Bemidji State University Policies

Policy Name: Institutional Review Board (formerly Human Subjects)	**Effective Date:** 9/29/2015
Policy Owner: School of Graduate Studies	Last Review: 2/1/2016
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POLICIES AND PROCEDURES FOR THE
USE OF HUMAN SUBJECTS IN RESEARCH

1. **POLICY**: It is the policy of Bemidji State University that all research involving human subjects conducted at this institution will be in accordance with federal regulations including but not limited to the "Guidelines for Protection of Human Research Subjects" 45 CFR 46 established by the National Institutes of Health, and regulations to protect human subjects, 21 CFR 50, 312, 812 as established by the Food and Drug Administration.

   The information found in this document is not a set of recommendations, but firm policies that will be enforced. This policy is not intended to infringe on the academic freedom of researchers. It is specifically intended to reaffirm that freedom while focusing on protection of human subjects and to comply with federal regulations. Safeguarding the rights and welfare of all those individuals involved as subjects in research, development, or related activities carried out or supervised by members of the faculty and staff of Bemidji State University is not only the responsibility of the individual members of the faculty or staff involved, but it ultimately and directly the responsibility of the University.

   To ensure adequate safeguards and to discharge the responsibility of the institution, no research (including grant applications), development, or related activity involving human subjects may be undertaken unless the University Committee appointed for the purpose has reviewed and approved such proposed activity.

2. **COMMITTEE:**

a. The President of the University will establish a Human Subjects Committee of not less than five members and, with advice of appropriate committees, boards, councils, or Deans of the University, appoint its members to terms of not more than three years. Membership on this committee is not restricted to members of the faculty of the

University but shall also include individuals drawn from various sectors of the community at large who are interested in or knowledgeable about the problems of protecting the rights and welfare of individuals who may be involved in research, development, or related activities including problems relating to securing consent. The President in consultation with the Senior Vice President for Academic and Student Affairs shall annually designate a Chairperson of the Committee.

b. The structure of the Human Subjects Committee will require the following:
1. One representative for each college and one person elected at large from the faculty association.
2. One representative from MSUAASF.
3. One representative of the Administration appointed by the President in consultation with the Senior Vice President for Academic and Student Affairs.
4. One lay representative from the community or surrounding area.
5. One representative of the medical profession or psychiatric profession, whichever is applicable to the research being conducted. The medical/psychiatric professional must not be associated with the University, and preferably be an MD.

c. No member of the Committee shall be involved in either the initial or continuing review of an activity in which the member has a conflicting interest, except to provide information requested by the Committee.

d. The Human Subjects Committee shall meet twice during the year, or as the need for review of proposals requires, and additionally for special meetings called by the Chairperson. A simple majority of the members shall constitute a quorum of the Committee's business. In the absence of the Chairperson, the members present shall elect a Chairperson pro tem to conduct the business of the meeting.

e. Records shall be kept by the IRB of the following:
1. A list of IRB members.
2. Written procedures for the IRB.
3. Minutes of IRB meetings, including attendance, voting, action, and a summary of discussions.
4. Copies of research proposals reviewed.
5. Sample informed consent forms
6. Statements of finding provided to subjects.
7. Subject debriefing protocols when required.
8. Reports of any injuries to human subjects.
9. Progress reports submitted by investigators.
10. Record of continuing review activities.
11. Copies of all correspondence between the IRB and the investigators.
12. Records shall be kept three (3) years after the completion of research.

3. RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS:

It is expected that research design will satisfy (completely) the following:

a. **MINIMAL RISK:** Research procedures should be designed such that subjects are not exposed to physical, psychological, or social risks significantly in excess of that normally encountered in daily life. Any possible risks imposed must be weighed against the scientific importance and the potential benefits of the research.

b. **CONFIDENTIALITY:** Research procedures shall not disclose confidential information, including names and/or salient identifying characteristics, to other than the investigator(s) and their research staff. Further adequate provisions must be made to protect the confidentiality of information that is to be retained over an extended period of time.

c. **DEFINITION OF HUMAN RESEARCH**: Any systematic investigation designed to develop or contribute to generalizable knowledge based on data obtained from human subjects. This includes both original studies and replications of existing studies performed by faculty, students, or others. The phrase *considered to involve human subjects as used in this Policies and Procedures for the use of Human Subjects in Research* is consider to involve a full range of activities described in this section. It is important to note that specifically excluded are activities whose primary focus in on benefiting the individual(s) involved in the procedure.

d. **ACTIVITIES INCLUDED AS RESEARCH**
   1. Physical, chemical, electrical or psychological stimulation of responses with the human body as well as interview, observation of behavior, administration of tests or other techniques of measurement, examination, or evaluation of individual humans.
   2. Observation of the performance of activities; or of physical or psychological reactions of individual humans or groups of human beings to stimuli which are either controlled by the investigator or are present in a normal non-manipulated environment.
   3. Observation or evaluation of the products of individual performance of tasks or reactions to stimuli in which human beings are directly involved through their active conduct or through giving consent to have procedures performed upon them.

e. ACTIVITIES SPECIFICALLY EXCLUDED

These activities are distinguished from research activities and may be classified as beneficial services. These activities include:

   1. Teaching/training of individuals.
   2. Performance of diagnostic evaluation of individuals which will directly benefit the individual, or the relation of an individual to whom the human participant has agreed to assist, or the mass screening of disease.
   3. Performance of therapeutic procedures for the direct benefit of the individual participating or for the relation of an individual participating as in the interviewing relative to counseling services.
   4. Course/instructor evaluations given to students in the specific course during the semester. The completion of the evaluations must be anonymous.

f. **CLINICAL TRAINING AND RESEARCH TRAINING**

Clinical training covers those procedures and activities that are used to teach students to engage in professional activities with human beings other than the teacher or student involved in the procedure. *Clinical training* is excluded from the scope of this policy. *Research training* is intended to train the student in the methodology and the procedures for conducting research involving human subjects and is involved in the scope of this policy.

1. There may be cases where the original procedure is performed as *Clinical training* or as *Diagnosis* or as *Therapy* and at some later date the case record, or product of such service, would be the subject of study. In this case, it is the subsequent use of records or products that will constitute research involving human subjects and is subject to this policy.
2. If *Research training* utilizes research designs, methodology, procedures, and/or techniques that are frequently used and does not violate minimal risk or confidentiality, then the original design must be approved by the IRB with periodic review every five years.

g. **CATEGORIES OF HUMAN RESEARCH**

1. Research funded by external agencies requiring review; e.g., DDHS. Such research will be reviewed by the IRB in accord with the appropriate agencies guidelines.
2. Research not funded by agencies requiring review but employing human subjects in a manner not explicitly exempted. Such research shall be subject to either an expedited or full review by the IRB (see section IV) and must conform to the principles outlined in this document.
3. Explicitly exempted research. Involved are projects of no or low risk as defined by the American Association of University Professors (AAUP). These guidelines are principally based upon those established by the U.S. Department of Health and Human Services (DHHS). Specifically exempt from full IRB review are:
    a. Research on normal educational practices that is conducted in schools.
    b. Research which involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) if the investigator will record the information so obtained in a manner that makes identification of the subjects impossible.
    c. Research involving survey or interview procedures where the subjects are legally competent, and where the investigator identifies himself/herself, and states that he/she is conducting a research survey interview.
    d. Research involving the observation (including observation by participants) of public behavior in places where there is a recognized expectation of privacy, except where both of the following conditions exist:
        1. Observations are recorded in such a manner that the human subjects can be identified directly or through identifiers linked to the subjects, and
        2. The observations recorded about the subjects, if they became known outside of the research, could reasonably place the subjects at risk of criminal or civil liability, be damaging to their social standing, or be damaging to the subjects' financial standing, employability or reputation.

e. Research involving the collection or study of the existing data, if either the data are publicly available, or the investigator will record them in a manner that makes identification of the subjects impossible.

