

## **Campus Policy on the Use of Human Subjects: Procedures and Practices for Research Using Human Subjects**

### **Critical Links and Documents**

- [Code of Federal Regulations](#)
- [CITI Course in the Protection of Human Subjects](#)
- [Request for Human Subjects Review Application: \(PDF\)](#)
- [Instructor's Approval and Blanket Exemption of Class Research](#)
- [FAQs for the Office of Sponsored Programs](#)
- [Tips for Students Preparing a Human Subjects Review Application](#)

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### **Members of the Committee**

Campus Human Subjects Administrator

Community Member

Counseling Center Director

Psychology Department Chair

Sociocultural & Justice Sciences Chair

Tenured Faculty, At Large\*

Tenured Faculty, At Large\*

\*Representatives from departments that frequently submit Human Subjects proposals.

The campus policy outlined in this document is designed to both facilitate the development and processing of proposals from members of the faculty, staff, and student body and to ensure that campus research conforms to the letter and the spirit of the Federal regulations governing the use of human subjects. This policy is in alignment with the [Code of Federal Regulations](#). It should be noted that on the Fredonia campus, the Institutional Review Board (IRB) is known as the Human Subjects Review Committee (HSRC).

The sections below are applicable to all research involving human subjects whether conducted by faculty, staff or students:

- A. [Human Subjects](#)
- B. [When to Submit an Application to the Human Subjects Review Committee](#)
- C. [The HSRC Review Process](#)
- D. [How to Prepare an Application](#)
- E. [Student Research and Faculty/Staff Sponsor Responsibilities](#)
- F. [Classroom Research](#)
- G. [Blanket Exemption of Class Research](#)
- H. [Informed Consent](#)

## I. Additional Policies

### A. **Human Subjects**

Research, experimentation, teaching, and other activities involving the use of human subjects conducted under the aegis of the State University of New York at Fredonia are under the jurisdiction of the campus Human Subjects Review Committee (HSRC). **Consequently, all such activities are subject to review and approval.** In deciding whether to approve projects, the committee will consider:

1. The rights and welfare of the individuals involved,
2. The appropriateness of the methods proposed to be used in obtaining subjects' informed consent, and
3. The risks to the human subjects and the potential benefits of the research.

While conscious of the serious implications of its charge, the committee is nevertheless concerned that its activities and jurisdiction not obstruct in any way academic research and teaching programs in which proper attention has been given to the rights and welfare of human subjects who may be involved as participants. It is inevitable there will be occasions when these two goals (the committee's responsible discharge of its duty and the freedom of an investigator to organize and conduct a project in the way he/she chooses) come into conflict. In such cases, the committee will work with investigators and make every attempt to resolve the problems. In so committing itself, however, the committee emphasizes that it does have final campus jurisdiction over studies using human research subjects.

Therefore it is incumbent upon those proposing the use of human research subjects to assure the committee that subjects' rights and welfare will be protected.

**IMPORTANT:** All faculty/staff research using Human Subjects must be submitted for review regardless of Category.

### B. **When to Submit an Application to the Human Subjects Review Committee**

It is the responsibility of the investigator to apply for approval to use human research subjects. It is recommended that the researcher refer to the Human Subject Regulations Chart: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>. All research must employ procedures designed to minimize the risk of physical, psychological, or social harm to subjects.

The following three categories of research activities should be used as a guide. Questions concerning the classification of a particular study into one of these three categories can be directed to the Campus Human Subjects Administrator ([Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu)).

#### **CATEGORY I • Exempt Research (No HSRC review required)**

Research projects in which the only involvement of human subjects will be of one or more of the following activities may be determined Exempt by the Campus Human Subjects Administrator:

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1. Projects involving collection of data through the use of opinion surveys, questionnaires or interviews for which response is voluntary and completely anonymous unless the information is identifiable and disclosure would place the subject at risk. **IMPORTANT:** Surveys and interviews of children (under 18 years of age) are NOT exempt.

2. Research conducted in established or commonly accepted educational settings, involving typical educational practices, such as research on regular and special education instructional strategies, research on the effectiveness of or the comparison among instructional techniques, curricula, classroom management methods, and in-class demonstration studies or laboratory exercises. **IMPORTANT:** Any study requiring that children be removed from their regular classroom situation for testing is NOT exempt.

3. Projects limited to the observation of public behavior for which anonymity of subjects is maintained. **IMPORTANT:** Observation of public behavior of children (under 18 years of age) is NOT exempt if the investigator is a participant observer.

