



## 611.8 Ethical Conduct of Research Involving Human Subjects and Institutional Review Board

### Purpose:

The purpose of this procedure is to operationalize BSC Policy 611.8 Ethical Conduct of Research Involving Human Subjects and Institutional Review Board. These procedure details are intended to protect the rights and welfare of human subjects in research.

### Procedure:

The IRB processes new applications, amendments, and continuing reviews to ensure research projects involving human subjects are conducted with the highest ethical standards by adhering to federal regulations and institutional policies. All projects that meet the common rule definition of research and involve human subjects must obtain IRB approval before conducting research. The (Code of Federal Regulations) [CFR §46.102 \(I\)](#) defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

This definition is further examined in the context of the terms, “systemic investigation” and “generalizable knowledge.”

**Systematic Investigation:** an activity that involves a prospective or predetermined plan to obtain data and conduct an analysis to answer research questions, test a hypothesis, or develop a theory.

**Generalizable Knowledge:** when the project intends to use scientific methods and procedures to create knowledge that has general applications outside of the specific study subjects.

If the project meets the definition of research (i.e., it involves a systematic investigation and/or does contribute to generalizable knowledge), the next set of questions is equally critical.

**Are Human Subjects Involved?** A human subject is a living individual about whom an investigator, whether professional or student, conducts research and obtains information through intervention or interaction.

**Intervention** includes physical procedures by which data is collected or manipulations of the subject or the subject’s environment for research purposes (e.g., exercise procedures, use of devices, cognitive tasks, etc.)



**Interaction** includes any communication or interpersonal contact between the investigator(s) and the subjects. This may include the use of in-person, mail, telephone, and online interviews/surveys to obtain information from human subjects.

### **Would the Investigator have Access to Identifiable Private Information?**

**Private information-** the CFR section [§ 46.102\(e\) sub-section \(4\)](#) defines private information as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).”

**Identifiable private information** is information for which the identity of the subject is or may readily be ascertained by the investigator either directly or indirectly using codes or a combination of data points. ([§ 46.102\(e\)sub-section 5](#)).

In summary, if your project meets the definition of research, thus involves human subjects, includes interaction or intervention with human subjects, or involves access to identifiable private information, an IRB review and approval is required before involving your participants. In the case of a grant project, if your grant is funded with the inclusion of human subjects or you have proposed to use human subjects’ data to evaluate the project, the processes and practices of the data collection and reporting must follow the federal regulations on human subjects.

Before submitting an IRB application, first determine if IRB review is required for your project. Applicants are encouraged to use the [IRB Determination Chart](#) as an additional guide in deciding whether a project requires an IRB review and approval. There may be additional state, local, or institutional regulations and policies necessary to be considered even if federal regulations for human research protections do not apply to your project. As an investigator, you must comply with all other federal, state, and institutional regulations and policies intended to ensure additional protection for human subjects participating in your project.

### **IRB Review Process and Approval Procedure**

All projects that meet the definition of research with human subjects must be reviewed and approved by the IRB before the data collection. The IRB recommends that investigators familiarize themselves with the different review levels to decide the type of review appropriate for their application.



**Exempt Review:** Some projects involving human subjects may be exempt from the requirements of the Federal regulations. However, this does not mean they are exempt from IRB reviews, it means the research is exempt from some federal policies for the protection of human subjects. Exempt status is determined when the project poses no more than minimal risk to participants. Projects that fall into the categories listed in the [CFR section § 46.104](#) qualify for exemptions. It is critically important to note, however, that decisions about whether studies are exempt from the Code of Federal Regulation requirements must be made by an IRB or an appropriate institutional official, not by the investigator.

**Expedited Review:** If the project presents no more than minimal risk and does not involve any vulnerable populations (i.e., children, prisoners, individuals with impaired decision-making capacity, and/or economically or educationally disadvantaged persons), it may qualify for expedited review. In general, research may qualify for expedited review if it falls into one of the federally approved [expedited review categories](#). The risks may be minimal but may have some sensitive aspects or procedures that require review by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

**Full Board Review: Projects** not eligible for an exempt or expedited review undergo review by a convened board. The most rigorous level of review typically involves projects that present more than minimal risks to subjects and may involve physically invasive interventions or surveys with vulnerable populations. For example, the research project may be subject to full review if it involves any of the following.

- a. Children under the age of 18.
- b. Prisoners as a population.
- c. Individuals with impaired decision-making capacity.
- d. Procedures that might cause physical harm or psychological/emotional distress.
- e. Experimental interventions, therapies, or treatments that have not been widely tested or approved for standard use.
- f. High levels of deception, manipulation, or risks to participants' autonomy or well-being.
- g. A complex research design requiring the expertise of multiple board members to evaluate.



## Criteria for Approval

After receiving the completed request from the researcher, the IRB will verify that

1. The IRB application form has been completed.
2. The researcher demonstrates appropriate training for your category of research per State Board of Higher Education [Policy 410](#), e.g. RCR via [CITI](#).
3. The researcher submits appropriate subject consent documentation.
4. The research is consistent with BSC's values, policies, procedures, and operations.
5. The potential effects of data collection and results dissemination are safe and effective.
6. The research meets the requirements of the [Protection of Human Subjects \(45CFR46\)](#).
7. The results will be disseminated in a fashion that would protect the identity of the participants. It must be noted that the names of individuals will not be used in the study unless the individuals grant permission in writing.

## Timeline and Notification of Approval or Disapproval

Once formal review begins, exempt projects, posing minimal risk to human subjects, take approximately ten working days to be processed. Applicants will be contacted concerning the status of the request within ten working days upon receipt of a complete application. Expedited projects take approximately ten working days to be processed. Studies needing full board review can take up to four weeks to be processed. The IRB Chair will provide feedback to applicants regarding any modifications that will be required in preparing the project for IRB approval. If a research application is denied, the notification will include the reason(s) for the denial. If a delay is necessary, an appropriate timeline will be negotiated with the applicant. It is the applicant's responsibility to plan and allow enough time for submission, review, and approval of the project.

## IRB forms

1. [IRB Application](#)
2. [Consent form Guide](#)
3. [IRB Determination Chart](#)
4. [Expedited Review Checklist](#)



**Contact the BSC IRB with your questions and comments.**

Office of Institutional Effectiveness

**Phone Contact:** 701-224-5491

**Email Contact:** [bsc.irb@bismarckstate.edu](mailto:bsc.irb@bismarckstate.edu)

**References:**

SBHE policy: 611.8 [Employee Responsibility & Activities: Research on Human Subjects](#)

SBHE policy: 410 [Responsible Conduct of Research](#)

BSC Policy: 308.1.2 [Code of Ethical Conduct](#)

BSC Policy: 308.4 [Conflict of Interest](#)

[45 CFR 46 | HHS.gov](#)

**History of This Procedure:**

First policy procedure: January 3<sup>rd</sup>, 2025.

Reviewed by Campus Council on July 24<sup>th</sup>, 2024, reviewed by Executive Council on January 3<sup>rd</sup>, 2025, and approved by Acting President on January 3<sup>rd</sup>, 2025. Non-substantive edits made, approved by VPAA Alicia Uhde on September 14, 2025.