

General Procedure - Institutional Review Board

Purpose:

The primary purpose of the Institutional Review Board (IRB) is to protect the welfare of human subjects used in research. All research requests meeting the following conditions must be reviewed by the IRB. This procedure is intended to assure college staff and students who may be affected by the research that the research is sound and does not violate board policy, college operating procedures, or federal regulations concerning protection of human participants.

Composition:

The IRB is chaired by a voting IRB member, the Institutional Research Analyst, who shall annually appoint four additional voting members to serve. These members include one dean or faculty member within Humanities, Arts, & Sciences, one dean or faculty member within the National Energy Center of Excellence, and one dean or faculty member within Current and Emerging Technologies. The final voting member will be someone not affiliated with the institution. Additional faculty or staff members may serve in an advisory capacity where appropriate, for instance, when an existing voting member is a Principal Investigator (PI) or co-PI on a protocol. Following are federal guidelines for determining membership:

[§46.107 IRB membership.](#)

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

Approval Procedure:

The following persons or groups of persons must comply with the Bismarck State College (BSC) approval to conduct research procedures:

1. Any person or group of persons who is neither employed by nor a student of BSC and who wishes to use BSC employees, students, records, or facilities as part of a research project or study.
2. Any BSC student or employee proposing to conduct a study that
 - a. Involves activities outside their regular assigned duties and involves human subjects;
 - b. Involves a grant application requiring IRB review.
 - c. Involves human subjects and is intended to result in an academic thesis, a conference presentation, or a publication.

After receiving the completed request from the researcher, the Institutional Review Board will verify the following items:

1. The Research Proposal Form has been completed.
2. The appropriate signatures have been obtained.
3. The proposed research is compatible with BSC's mission and purpose and is education-related. The research should deal with the teaching/learning environment or with the college's policies, procedures or operations.
4. The proposal meets the requirements of Protection of Human Subjects (45CFR46).

5. The results will be disseminated in a fashion which would protect the identity of the participants and, if appropriate, the college. It must be understood that names of individuals will not be used in the study unless the individuals grant permission in writing. The name of Bismarck State College will be used only if the Institutional Review Board grants permission.

Criteria for Approval:

Individuals requesting authorization to conduct research must complete a Bismarck State College Research Proposal form (see attachment). The IRB chairperson, or designee, will conduct an initial review. Approval of the proposal will be based on the following criteria:

1. Compatibility with the college's mission and purpose.
2. Acceptability of the potential effects the collection of data and the dissemination and use of results may have on BSC students, personnel, operations, and the community.

Timeline and Notification of Approval or Disapproval:

Ordinarily the requestor will be contacted concerning the status of the request within ten working days of receipt of the proposal. If possible, approval or denial of the request will be made at that time. If a delay is necessary, an appropriate timeline will be negotiated with the requestor.

If a research request is denied, the notification will include the reason(s) for the denial. A revised proposal, or sections thereof, may be submitted for reconsideration.

Research Proposal Form

Note: Please complete this form and attach brief responses to the issues raised, keeping in mind that the primary concern is the potential risk—physical, emotional, or other—to the participants, as well as the protection of their rights. Submit the proposal and supporting documents to the Institutional Review Board, c/o Office of Institutional Effectiveness and Strategic Planning, Bismarck State College.

Principal investigator:

Title:

Institution:

Address:

Phone: Fax: Email:

Research/Project Title: _____

Data Collection/Project Start Date: _____

Research/Project Description:

Using the guidelines on the next pages, address the following in a narrative.

- Briefly describe the purpose of your study and what will the participants be asked to do, what are the processes and procedures for data collection. Append relevant instruments (protocols, questionnaires, surveys, etc.).
- Describe any potential risks or benefits (emotional, physical, social, or political) to your participants.
- Give the anticipated ages, sex, and number of participants, and explain how, when, and where they will be recruited.
- Describe the procedures for obtaining informed consent as provided for the Code of Federal Regulations, section 46.116. Append any forms used.