4. Research involving the collection or study of existing data, documents, or records if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**N.B.** Projects conducted as instructional demonstrations where subjects are not solicited from outside the classroom do not need to be reviewed by the HSRC. Care should be taken to protect the rights and welfare of students who act as subjects. However, if classroom demonstration data is to be published or presented, then an application to the Campus Human Subjects Administrator is necessary.

**IMPORTANT:** An Exempt determination cannot be made by the researcher (see Section C The HSRC Review Process for submission procedures).

### **CATEGORY II - Research Activities Subject to Expedited Review**

Projects that do not meet the criteria for Category I and involve no more than minimal risk to the subjects may be considered for an Expedited Review. Minimal risk is defined as "...the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons" (Department of Health and Human Services Code of Federal Regulations: [45 CFR 46.303\(d\)](#)).

Projects that are eligible for Expedited Review include the following:

1. Most laboratory investigations of cognition, perception, social behavior and personality.
2. Any long term investigation of the same individuals where identifying information (including coding schemes) must be maintained with the subject's data.

3. Studies that require the examination of existing data or specimens that are not publicly available.
4. Studies involving the collection of audio or video recordings/images.
5. Studies of healthy individuals involved in moderate exercise.

### **CATEGORY III - Research Activities Subject to Full HSRC Review**

Projects that do not meet the criteria for Exemption (Category I) or Expedited Review (Category II) because subjects will be exposed to more than minimal risk (e.g., physical or psychological harm, use of invasive techniques or unusual therapeutic techniques), must undergo Category III, Full Committee Review.

Other projects requiring Full Committee Review include the following:

1. Projects requiring the use of deception.
2. Projects requiring the use of subjects from populations in need of special protection, such as prisoners, individuals with disabilities, pregnant women, and children (except for studies using children that fall under the educational research exemptions described previously).

### **C. The HSRC Review Process**

The HSRC conducts business during the academic year. Protocols are reviewed only when classes are in session during spring and fall semesters and must be submitted at least three weeks prior to the end of the semester if approval is needed during that semester. Keep in mind that data collection will take additional time, so planning ahead is important if the project must be completed before the semester ends.

### **CATEGORY I Exempt**

Investigators who feel their projects fall under this category must send an email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu) that briefly describes the nature of the project (including instruments to be administered) at least three weeks before the anticipated start of the project. It is important to note that even if a project is determined to be Exempt, the investigator must still submit completed hard copy HSR application to the Campus Human Subjects Administrator at E230 Thompson Hall and an electronic PDF copy via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu). If the proposal is incomplete, specific changes will be requested for further review.

### **IMPORTANT:**

- **No research can commence until approval is issued.**
- **An Exempt determination cannot be made by the researcher.**
- **Studies falling into the exempt category will be reviewed within approximately three weeks.**

## **CATEGORY II Expedited**

Investigators who feel their projects fall under this category must send both a completed hard copy HSR application to the Campus Human Subjects Administrator at E230 Thompson Hall and an electronic PDF copy via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu). The application will be sent to one member of the HSRC for review if it is determined that it can be expedited. To minimize the potential for coercion or conflict of interest, the reviewer will be a committee member who does not work in researcher's home department. An expedited review can take up to three weeks. The HSRC member to whom the application was sent will evaluate the effectiveness of procedures designed to protect human research subjects. If these procedures are not deemed adequate, specific conditions will be placed and changes will be requested. The researcher will be notified of either approval or concerns via email from the Campus Human Subjects Administrator. The applicant will be responsible for submitting any necessary revisions prior to commencing the study.

### **IMPORTANT:**

- **No research can commence until approval is issued.**
- **Studies falling into the expedited category will be reviewed within approximately three weeks**

## **CATEGORY III Full Committee Review**

Investigators who feel their projects fall under this category must send both a completed hard copy HSR application to the Campus Human Subjects Administrator at E230 Thompson Hall and an electronic PDF copy via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu).

During a Full HSRC review, committee members meet face-to-face to evaluate procedures designed to protect human research subjects. Researchers are welcome, though not required, to attend meetings. If these procedures are not deemed adequate, specific conditions will be placed and changes will be requested. The researcher will be notified of either approval or concerns via email from the Campus Human Subjects Administrator. The applicant will be responsible for submitting any necessary revisions prior to commencing the study.

