

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

Purpose:

The purpose of this policy is to articulate the commitment of Bismarck State College (BSC) to protect the rights and welfare of individuals participating in research studies. The BSC Institutional Review Board (IRB) is entrusted with the responsibility of reviewing and overseeing research that involves human subjects, ensuring that such research is conducted ethically and in compliance with the Code of Federal Regulations as outlined in [45 CFR 46](#) (Subparts [A](#), [B](#), [C](#), and [D](#)). This policy emphasizes adherence to the regulatory policies and guidelines in the Code of Federal Regulations. This does not exempt researchers from complying with the applicable laws of the state of North Dakota, and the policies and procedures set forth by the North Dakota University System. This comprehensive approach aligns with the National Institute of Health's [Guiding Principles for Ethical Research](#) ensuring rights, dignity, and welfare of research participants are prioritized and safeguarded at all levels of research.

Policy:

Bismarck State College is committed to upholding the highest ethical standards in all research activities involving human subjects. All research involving human subjects conducted by faculty, staff, students, or any individual associated with BSC, regardless of the source of funding, must undergo review and receive approval from the BSC Institutional Review Board (IRB) before the research begins. Bismarck State College also requires that the members of the IRB, Primary Investigators (PI), and Co-primary investigators complete the appropriate Collaborative Institutional Training Initiative (CITI) training. Compliance with this policy and the IRB's decisions is mandatory for all investigators. Failure to comply may result in suspension or termination of the research project.

Definitions:

Human Subject Protection

Investigators must ensure the safety, well-being, and protection of the fundamental rights of research participants. This involves treating research participants with dignity, respect, and fairness throughout the entire research process. Investigators must take proactive measures to protect participants from potential harm, both physical and psychological, while steadfastly upholding their rights, which encompass the right to privacy, autonomy, and the provision of informed consent.

Confidentiality

Investigators should take measures to protect the identity and personal information of research participants. This includes using codes or pseudonyms to anonymize data and ensuring that only authorized personnel have access to sensitive information.

Informed Consent and Assent

Before engaging in any research activities, unless waived by the IRB, investigators must adequately inform research subjects about the usage and access of their data. Subjects should voluntarily provide informed consent, demonstrating their understanding of how their safety and privacy will be protected. When research involves minors, [CFR 46.408](#) mandates investigators to solicit and obtain both assent from the children and parental or guardian's permission for their involvement in the study.

Data Security

Investigators should employ secure methods for storing and transmitting research data to prevent unauthorized access or breaches. This may include encryption, password protection, and secure storage protocols.

Data Retention and Disposal

Investigators should develop a clear plan for the retention and eventual disposal of research data to prevent subsequent harm to participants' privacy.

De-identification

When publishing research findings, investigators should take steps to fully de-identify data to protect the privacy of participants, ensuring that no individual can be readily identified from the published information.

Equitable Subject Selection

Investigators must demonstrate a high level of impartiality, sensitivity, and ethical responsibility when conducting research involving vulnerable populations. They must ensure that the rights and welfare of these individuals are protected and that the research is conducted ethically and respectfully.

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](#)

History of This Policy:

First policy: January 3rd, 2025.

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