



OVERVIEW: This policy provides the standards and guidelines required for conducting research involving human participants.

OFFICE/DEPARTMENT RESPONSIBLE: Grants Development

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I. Introduction

The purpose of these guidelines is to assist researchers planning to conduct research involving human participants to submit your proposal for review to the Institutional Review Board (IRB). This is a collaborative process intended to result in research procedures which accomplish your research objectives while protecting the rights and welfare of the participants. The IRB tries to be as flexible as possible and reviews each project as a separate case. The IRB sees its role as primarily educational and facilitating, and encourages consultation at all stages of the research process.

II. Frequently Asked Questions

A. What is human participants research?

“Human participants research” is defined as a systematic investigation designed to develop or contribute to general knowledge, which involves the collection of data from or about living human beings. All student research involving human participants outside their own classroom is included in this category. (Federal regulations definition – 45 CFR 46.102.)

B. Why must it be reviewed by the IRB?

Federal and state laws require this protection. Additionally, it is College policy to ensure that the rights and welfare of human participants are adequately protected in research conducted under its auspices.

C. Who must submit material for review?

Any faculty, staff, student or external person who wants to conduct human participants research under the auspices of the College or on the grounds of the College must have prior approval of the College’s IRB. But if the research results will be disseminated in publications or presentations, then the research must receive **prior** approval. If no dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, the researcher should submit the project for approval before beginning research. Research conducted for course evaluation, institutional research, or ongoing College processes does not need to be reviewed.

D. How is it submitted?

The guidelines and forms you need can be found at the IRB website at <http://www.brockport.edu/irb/> Forms are submitted to the IRB administrator in the Office of Academic Affairs.

E. When does it have to be submitted?

Proposals may be submitted at any time during the academic year. Depending upon the level of your review category and the time of the year, proposals are generally approved within two weeks after a complete application is submitted. If you are submitting a grant proposal to an external funding source that involves human participant research, please call the IRB

Office at (585) 395-2523. The IRB cannot give its approval or disapproval of human participants research projects already conducted. All research involving human subjects must be reviewed and approved **prior** to conducting the research.

F. Who reviews my application?

The College has authorized the Institutional Review Board (IRB) to review and approve human participants research. The IRB is a campus-wide committee made up of faculty members from several different departments, and at least one person from the community. Staff support is provided by the through the Grants Development Office in the Division of Academic Affairs. There are three different levels of review by the IRB depending upon the activities you are conducting.

G. How will my application be reviewed?

The review process focuses on the procedures affecting the rights and welfare of human participants including issues of risks to participants, informed consent, voluntary participation, equitable selection of participants, and maintaining confidentiality. These are based upon federal regulations.

1. **Risk/benefit** — To approve research the IRB will determine that the following requirements are satisfied:
 - a. Risks to participants are minimized by using procedures that are consistent with sound research design and which don't unnecessarily expose participants to risk.
 - b. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of knowledge that may reasonably be expected to result from the research. The IRB will examine study design or scientific merit of a proposed study only within the context of its risk/benefit analysis.
2. **Equitable selection of participants and recruitment** — Selection criteria will consider all populations that might potentially benefit from the research. The IRB ensures that the recruitment of participants is equitable and free from coercion.
3. **Informed consent process** — Informed consent must be sought from each prospective participant or the participant's legally authorized representative. Their participation must be voluntary.
4. **Privacy and confidentiality** — The IRB will determine that adequate provisions have been taken to protect the privacy of participants and for ensuring confidentiality of an individual's participation and confidentiality of study data.
5. **Special populations** — When some or all of the participants are likely to be vulnerable to coercion or undue influence (such as

children, prisoners, pregnant women, persons who are physically or mentally disabled, or economically or educationally disadvantaged persons) additional safeguards must be included in the study to protect the rights and welfare of these participants.

6. **Research design** — Project is scientifically sound. Is the hypothesis clear? Is the study design appropriate to prove the hypothesis? Will the research contribute to general knowledge?

H. Where can I get assistance?

Contact the IRB office at (585) 395-2523 or go to our website at <http://www.brockport.edu/irb/>