### **IMPORTANT:**

- **No research can commence until approval is issued.**
- **Studies requiring review by the full board (i.e. your study does not meet the expedited criteria) could take a month to 6 weeks for review.**

## **D. How to Prepare an Application**

In order for the HSRC to have adequate information on which to base its review of a proposed project, the researcher must complete and submit a HSR application. The HSR application can be found at <http://www.fredonia.edu/SponsoredPrograms/humansubjects.asp> and consists of Part I, a two-page cover sheet, and Part II, a written description of the project. The written description must be organized and numbered in the format specified in Part II of the application and should provide detailed information on the eight items in the section.

## E. Student Research and Faculty/Staff Sponsor Responsibilities

\*All students conducting research need to be sponsored by a faculty or staff supervisor/instructor. Hereafter, the faculty or staff supervisor/instructor will be referred to as “Sponsor.”

### Student Research

All student investigators must have a Fredonia sponsor who is responsible for insuring that all procedures of the project are in compliance with the Campus Policy on the Use of Human Subjects:

1. The State University of New York at Fredonia does not require student projects to be reviewed **if the data will not be disseminated beyond the institution.**
2. In cases where the sponsor believes there may be some risk to the human subjects involved, student research proposals should be submitted to the HSRC for approval, even if the data collected will not be published or presented outside of the classroom, (psychological or otherwise).
3. If there is any intent to publish, present, or otherwise disseminate research data or findings outside the course in the future (e.g., for a Senior Paper, a Master’s Thesis, by the instructor), an application **must** be submitted for **review and approval by the HSRC prior to the start of recruitment and data collection.**
4. Students should discuss the purpose and intent of their research with their sponsor so that they can determine whether HSRC review is necessary.

Even if not submitting the HSR application to the HSRC, all student investigators must submit to their sponsor a completed HSR application describing in detail the nature of their research and the step-by-step procedures planned to collect data and ensure the protection of human research subjects. The HSR application must include an informed consent process, including the appropriate consent form(s). **If this is not being submitted to the HSRC, the sponsor should keep a copy on file in their office for three years.**

Student research projects that will be submitted for review by their sponsor should include both a completed hard copy HSR application to the Campus Human Subjects Administrator at E230 Thompson Hall and an electronic PDF copy via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu). The sponsor must sign the HSR application certifying that the project is under his/her supervision and attesting that they have reviewed the material in the application.

All student investigators and their sponsor must complete CITI training (Collaborative Institutional Training Initiative at the University of Miami), an online course in the protection of human subjects that can be found at <https://www.citiprogram.org>. **This online training must be completed even if there is no intent to submit the HSC application to the HSR Committee.** Fredonia requires successful completion of Course 1, the Basic Course, before approval of any project using human research subjects.

In general, it is advisable for students to select research projects that are Exempt

(Category I) or eligible for Expedited review (Category II). In this way, approval for the projects will be conducted as soon as possible. Students are not, however, prohibited from conducting research in Category III, but additional time may be required to obtain approval from the full HSRC. In all cases, it is the responsibility of the sponsor to ensure that students use only approved procedures.

### **Sponsor Responsibilities Regarding Student Research**

Please review section on **Student Research** to determine whether the student needs to submit an HSR application to the Committee. Sponsors must carefully read and review student projects as outlined on each HSR application and evaluate:

1. The rights and welfare of the individuals involved,
2. The appropriateness of the methods proposed to be used in obtaining subjects' informed consent, and
3. The risks to the human subjects and the potential benefits of the research.

Sponsors must complete and must ensure their students have completed CITI training (Collaborative Institutional Training Initiative at the University of Miami), an on-line course in the protection of human subjects that can be found at <https://www.citiprogram.org>. The campus requires successful completion of Course 1, the Basic Course, before approval of any project using human research subjects.

Sponsors must sign and date each application, verifying they have reviewed and approved of the project, in particular that the rights and welfare of the subjects are protected, the methods are appropriate, and any risks are outweighed by benefits of the research.

### **F. Classroom Research**

The State University of New York at Fredonia does not require student projects conducted in courses to be reviewed **if the purpose of these projects is only pedagogical in nature. However, all students conducting research must fill out an HSR application to be held on file with our office on campus (See Section E above). If a sponsor has students who might present their research outside of the classroom or submit a paper for publication, the student research must be submitted and approved by the HSRC.** While the HSRC does not require review of classroom projects, it is understood that instructors in these courses are providing the appropriate supervision of students, are teaching students the ethics of human research, and ensuring that students are conducting research in a proper manner. Any student research proposal may be submitted to the HSRC for approval, even if the data collected will not be published or presented outside of the classroom. In cases where the sponsor believes there may be some risk to the Human Subjects, student research proposals should be submitted to the HSRC for approval, even if the data collected will not be published or presented outside of the classroom, (psychological or otherwise).

