**PROTOCOL TEMPLATE**

*For continuations, please use Request for Continuation template.*

**Researcher:** Click here to enter text.

 **Campus Email Address:** Click here to enter text.

 **Campus Telephone No.:** Click here to enter text.

**Faculty Sponsor (for student projects):** Click here to enter text.

**Campus Email Address:** Click here to enter text.

 **Campus Telephone No.:** Click here to enter text.

**Project Title:** Click here to enter text.

**Required Information**

**A. PURPOSE, RESEARCH VARIABLES, AND POPULATION**

Purpose of the study – State concisely and realistically what the study is intended to accomplish.

Click here to enter text.

Background – Briefly state the background of the study and identify the main question the current study is intended to address. *For most projects, this should be at least a few paragraphs in length and should reference prior research.*

Click here to enter text.

Characteristics of the Subject Population – The following information should be provided:

1. Age Range – What is the age range and why was it chosen?

Click here to enter text.

1. Sex – What is the sex of the subjects? If there is a restriction, provide the rationale.

Click here to enter text.

c. Number – What is the estimated number of subjects?

 Click here to enter text.

d. Inclusion Criteria – What are the specific inclusion criteria?

 Click here to enter text.

e. Exclusion Criteria – What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.

 Click here to enter text.

f. Vulnerable Subjects – If vulnerable subjects will be included (children, prisoners, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons), provide justification of the need to use these subjects in research.

 Click here to enter text.

 **B. METHODS AND PROCEDURES**

Methods of Subject Selection – Describe the study’s method(s) of identification and recruitment of prospective subjects. Submit a copy of any planned advertisements with your submission.

Click here to enter text.

Study Site – State the location(s) where the study will be conducted. The letter of approval to conduct the study from all non-SUNY Canton sites must be included with your submission.

Click here to enter text.

Methods and Procedures Applied to Human Subjects – Describe in detail the study design and all procedures (sequentially) to be applied to subjects. How long will the study take each participant? How many sessions are required? What will participants be required to do?

Copies of any instruments to be used, such as surveys, rating scales, or questionnaires, must be included in your submission.

 *It is the responsibility of the Institutional Review Board to weigh risks and benefits to participants. The scientific merit of each project is of interest only as far as it affects the potential benefits of a study. Accordingly, the IRB may make comments and/or suggestions about scientific methodology to improve the quality of research designs.*

Click here to enter text.

 **C. RISKS/BENEFITS**

Potential Risks – Identify the potential risks of the study. Specify the types and levels of risk. *Please note that no study is considered “no risk.” Minimal risk is defined as risk not greater than that encountered in everyday life.*

Click here to enter text.

Protection Against Risks – For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

Click here to enter text.

Potential Benefits – Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

Click here to enter text.

Compensation for Participation – Describe any monetary or other forms of compensation which will be provided to subjects and any conditions which must be fulfilled to receive compensation.

Click here to enter text.

Alternatives to Participation – Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

Click here to enter text.

Information Withheld – Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

Click here to enter text.

Deception – Identify the nature of any deception of subjects to be employed, and provide justification for this deception.

Click here to enter text.

Debriefing – Describe the procedure for post-study debriefing of subjects.

Click here to enter text.

 **D. CONFIDENTIALITY**

Describe explicitly how your research records will be stored and how this information will be protected and kept confidential. If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations.

 Click here to enter text.

**E. CONSENT PROCEDURE**

 How will consent be assured? Studies that are exempt do not always require written informed consent.

However, aside from research that only involves observation in public areas, there must be a consent process.

See Informed Consent template on the SUNY Canton IRB website.

Please note that an informed consent form or a consent statement addresses five critical points: 1) subject participation in the study is voluntary (provide a description of the procedure to be used if choosing not to participate); 2) a statement of the subject’s right to withdraw at any time and a clear description of the procedures for withdrawal from the study without penalty; 3) subjects are informed of the level of risk (from ‘minimal risk’ through the level appropriate to the study) and the means of protecting the subjects from known risks or minimizing the risk; 4) confidentiality is ensured; and 5) the means by which confidentiality is to be ensured is elucidated. While it is not mandatory that an Informed Consent Form is identical to the example, the five points listed above are critical elements of any form an investigator may develop. It is important to include sufficient specific information regarding the purpose and nature of your study to ensure that subjects are fully informed. A copy of the Informed Consent Form should be given to each subject who participates in the study.

Mailed surveys ordinarily receive expedited reviews and do not need consent forms except when one of the following conditions prevail: 1) the person’s name or other identifier is known to the researcher; or 2) the content of the survey puts the respondent at risk for emotional, physical, or other types of distress. If an informed consent form is not required, the researcher should use a cover letter to potential subjects which addresses all the elements of informed consent previously described. Please include a copy of this cover letter with your protocol.

 Click here to enter text.