

**FAQ’s About the Human Subjects Review Committee (HSRC) Process**

**The Office of Sponsored Programs is responsible for administering the review of research with human subjects. At Fredonia, this committee is called the Human Subjects Review Committee. Federal regulations provide guidance for these committees, often called Institutional Review Boards (IRB). Fredonia’s HSRC has provided these FAQs to assist faculty, staff and students navigate the human subjects review process.**

**1. What kinds of studies need HSRC approval?**

Any research conducted using living human participants must follow the guidelines in the Campus Policy on the use of Human Subjects.

The Code of Federal Regulations (45 CFR 46.102 (d)) defines research as a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Federal Regulations (45 CFR 46.102) define a human subject as **any living individual** about whom an investigator obtains data through observation, interaction, manipulation of the environment, application of procedures or treatments, administration of therapies, communication, interpersonal contact, or physical procedures.

The submission of the HSRC form entails filling out the Request for Human Subjects Review. The Office of Human Research Protections provides a [useful chart](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html) to assist researchers with HSRC questions concerning their research.

**2. Federal regulations require that all researchers and sponsors receive training.  How do I meet this requirement at Fredonia?**

At Fredonia, all faculty, staff, and students who wish to submit research for review by the Fredonia HSRC must complete the online training program available at [www.citiprogram.org](http://www.citiprogram.org/).  You will need to register for the course and select State University of New York at Fredonia as your institution.  Once you have completed the training, please retain a copy of the training completion certificate for your records.  You will need to attach this certificate along with any Human Subject proposals that you submit. The online training approval is valid for two years. After this, refresher courses must be completed.

**3. I am collecting data from my class to determine if students like a new teaching method. Do I need to go through the HSRC to collect these data?**

If you are collecting data only to improve your course and will not be sharing the results (presenting them or publishing them), you do not need to fill out a Request for Human Subjects Review. If, however, you think you may want to present or publish your results, you need to submit a Human Subjects Review application.  If you are collecting data from students in your class, it is imperative to make sure they know that refusing to participate will not affect their grades.  Because collection of data from your class can be seen as coercive, it is essential to be cautious when asking students to participate.

**4. What about student research?**

The State University of New York at Fredonia does not require student projects to be reviewed **if the purpose of these projects is only pedagogical in nature.  If you have students who might present their research outside of the classroom or submit a paper for publication, they must go through 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 not performing research that is at all questionable. 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. 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.

### 5. Is HSRC review needed for class-related projects?

It depends. See Section F. Classroom Research in Campus Policy on the Use of Human Subjects

### 6. Do service-learning projects require HSRC approval before students begin their service-learning?

HSRC approval is not required for service-learning and community-based learning course projects, however, this activity must still be planned and carried out in an ethical and legally responsible manner. Projects involving special populations (e.g., youth under age 18; prisoners, individuals with physical or mental disabilities; economically or educationally disadvantaged; institutionalized individuals; pregnant women) require additional safeguards. In these cases, researchers should contact the Human Subjects Administrator to determine whether HSRC approval is required.

### 7. Are HSRC applications required for students participating in the Study Abroad programs?

If you anticipate becoming involved in a research project in a research project involving human subjects, during a study abroad you need to contact the HRSC Administrator for more information: Dr. Judith Horowitz at Human.Subjects@fredonia.edu

**8. For research with school-age children, do both the parent and the child have to give consent?**

Yes. Parental consent is required first; the child must also give their assent to participate Details can be found in Section H of the Campus Policy on the Use of Human Subjects.

### 9. What is required for off-campus research?

Research that is physically conducted off campus (schools, hospitals, community agencies, NGOs, businesses) requires documented approval from that site.

**10. How do I apply for approval?**

First read over Campus Policy on the Use of Human Subjects, second, determine the category under which your research falls. Third, complete the appropriate application process.

### 11. Do I need to go through the HSRC process if my project is exempt?

Yes. If the proposed research activity involves human participants and may contribute to “generalizable knowledge,” it still must be submitted and reviewed by the HSRC before any recruitment or involvement of human participants. Exempt research is a classification determined by the HSRC Administrator.

**12. Where do I submit the form?**

Completed forms should be taken to the Office of Sponsored Programs and should also be emailed to the Human Subjects Administrator on Campus (Dr. Judith Horowitz). You will be notified via email or any questions, if changes need to be made or if the project has been approved as is. All HSRC requests will be archived in the Office or Sponsored Programs.

**13. How long will the review take?**

If your study falls into the exempt or expedited categories, the review process will usually be completed in approximately three weeks.  If your study requires review by the full board (i.e. your study does not meet the expedited criteria), the review could take 4 to 6 weeks.

**14. Can I start collecting data before I receive approval?**

Absolutely not! You must have approval before any data are collected.

**15. How will I know that my research has been approved?**

You will receive an email from the Human Subjects Administrator indicating that you have been approved. Please note that approvals will be good for one year from the date of approval unless you state on your application that the data collection will last less than one year.

**16. How long does a researcher need to keep records of the research?**

Researchers must keep documents showing informed consent in a secure place for three years after the conclusion of the research. Some agencies that sponsor research may have a longer retention requirement.

### 17. What happens if I conduct human research without HSRC approval?

You will place the university out of compliance with Federal requirements that regulate human subjects research. This can result in Federal or HSRC actions that will prevent you, your Department/Division, or the university from conducting any future human subjects research.

**Data collected without HSRC approval cannot be used in theses, dissertations, or publications. This may ultimately prevent students from fulfilling graduation requirements. Students and instructors are urged to plan carefully when deciding whether or not to submit a Request for Human Subjects Review.**

**18. Who can I contact if I have questions?**

Fredonia’s Human Subjects Administrator, Dr. Judith Horowitz, at Human.Subjects@Fredonia.edu

**19. I still have questions.**

If you are collecting any data from human subjects and are unsure if it constitutes research, or if you have questions about the difference between research activity and a research project which might require HSRC review, please contact the Human Subjects Administrator on Campus.