If there is any intent to publish, present, or otherwise disseminate research data or findings outside the course in the future (e.g., for a Senior Paper, a Master's Thesis, by the instructor), an application **must** be submitted for **review and approval by the HSRC prior to the start of**

**recruitment and data collection.** Students should discuss the purpose and intent of their research with their sponsor so that they can determine whether HSRC review is necessary.

### **G. Blanket Exemption of Class Research**

The review process for Blanket Exemptions can take several weeks.

The Blanket Exemption form should be used by faculty or staff who are submitting student research proposals that they believe to be Exempt (Category I) but may result in publications or presentations outside of the institution. The State University of New York at Fredonia does not require student projects conducted in courses to be reviewed **if the purpose of these projects is only pedagogical in nature.**

#### **INSTRUCTORS SUBMITTING A BLANKET EXEMPTION FORM MUST:**

1. Ensure that all procedures of the students' research are supervised by the instructor.
2. Provide a completed *Instructor's Approval and Blanket Exemption for Class Research* form found at <http://www.fredonia.edu/SponsoredPrograms/humansubjects.asp>.
3. Include completed and signed student HSR application with the *Instructor's Approval and Blanket Exemption for Class Research*
4. Provide a list of student names and project titles for consideration.
5. Collect and attach copies of the students' CITI Training (Collaborative Institutional Training Initiative at the University of Miami) Certificates (Course I, the Basic Course) from the online course in the protection of human subjects that can be found at <https://www.citiprogram.org>.
6. Submit hard copies of the above documents (*Instructor's Approval and Blanket Exemption for Class Research*, the completed and signed HSR applications, list of student names and research projects, and CITI Training Certificate of Completion [Course I, the Basic Course]) to the Campus Human Subjects Administrator at E230 Thompson Hall and an electronic PDF of these documents via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu).
7. Keep records. In accordance with campus policy, instructors must keep records, including application forms, informed consent documents, and data for a minimum of three years.

When in doubt about whether or not a research project is Exempt, the instructor should contact the campus Human Subjects Administrator to determine the appropriate research category (Exempt: Category I; Expedited: Category II; Full Committee Review: Category III). This should be done as early in the semester as possible.

#### **IMPORTANT:**

- **No research can commence until approval is issued by the Campus Human Subjects Administrator**

### **H. Informed Consent**

Informed consent, a crucial element of human subjects' research, is a process, not just a form. Informed consent means the knowing consent of an individual or his/her legally authorized representative who is able to exercise free power of choice without undue inducement or any



form of force, fraud, deceit, duress or other form of constraint or coercion. There are very few research situations which do not require a participant's signature on an informed consent form. Permission from the HSRC is always necessary for waiving this requirement.

The Informed Consent process should:

1. Provide sufficient opportunity to the prospective subject or his/her representative to consider whether or not to participate, including sufficient time to review and consider the Informed Consent Form;
2. Minimize the possibility of coercion or undue influence;
3. Employ a consent form that provides information in language that is understandable to the prospective subject or his/her representative;
4. Follow an appropriate and culturally-sensitive process of information sharing leading up to and including obtaining the participant's signature on the informed consent form;
5. Should utilize Child Assent process if the prospective subject is a child under age 18. Therefore the researcher must create both an informed consent form for parents/guardians and a child assent form, as delineated below.

The subject, or his/her representative, cannot be made to waive or appear to waive any of his/her legal rights, or release the investigator, the sponsor, the institution or its agents from liability for negligence.

The actual procedure to be utilized in obtaining legally effective informed consents must be fully documented. This is accomplished by using a written Consent Form, which must contain **all** the elements listed below. The Consent Form must be read by or to the subject or his/her legally authorized representative and signed by the person giving consent. The signed Consent Form must be kept secure in the investigator's files for at least three years following the completion of the study.

When Child Assent Form is necessary, the Form must be kept secure in the investigator's files for at least three years following the completion of the study. Details regarding the specifics of the Child Assent Form and process are stated below.

**IMPORTANT: The final Consent Form that will be administered to subjects must first be approved by the HSRC before it can legally be administered.**

**The Informed Consent Form** must include:

- a statement that the study is research
- the purpose of the research study
- a description of procedures
- how long subjects will be involved in the study
- both the potential benefits and the risks and/or discomforts of participants
- how confidentiality of subjects and their data will be maintained
- the statement that participation is voluntary and that the subjects can withdraw at any time without penalty; and

- the names, phone numbers, campus addresses and campus email addresses of the PIs, the faculty or staff sponsor (if student research is being submitted) and the Campus Human Subjects Administrator.