4. THE REVIEW PROCESS

A. For research involving human subjects risks of harm must be (1) of no greater probability or magnitude than those encountered in daily life or during performance in routine physical or psychological examination or tests; or (2) reasonable in relation to expected benefits of the research, and minimized by the use of the safest procedures. The review process is dependent on the amount of risk involved in regard to the human subjects. There are three forms of review which include:

1. **Exemptions from IRB Review**
   Projects associated with university courses (other than capstone projects and graduate theses) if the identity of a research subject is protected, and the subject is at minimal risk. The IRB recommends that departments conduct internal reviews on this type of research activity.

<u>Approved by the BSU Human Subjects Committee in February of 2014</u>: "There is no need to file when the research only involves Bemidji State University students 18 years of age and older, subject identity is kept confidential, the data is only used for classroom purposes or for evaluation/improvement of existing programs, and will only be used for internal purposes (i.e. and will NOT be used for any future publications or presentations)."

When secondary data sets are publicly available and have no identifying information, investigators will still need to file but claim <u>exempt status</u>. These will be reviewed by the Human Subjects convener or designee.

2. **Expedited Review**
   A review by the chair of the IRB and/or one other member of the IRB for research that involves no more than minimal risk, or to review minor revisions in previously approved research, or review revisions for proposals that were approved with contingencies.
3. **Full Review**
   A review of proposals by the entire IRB. This will be conducted for research that involves greater than minimal risk, or the research is of a psychologically sensitive nature.

B. INSTRUCTIONS

Use of human subjects in research requires approval from the Human Subjects Committee (IRB) **before** the research procedures are implemented and data are collected. Materials for review should be submitted to the IRB chair. If necessary, the

IRB chair will call a meeting of the full committee within 10 duty days of receipt of the materials. Review results will be given to researchers within an additional 10 (duty) days of the meeting.

The IRB will not review proposals that do not include:

1. Complete all items on the IRB Human Research Approval Form and Ethical compliance Questionnaire (See Attachment A) and attach it to the documents being submitted for review.
2. A 100-150 word abstract or summary of the proposed study.
3. A complete statement of the research methods, including copies of the instruments(s) being used to collect data (see Ethical Compliance Questionnaire). **Do not include literature review chapters or proposals.**
4. An Informed Consent Form (See attachment B for further description and sample consent forms)
5. Signed letter of permission from an institutional representative, if research is to be conducted in an institution such as a school, hospital, etc.
6. Debriefing Statement (See attachment C for further description and sample)
7. The original and six copies of this information are required for a Full Review. The original and one copy of this information are required for an Expedited Review.

5. MONITORING ONGOING RESEARCH

The IRB shall maintain ongoing review of nonexempt human research with respect to subjects' rights.

Monitoring procedures shall be arranged at the time of the review on a case-by-case basis. All projects will minimally be required to file a yearly report addressing the status of subject treatment.

Investigators who report substantial changes that may impinge on human subjects may be subject to further review by the IRB. Such a review shall occur at the discretion of the IRB.

Depending upon the particular circumstances of the research, one or more of the following actions may be employed as part of the monitoring procedure:

1. Discussions with the investigators.
2. Discussions with subjects who participated in the research.
3. Discussions with other persons involved in the research (E.g. assistants).
4. Site visits.
5. Solicitation of further documentation on research methodology impinging on human subjects.

6. COMPLAINTS

Anyone who believes that the rights of any human subject involved in a BSU related research project are being violated is encouraged to inform the IRB of their concern. The IRB will investigate the complaint to determine if, in the committee's majority opinion, it is valid. If so, the IRB shall require either (1) the problem be remedied or (2) the research be discontinued.

Notification of such action will be forwarded to the investigators and any appropriate agencies and/or university personnel (e.g., president, dean, department head, etc.)

January 2016

Policy:		
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