

Request for Human Subjects Review

Complete both Part I and Part II of this application.

Return to Human Subjects Review Committee, SUNY Fredonia, 170 Reed Library,

Phone: 716 673-3569; sponsored.programs@fredonia.edu.

Part I

Project Name: _____

Principal Investigator #1: _____

Check one of the following: Faculty/Staff Principal Investigator

Student Principal Investigator

Signature of Principal Investigator #1 _____

Department: _____ Phone Number: _____

Campus Address: _____

Email Address: _____

Principal Investigator #2: _____

Check one of the following: Faculty/Staff Principal Investigator

Student Principal Investigator

Signature of Principal Investigator #2 _____

Department: _____ Phone Number: _____

Campus Address: _____

Email Address: _____

Additional Principal Investigators' information should be in the same format on an attached sheet.

STUDENT PRINCIPAL INVESTIGATORS MUST LIST THE SUPERVISING FACULTY MEMBER AND HAVE THE FACULTY SPONSOR SIGN THE FACULTY VERIFICATION THAT APPEARS BELOW.

Faculty Sponsor: _____

Faculty Verification: I have read this student's Application for Human Subjects (Part I and Part II). I accept responsibility for the manner in which this study will be carried out. I am convinced that benefits from this research outweigh any risks.

Signature of Faculty Sponsor

Date

Number of Subjects: _____

Type of Subjects: Male Female

Check all that apply: Adults, note the age range: _____

Special subjects (Protected classes)

Pregnant women Children (<18 years of age)

Individuals with disabilities Prisoners

Other vulnerable group(s) _____

Type of Procedures:

Check all that apply

- Review of records
- Observation
- Videotaping
- Threats/Embarrassment
- Standardized Tests
- Other (specify) _____
- Interview
- Audio taping
- Photographs
- Survey (mail-in, phone, in-person, in-class, online)
- Recording of identifiable personal data
- Hypnosis
- Deception
- Self-disclosure

Where will research take place? Off campus: Indicate place _____
 On campus: Indicate place _____

Time and Length: Date study will begin _____ Date study will end _____

Will subjects be compensated? No Yes
 If yes, specify nature and/or amount _____

Under what terms will subjects be compensated: _____

Who will obtain consent?

I have read the SUNY Fredonia Campus Policy on the Use of Human Subjects:

<http://home.fredonia.edu/sponsoredprograms/propose>

I have completed the CITI On-Line Human Subjects Protection Training. A Certificate (or copy) is to be attached and included with your application:

Attached

NOTE: For students, the supervising faculty member must have also completed the training.

Committee Use Only

Type of Review: Exempt Expedited Full Committee Emergency

Approval Date _____ Closure Date: _____

Memorandum received: _____

Starting Research: Yes No

Ended Research: Yes No

Application for the Use of Human Subjects - Part II

Please address each numbered item in the order given. Incomplete applications will be returned to the principal investigator. If there are sections that are not applicable to your research, please explain why. Use the following as your guide:

1. Name the principal investigator. Describe his/her qualifications and any relevant experiences; **attach a copy of the vitae of the principal investigator and faculty sponsor, if appropriate**. If a student has been identified as the principal investigator, the role of the faculty sponsor(s) in guaranteeing compliance with the procedures outlined in this application as well as compliance with the regulations governing the use of human subjects must be clearly stated.

Faculty sponsors are required to meet with student researchers to review human subjects protection and to monitor data collection.