### **The Child Assent Process:**

Legally, children are not able to give [informed consent](#) until the age of 18. Before taking part in a research study, the child is asked for his/her assent. Assent means that the child agrees to participate in the study. The child may also choose not to participate in the study (dissent).

To participate in the assent process, children must be mature enough to understand the research study and what they are expected to do. Some children as young as 7 years old may be able to participate. However, this age varies depending on the child. As with the informed consent process, the assent process is meant to be an ongoing conversation between the child and researchers.

Parents or guardians give permission through informed consent for their child to join the research study. This must occur PRIOR to child assent being obtained. **All custodial parent(s) need to give permission if there is greater than minimal risk AND no prospect of benefit to individual subjects. If there is minimal risk, or no anticipated risk, the permission of one custodial parent is acceptable.** See [HHS Order of Permission and Assent](#) for guidance on the order in which parental/guardian permission and child assent should be sought. The researcher should develop an **informed consent form for parents/guardians** using the criteria for the Informed Consent.

After parental/guardian permission is obtained, the researcher explains the child assent procedures to the child in age-appropriate language, including what it means to participate in the study and the expectations of the child. The researcher may use written forms, videos, graphics, and other visual aids to help explain the research study. The child is encouraged to ask questions.

It may take several sessions before the researcher feels that the child has a clear understanding of what the study involves. At that point, the child is asked to show assent or dissent by signing a form, checking off a box that says "yes" or "no," or indicating "yes" or "no" via symbols.

The Child Assent Form is not needed for children from infancy to 6 years old. However, the Informed Consent Form from parent(s)/guardian(s) is necessary.

The Child Assent Form and the Informed Consent Form (parent/guardian) must be kept secure in the investigator's files for at least three years following the completion of the study.

**IMPORTANT: The final Child Assent Form that will be administered to subjects must first be approved by the HSRC before it can legally be administered.**

**The Child Assent Form** for children between the ages of 7 to 18 must meet the criteria of the Informed Consent Form and explain in age-appropriate language, considering the age, maturity and psychological state of the child:

- a statement that the study is research
- the purpose of the research study
- a description of procedures
- how long subjects will be involved in the study
- both the potential benefits and the risks and/or discomforts of participants
- how confidentiality of subjects and their data will be maintained
- the statement that participation is voluntary and that the subjects can withdraw at any time without penalty
- that the child's parent/guardian knows the child has been asked to be a part of the study
- that the child should ask the parent/guardian or researcher(s) any questions about participating
- the names, phone numbers, campus addresses and campus email addresses of contact people with knowledge of the study, including the Campus Human Subjects Administrator

#### **I. Additional Policies**

- The Office of Sponsored Programs oversees the HSRC. All communication with the HSRC should be through the Office of Sponsored Programs via email at [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu) or by calling 716-673-3528.
- The HSRC conducts business during the academic year. Applications are typically reviewed only when classes are in session during spring and fall semesters and must be submitted at least three weeks prior to the end of the semester if approval is needed during that semester. Research to be considered for Exempt status can be submitted throughout the year.
- All official business is conducted via email. An electronic PDF of all required documents must be submitted via email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu). Additionally, hard copies of all required documents (completed Part I and Part II HSR application, signed cover sheet, and CITI Training Certificate of Completion) should be submitted to the Campus Human Subjects Administrator at E230 Thompson Hall. Notifications of committee concerns as well as approval are sent via email.
- The approval for a project is in effect for a period of one year from the approval date. If a project continues beyond one year and the investigator/instructor has not made any significant changes in the procedures outlined in the original protocol, an email to the Campus Human Subjects Administrator requesting an extension is all that must be submitted. **Any significant change requires a new review by the HSRC.**
- All documentation, including informed consent forms, must be retained by the investigator/instructor for a period of three years after the research is concluded or otherwise terminated.

- **Within thirty (30) days of the conclusion of data collection on an approved project, researchers must send an email to [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu) indicating project termination and specifying any difficulties that occurred with the use of human subjects.** If problems arise at any point during the project, they must be reported to the Campus Human Subjects Administrator via email at [Human.Subjects@fredonia.edu](mailto:Human.Subjects@fredonia.edu) or by calling 716-673-3528.