*Montana State University-Northern Institutional Review Board (IRB)*

**Request for Review**

The human subjects regulations *[45 CFR Part 46]* define **research** as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” *[45 CFR 46.102(d)]*. A **human subject** is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information” *[45 CFR 46.102(f)].*

# Part 1 - Application Information

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| Principal Investigator |  |
| **Department** |  |
| **Title** |  |
| **MSUN Sponsor:** |  |

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| **Title of Project** | **Purpose of Project (one or two sentences)** |
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| **Consultants or co-investigators, if any** | **College or Department** |
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**Request for:**

* Exemption
* Expedited Review
* Full Review
* Continuing Review

However, some research involving human subjects may be exempt from the regulations. Please note that an exemption can be invoked only if **all** components of the research fit the category as described. You may find the decision chart helpful. For a copy of this chart, please contact the Grants and Sponsored Activities Office at 265-3726 or IRB@msun.edu.

**DIRECTIONS**: All research involving data collection or other investigations using human subjects must be reviewed and approved by the University’s Institutional Review Board for the Protection of Human Subjects (IRB). However, some types of research may be exempt from federal regulations for the protection of human subjects. While the researcher may request that his/her study be classified as exempt, only the IRB may determine whether a research project is, in fact, exempt or non-exempt. Please answer the following questions to determine whether you should submit a request for exemption.

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| 1. Does your research involve pregnant women, fetuses, or prisoners?

 1. Does your research involve using survey or interview procedures with children?
2. Does your research involve the observation of children in settings where the investigator(s) will participate in the activities being observed?
3. If data are to be recorded by audiotape or videotape is there potential harm1 to subjects if the information is revealed or disclosed?
4. If the subjects are to be identifiable either by name or through demographic data, is there potential harm to participants if the information is revealed?
5. Will collection include sensitive data (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of family member, memories of physical abuse)?
6. If the data, documents, records, or specimens are originally labeled in such a manner that subjects can be identified, directly or indirectly through identifying links, is the investigator recording the data in such a way that subjects can be identified, directly or indirectly through identifying links (i.e., demographic information that might reasonably lead to the identification of individual subjects – name, phone number; **or** any code number that can be used to link the investigator’s data to the source record – medical record number or hospital admission number)?
 | \_\_\_YES \_ \_\_NO\_\_\_YES \_ \_\_NO\_\_\_YES \_ \_NO\_\_\_YES \_\_\_NO \_\_\_YES \_\_\_NO\_\_\_YES \_\_\_NO\_\_\_YES \_\_\_NO |
| If you answered NO to **all** of the questions above, complete Part I, Request for Exemption.If you answered YES to **any** of the questions above, please complete Part II, the Initial Review Application Form, instead of this Request for Exemption.Please send the appropriate completed form to the IRB, c/o Provost Office, Montana State University-Northern, Havre, Montana 59501. Electronic submission to IRB@msun.edu is strongly encouraged and is likely to result in a quicker review process. You may not start your research until you have received written notification from the Board that your research qualifies as exempt. |
| Signature of Investigator | Date |

# Section Two: Additional Materials

Please attach the following materials to this request:

1. IRB Application
2. Summary of research protocol (note: include procedures needed to ensure participant anonymity)
3. Informed consent document (if applicable)
4. Copies of any survey, questionnaire, or interview instruments
5. Copies of any recruitment advertisements
6. Website addresses, if applicable
7. Certificate of completion of education in the protection of human research subjects.

# Section Three: Approvals FOR IRB USE ONLY

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| 1. Exemption Allowed (Category \_\_\_\_\_)
2. Exemption Not Allowed (Please see Comments)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of IRB Chair \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date | Comments: |

**Part II – Application for IRB Review**

**Section l: Additional Project Information**

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| Estimated duration of total project |  |
| **Estimated total number of subjects (including control subjects)** |  |
| **Age range of subjects** |  |
| **Sex of subjects** |  |
| **Where will study be conducted?** |  |
| **Source of subjects** |  |

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| **Grant Support for Project (if any)** | **Commercial Support for Project (if any)** |
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# Section Two: Information for IRB Review

Please answer each specific question and use additional sheets as needed. A response of “See attached project description or grant application” is not sufficient.

**1. Background.** Provide a brief historical background of the project with reference to the investigator’s personal experience and to pertinent scientific literature. *Use additional sheets as needed.*

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**2. The plan of study.** State the hypothesis or research question you intend to answer. Describe the research design, methods, interventions, and procedures (including standard or commonly used interventions or procedures) to be used in the research. Specifically, identify any interventions, procedures, or equipment that are innovative, unusual, or experimental. Where appropriate, provide statistical justification or power analysis for the number of subjects to be studied. *Use additional sheets as needed.*

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**3. Risks.** Indicate what you consider to be the risks to subjects and indicate the precautions to be taken to minimize or eliminate these risks. If any data monitoring procedures are needed to ensure the safety of subjects, describe them. *Use additional sheets as needed.*

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# Section Three: Selection of Subjects and the Informed Consent Process

**1. Populations.** Indicate whether this project involves any of the following subject populations?

1. Children (Children are defined by Federal law as anyone under age 18.)
2. Prisoners
3. Pregnant women
4. Cognitively impaired or mentally disabled subjects
5. Economically or educationally disadvantaged subjects

If you indicated any of the above, in the space below, please describe what additional safeguards will be in place to protect these populations from coercion or undue influence to participate. *Use additional sheets as needed.*

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**2. Subjects.** Describe how subjects will be recruited and how informed consent will be sought from subjects or from the subjects’ legally authorized representative. If children are subjects, discuss whether their assent will be sought and how the permission of their parents will be obtained. *Use additional sheets as needed.*

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**3. Compensation.** Will subjects receive any compensation for participation in cash or in kind?

1. Yes. *If so, please describe amount or kind of compensation in the space below.*
2. No.

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**4. Fees.** Will any finder’s fees be paid to others?

1. Yes. *If so, please describe the amount below.*
2. No.

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Section Four: Privacy and Confidentiality of Data and Records

**1. Sensitive Information.** Will identifiable, private, or sensitive information be obtained about the subjects or other living individuals? Whether or not such information is obtained, describe the provisions to protect the privacy of subjects and to maintain the confidentiality of data. *Use additional sheets as needed.*

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# Section Five: Conflict of Interest

# 1. Conflict of Interest Form (May be required if study is grant funded.). Is there a current Conflict of Interest form for each investigator on file at the Grants & Sponsored Activities Office (GSAO)?

# Yes

# No. *If not, please fill out the form (which can be obtained by contacting the GSAO at 265-3526. When complete, forward the original to Grants and Sponsored Activities, and attach a copy to this application.*

**I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the project design or informed consent document and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study. I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Investigator | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |

If more than one department or administrative unit is participating in the research and/or if the facilities or support of another department are needed, then the dean or administrative official or each unit must also sign this application. The Dean or Director of graduate studies must sign each application for graduate students.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Authorized Signature and Title | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Authorized Signature and Title | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |

# Section Six: Attachments

Please attach the following items in order for the IRB-committee to review your research:

*Note: provide the original plus 8 copies of all materials for FULL review; original plus 1 copy of all materials for EXEMPT and EXPEDITED review.*

* IRB Application form.
* The informed consent document.
* Any recruitment notices or advertisements.
* Any survey instruments, psychological tests (other than standard, commercially available instruments), interview forms, or scripts to be used in the research.
* Certificate of completion of education in the protection of human research subjects.
* Investigator’s qualifications (CV or biosketch).
* Formal research protocol, if available.
* Grant application, if applicable.