2. Clearly explain the procedures involved to carry out your study *in detail*. What is the overall goal of your study and what are your specific objectives? What will you do? What will the subjects do? A list of the steps in your study is often helpful. It is important that you clearly and succinctly describe your research protocol in enough detail that an uninformed reader can understand what is involved in your research project.
3. Describe the individuals who will participate in your study, noting their age (or age ranges), gender, ethnic background, and health status (if known). Mention other characteristics that make your subjects identifiable (for example, “elderly males **living in supervised living arrangements in rural Chautauqua County**). There are protected classes of subjects (i.e., pregnant women, children under the age of 18 years, individuals with disabilities, prisoners, and any individual viewed as vulnerable). If your subject pool includes members of these protected classes or has the potential for inclusion of these protected classes, a full Human Subjects Review Committee review will be necessary and the more complete your Request for Review, the more likely a timely approval will be issued.
4. Identify the data you intend to collect and how you will collect those data. Mention all instruments you will use and **attach a copy of these instruments to your application**. Please note that if you are using a piece of equipment, you only need to describe that equipment. Describe how you will use the information you collect; to further research on your topic, to further research, to provide some form of treatment, to improve student performance, etc. Describe how your data will be safely stored in a protected environment: data/videotapes/audiotapes you collect during and what you will do with them upon the completion of the study.
5. Describe how you will recruit subjects for your study and how you will handle obtaining their informed consent for participation. Informed consent is one of the most important components of conducting research that involves living human subjects. State who will obtain consent and what information on your study will be provided to potential subjects. Federal regulations mandate that if a research study involves subjects under 18 years of age, consent must be obtained from the parent or legal guardian **AND** the minor child. You must have two separate forms when minor children are involved in your research: a parent consent form and a child assent form. Here at SUNY Fredonia, a child’s assent form must be included in research protocol involving children ages 5 to 17 years. The language used in a minor child assent form must be appropriate to the age of the child. **You must attach a copy of all consent forms to your application.**

To ensure that your consent forms meet federal standards, please include

- a. A statement that this is research
- b. The purpose of your study
- c. A description of your procedures
- d. How long subjects will be involved in your study
- e. Both the potential benefits and the risks and/or discomforts of participants
- f. Any alternatives to the treatment you provide, if appropriate
- g. How confidentiality of subjects and their data will be maintained
- h. A statement that participation is voluntary and that the subjects can withdraw at any time without penalty; and
- i. The names and phone numbers of contact people for your study.

6. This component contains four parts:
 - a. Identify any potential risks: physical, psychological, social, legal, or another type of risk. Describe the likelihood of these risks occurring and their seriousness. Describe alternative treatments that might be advantageous to the subjects.
 - b. Where appropriate, state how you will ensure that your subjects receive necessary medical or professional intervention if they have adverse effects to your treatment/research protocol.
 - c. Tell how you will maintain the safety of your subjects during your study.
 - d. If there are risks in your study, tell how the risks are balanced by the benefits to be gained by the subjects from their participation in your study. Also, mention the relationship of the risks to the knowledge that will be gained from your study.
7. If your study deals with a sensitive issue and/or the data you collect deals with criminal acts, sexual conduct and behavior, drug and alcohol use, sensitivity and awareness to potential risks, and/or liabilities to your subjects, you will need to clearly state the precautions taken to minimize risks or liabilities.
8. Mention how you will prevent any risk to violating the confidentiality of the subjects involved in your study.

Questions about your research project or how this application should be completed, contact any of the following individuals:

<p>Judy Horowitz, Human Subjects Administrator and Associate Provost, Graduate Studies, Sponsored Programs and Faculty Development Phone: 673-3335; judith.horowitz@fredonia.edu</p>	<p>Jack Croxton, Member, Human Subjects Committee, Chair Psychology Department, Phone: 673-3129; jack.croxton@fredonia.edu</p>
<p>Brian Masciadrelli, Chair, Human Subjects Committee, Professor, Social Work, Phone: 673-3205; brian.masciadrelli@fredonia.edu</p>	<p>Bridget Russell, Member, Human Subjects Committee, Associate Professor, Communication Disorders and Sciences, Phone: 673-4616; bridget.russell@fredonia.edu</p>
<p>Carrie Fitzgerald, Member, Human Subjects Committee, Associate Professor, Language, Learning, and Leadership, Phone: 673-4652, carrie.fitzgerald@fredonia.edu</p>	<p>Cynthia Wickwire Lundquist, Community Member, Human Subjects Committee, Pastor, First Presbyterian Church of Fredonia, Phone:679-1501; wickwire@fredonia.edu</p>
<p>Tracy Stenger, Member Human Subjects Committee, Executive Director of Student Wellness and Support, Phone: 673-3271; tracy.stenger@fredonia.edu</p>	<p>Paul Benson, Secretary, Human Subjects Committee, Grant Development Specialist, Phone 673-3569; paul.benson@fredonia.edu</p>