

**State University of New York at Canton  
Institutional Review Board**

**Sample Informed Consent Document**

The following sample informed consent document includes instructions to the person writing the document, followed by sample language that may be used in the actual document. *{Instructions to the person preparing the form are always written in script and enclosed in brackets, like this.}* Sample language that may be used in the actual document is always written in standard typeface, like this.

The consent form must be printed on the principal investigator's University department letterhead. If the investigator is a student, the Faculty Advisor's department letterhead should be used. It is recommended that the document include section headings in bold type. For on-line consents, letterhead is not required.

**Required Elements for Consent Document**

**Title of Study:** *{The title on the consent form must match the title on the application except in cases where revealing the true purpose of the study would compromise the results. In those cases, the rationale for the variance must be clearly explained in the IRB application.}*

**Introduction:** *{Informs participant that this is a research project and identifies the investigators in charge of conducting the research and shall include their contact information.}*

You are invited to participate in a research project being conducted by {name}, a {faculty member, student, etc.} in the Department of {dept. name}, at SUNY Canton.

**Purpose:** *{Provide a statement of the purpose of the study.}*

**Procedures:** *{Describe what the participants will be asked to do for the study. Include all procedures, including number, frequency and duration. Differentiate between procedures that are for research and those that are standard, i.e., teaching methods, assignments, etc. Describe any other data to be collected such as personal records, written material, teacher comments. Specify any post-study follow-up.}*

**Exclusion:** *{Only include if applicable. Clearly list criteria that would prevent an individual from participating or make someone ineligible to participate. For instance, that the sample will only include women, certain majors, children, etc.}*

**Risks and Discomforts:** *{For each procedure/activity that is part of the research, describe the immediate and long range discomforts/risks (physical, psychological, social, legal, and economic) and their consequences. Explain safeguards or precautions that will be taken to reduce the occurrence of adverse effects. Explain what treatment or assistance will be available if an adverse effect occurs. For example, in studies in which subjects are asked to discuss emotionally sensitive topics, the IRB requests that either an individual be present who can provide counseling assistance, or referral information be provided to subjects. If there are no known risks, include a statement to that effect.}*

**Benefits:** *{Only include one of the following choices. This statement should describe reasonable benefits to the participants as a result of participation in the research. If you are evaluating a program*

*or intervention, do not describe the benefits of participation that would have occurred anyway. If the individual participant will receive NO DIRECT BENEFIT, this must be explicitly stated. Payment for participation is NOT considered a benefit of the research.}*

The benefits to you for participating in this study may be \_\_\_\_\_. However, you may receive no benefit from participating in this study.

OR

You will receive no direct benefit from your participation in this study, but your participation may help us better understand \_\_\_\_\_.

**Alternatives:** *{Provide a statement describing appropriate alternative procedures or courses of action, if any, which might be substitutes for participating in the research. If the only alternative is simply to not participate in the study, you do not need to include this section.}*

**Payments to Participants:** *{Include if financial reimbursements or recruitment incentives are to be given to participants, including extra credit in a class. Specify dollar amount and form of payment, i.e. cash, gift certificate, item, amount of extra credit. Explain if and how the payment or credit will be prorated if the participant withdraws. Also indicate when payment will be received, eg, at end of session, one week later, after each intervention, etc.}*

**Right to refuse or withdraw:** *{Provide a statement explaining that participation is voluntary and that refusal to participate or withdraw from the study at any time will involve no penalty or loss of benefits to which they are otherwise entitled. For most survey research, simply stating that participation is voluntary is sufficient. For projects involving students, this should include a statement that failure to participate will in no way affect their grade. For projects involving prisoners, include a statement that participation, or non-participation, will in no way influence their case.}*

**Anonymous and Confidential Data Collection:** *{Indicate whether data collection will be (a) anonymous or (b) confidential.}*

*The term anonymous is used when the investigator collects no identifying information about subjects, and thus, an individual data sheet cannot be connected with a specific subject (by the investigator or anyone else) once the data is collected. Tape-recordings or videotapes, by their very nature, cannot be considered anonymous.*

*Confidential, in contrast, refers to data which is collected in a way that it can be linked to an individual subject. For example, assigning subjects numbers, but then keeping a "key" that links the numbers to identifying information, is a procedure one might use in order to preserve confidentiality. Not identifying subjects by name or any other identifying information in reports and presentations also is a measure taken to preserve confidentiality. If individual subject data are used as illustrative examples, you must assure subjects that this will be done in a way that does not allow identification of the participant. Care must be taken to not only protect subjects' names, but also other details about them or their experiences that would allow them to be identified. Occasionally, it is important to the research to identify an individual who participated, or subjects themselves may wish to have their contribution attributed to them. This is most likely to occur in some qualitative studies, and is acceptable as long as specific written permission is granted by the subject.*

*The following sample statements are provided – modify as needed:*

**For Anonymous data** - No identifying information will be included in the data you provide. Your signed consent form will be kept separate from your data, and nobody will be able to link your responses to you.