For Non-Exempt Projects Only:

- If minors are involved, describe the procedures for obtaining consent to participate from the minors capable of giving consent, as well as the procedures to obtain parental or guardian consent.
- If risk is involved, explain how the knowledge to be gained and/or the benefits to the research participants from the proposed research justify any risks the participants might incur.
- Explain what, if any, support services will be provided in the event of harm to a participant.

Signatures

Certification

I certify that I have read and understand the policies and procedures for research projects that involve human participants and that I intend to comply with the Bismarck State College procedures for research involving human participants. Significant changes in the research protocol for an approved study must be submitted to the IRB and approved prior to those changes being put into practice.

Researcher/Project Director

Signature: _____ Date _____

Department Chair/Program Director

Signature: _____ Date _____

Check one of the following, indicating the category into which this research falls according to Title 45, Code of Federal Regulations, Part 46:

- Project is exempt. **Cite exempt category (see Guidelines):**
- Project is referred to Institutional Review Board for review.

IRB Chairperson

Signature: _____ Date _____

Bismarck State College Research Project Guidelines

Institutional Review Board Criteria for Ethical Research

The following requirements for the approval of research is based upon the *Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects, (revised June 23, 2005)*. The scope and interpretation of this checklist are determined by reference to that original document.

Requirements of All Research:

- Risks to participants, where they exist, will be minimized and are reasonable in relation to anticipated benefits. (46.111a 1-2)
- Participants will be equitably chosen, especially in the case of vulnerable populations— children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (46.111a 3)
- Documentation of informed consent will be obtained from each participant or participant’s legal representative. (46.111a 4-5; see Required Elements for Informed Consent below)
- Measures will be taken to monitor data collected to insure the safety and privacy of the participants. (46.111a 6-7)
- In the case of vulnerable populations, additional safeguards will be included to prevent coercion or undue influence by the researcher. (46.111b)

Required Elements for Informed Consent:

- The consent form provides a clear and non-technical explanation of the research project— sufficient to inform a participant’s decision to participate or not. (46.116a 1)
- The consent form describes any foreseeable risks or discomforts, as well as possible benefits to the participant. (46.116a 2-3)
- The consent form informs the participant of the extent to which confidentiality will be maintained. (46.116a 5)
- The consent form identifies a person to contact should questions regarding the research or the participant's rights arise. (46.116a 7)
- The consent form provides a statement that participation is voluntary and that refusal to participate or termination of participation will result in no harm to the participant. (46.116a 8)

When appropriate the following should also be included:

- If relevant, the consent form describes any alternative treatments being withheld by the researcher that might be advantageous to the participant. (46.116a 4)
- The consent form explains any compensation to be provided should harm to the participant occur. (46.116a 6)

Criteria for a Project to be Exempt from Review

To be exempt from review, a project must be in one of these categories:

Categories (one of the following):

- Research in common educational settings, involving normal or special educational practices. (46.101b 1)
- Research involving educational tests, surveys, interviews, or observation unless confidentiality cannot be maintained or disclosure places the participants at risk. (46.101b 2)
- Research involving elected or appointed public officials or candidates for office, even when confidentiality cannot be maintained or disclosure places the participants at risk. (46.101b 3)
- Research involving the study of existing data either publicly available or recorded by the researcher(s) in a manner that maintains confidentiality. (46.101b 4)
- Institutional or organizational research designed to improve service or benefits when approved by the agency's head. (46.101b 5)

References:

- SBHE Policy 611.8 – Employee Responsibility and Activities: Research on Human Subjects
- [§46.107 IRB membership](#)

Adapted from:

- [Oakton Community College,
<http://www.oakton.edu/resource/oir/institutionalreviewboard.pdf>, January 2004](#)
- [Sinclair Community College, \[www.sinclair.edu\]\(http://www.sinclair.edu\), November 2006](#)

History of This Procedure:

First procedure draft December 8, 2006.

Revisions – August 2, 2013; reviewed by the Operations Council on December 14, 2016 and approved by the Executive Council on January 3, 2017.