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 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
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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 Provost and Vice President for Academic 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 Provost and Vice President for Academic Affairs.
   4. One representative from the community or surrounding area.

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 detail how the following are satisfied:

   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 considered to involve a full range of activities described in this section. It is important to note that specifically excluded are activities whose primary focus is 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
方法和程序进行研究，并且涉及人类受试者，并且涉及政策的范围。

1. 有可能存在情况，原始程序是作为临床培训或诊断或治疗，在某些较晚的日期，个案记录，或产品，如该服务，将是研究的对象。在这种情况下，它将是随后的使用，个案记录或产品的研究，涉及人类受试者，并且受该政策的约束。
2. 如果研究训练利用研究设计，方法，程序，和/或技术，频繁使用，并不违反最小风险或保密，那么原始设计必须由IRB批准，并定期审查每五年。

g. 人类研究的类别:
1. 由外部机构资助的研究需要审查;例如，DDHS。此类研究将由IRB审查，与适当的机构的指南一致。
2. 未由要求审查的机构资助，但使用人类受试者的研究，将受到IRB的简略或全面审查(见第四章)，并且必须根据该文件中概述的原则。
3. 明确排除研究。包括项目为无或低风险，由美国大学教授协会(AAUP)定义的。这些指南主要是基于美国卫生和人类服务部(DHHS)。具体排除在全面IRB审查的有：
   a. 研究正常教育实践，是在学校进行的。
   b. 研究涉及的使用教育考试(认知，诊断，智力，成就)如果研究者将记录的信息，以一种方式使受试者无法识别。
   c. 研究涉及的问卷或访谈程序，受试者是合法的，并且研究者声明，他/她是进行一个研究问卷或访谈。
   d. 研究涉及的观察(包括观察参与者)的公共行为，在地方有公认的隐私，除了以下条件：
      1. 观察记录以一种方式，使受试者可以被直接或通过与受试者关联的标识符识别，和
      2. 观察记录关于受试者的信息，如果它们被知道，可能会在研究之外，会合理地使受试者处于犯罪或民事责任，损害他们的社会地位，或损害受试者的经济地位，可雇用或名誉。
   e. 研究涉及的收集或研究中已有的数据，如果这些数据是公开的，或研究者将记录的信息，使受试者无法识别。
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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.

   **Approved by the BSU Human Subjects Committee in February of 2014:** “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 exempt status. 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:
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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.)