OR – No identifying information will be collected, and your anonymity is further protected by not asking you to sign and return the informed consent form.

**For Confidential data** - Any identifying information collected will be kept in a secure location and only the researchers will have access to the data. Participants will not be individually identified in any publication or presentation of the research results. Only aggregate data will be used. Your signed consent form will be kept separate from your data, and nobody will be able to link your responses to you.

**Confidentiality of records:** *{This section should describe the extent to which confidentiality of records will be maintained, i.e., coding of data, any limitations to confidentiality, disposition of data at the conclusion of the study. Address all forms of data to be collected – written, audio, video. Confidentiality procedures explained here must be consistent with those stated in the IRB application.}*

**Who to contact with questions:** *{Provide an explanation of whom to contact for answers to pertinent questions about the research. If the investigator is a student, also include the advisor's name and number. Use of home numbers is not advised. Also include the IRB approval and contact information for questions regarding the rights of research participants.}*

If you have any questions about this study, you may call {investigator} at {campus number} or {advisor's name, if investigator is a student} at {phone number}. This project has been reviewed and approved by SUNY Canton Institutional Review Board. If you have any questions about your rights as a research participant, you may call the IRB at (315) 386-7620.

**Acceptance & signature:** *{Provide a statement in which the participant affirms his/her understanding and willingness to be involved in the study. This will vary depending on whether or not the IRB has approved a waiver of signed consent.}*

*The researcher may request, and the IRB may grant, a waiver of signed consent if one of the following conditions is true and is stated in the application:*

- 1. The only record linking the subject to the research would be the consent form, and the principal risk is potential harm from breach of confidentiality.*
- 2. The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.*

*Use the following statement and signature line when a signed consent will be returned to the investigator:*

I have read the information provided above and all of my questions have been answered. I voluntarily agree to participate in this study. I will receive a copy of this consent form for my information.

\_\_\_\_\_  
**Participant Signature**

\_\_\_\_\_  
**Date**

*Use the following statement when a waiver of signed consent has been approved:*

I have read the information provided above and all of my questions have been answered. I voluntarily agree to participate in this study. My completion and return of this [survey, instrument, questionnaire] will serve as my consent. I have been given a copy of this consent form for future reference.

*Use the following statement for on-line consents:*

I have read the information provided and all of my questions have been answered. I voluntarily agree to participate in this study. My completion and return of this [survey, instrument, questionnaire] will serve as my consent. I may print a copy of this consent statement for future reference.

*[The signed consent form should be placed in the investigator's study file. Identifying data should be kept in a separate file and linked with a code through a link list. A copy of the consent form must be given to each participant for their information (it may be unsigned.)]*

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**Research Involving Minors (under 18)** – see the Guidelines for Parental Consent and Child Assent for Children under 18.

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**Additional Clauses for Special Circumstances – use only if applicable to your study**

**Abuse:** *{Include the following statement if the nature of the research study makes it likely for participants to reveal reportable information.}*

The investigator has ethical and legal obligations to report suspected child abuse or neglect and to prevent you from carrying out any threats to do serious harm to yourself or others. If keeping information obtained in this study private would immediately put you or someone else in danger, the investigators would release that information to protect you or another person.

**Audio and Video Taping:** *{If you wish to tape subjects, please include a request to tape explaining the type (e.g. videotaping in the classroom, audio taping, single or group interviews, etc.), and the disposition of the tape(s) when the study is complete. If the tapes will be used for any other purpose, clearly state the who, where, and why of the other use; if there is no other use of the tape, simply stating that it will be erased when the study is complete is sufficient.}*

**Certificate of Confidentiality:** *{Use the following paragraphs ONLY if a Certificate of Confidentiality is being requested through the National Institutes of Health. This Certificate places legal burdens on an investigator and is not issued lightly. Most studies do not need a Certificate of Confidentiality. Please contact the IRB at 315-386-7620 if you are unsure of the need for this.}*

To further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other

proceedings\*. Disclosure may be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

*\*The researchers should include language such as the following if they intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.*

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. *{The researchers should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.}*