photographed or recorded.

**Required Text for Consent Forms:**

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

**11. Payments to subject for participation in the study (include only if applicable):**

Provide information on financial payments or reimbursement of expenses. Indicate on the consent document if full payment is given if the subject withdraws from participation in the research study.

**12. Contact Information**

The name, academic title, and telephone number of the investigator should appear on the consent form. If a researcher is a university student, the name and telephone number of the faculty advisor must also be provided. A copy of the consent MUST be provided to the participant for reference to the contact information.

**Required text:** *"One copy of this document will be kept together with the research records of this study. Also, you will be given a copy to keep."*

**13. IRB Contact Information and Human Rights Statement**

Include the following information in a separate paragraph after the principal investigator contact information.

**Required text:** *"If you have any questions concerning your rights as a research participant that have not been answered by the investigator or if you wish to report any concerns about the study, you may contact the IRB chair, Nancy Winters, at [winternn@delhi.edu](mailto:winternn@delhi.edu) or (607) 746.4813."*

**14. Voluntary nature of participation**

Include a description that participation is voluntary and describe what participants are required to do if they wish to withdraw or not participate.

**Required text:** *"Your participation in this project is voluntary. Even after you agree to participate in the research or sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise have been entitled."*

**Example Text to Inform Participants of how to withdraw or not participate:**

*"You may choose not to answer any questions and may refuse to complete any portions of the research you do not wish to for any reason."*

*"If you do not wish to participate, hand in a blank questionnaire."*

**15. Consent of the subject**

For those consent forms to be signed by the participants, include a line for the participants name, signature and date.

**Required Text for Consent Forms:** *"I have read, or been informed of, the information about this study. I attest to being 18 years of age or older. I hereby consent to participate in the study."*

**Internet research:** As it may be difficult to get a signed consent form over the Internet, where signature is required, investigators must indicate to the IRB how they plan to obtain consent from the participants.

**ADDITIONAL ELEMENTS OF CONSENT TO BE INCLUDED WHEN APPROPRIATE**

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
3. Any additional costs to the subject that may result from participation in the research
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
6. The approximate number of subjects involved in the study

