APPLICATION FOR HUMAN SUBJECTS RESEARCH APPROVAL

MSUB requires all projects that involve human subjects undergo review by the Institutional Review Board (IRB). Approvals are valid for 12 months and may be eligible for a 6-month renewal. For more information regarding human subject research, see <http://www.msubillings.edu/orc/pdf/IRB_Guide.pdf>.

Make sure you have the current application form. Old forms will **not** be accepted.

**1. Date:**

**2. Project Title:**

**3. Principal Investigator**

Name

Email

Address

Phone

Relationship to MSUB: [ ] Faculty [ ] Staff [ ] Graduate Student [ ] Undergraduate Student

 [ ] No Affiliation, explain:

 College/Department:

**4. Faculty Sponsor** - requiredfor student projects.

Name

Email

College/Department:

**5. Co-Principal Investigators**

1. Name

Email

1. Name

Email

1. Name

Email

1. Name

Email

1. Name

Email

1. Name

Email

**6. Training:** PI and all CO-PIs need to complete the Human Subjects Researching Training through the CITI Program. The training is free, and can be found at this web address: <https://about.citiprogram.org/en/series/human-subjects-research-hsr/>

 Certification for the PI and **all** Co-PIs **must be attached** or application will not be considered.

**7. Application Type:** [ ] New [ ] Renewal

 [ ] Modification/Addendum, explain:

[ ] Change of Status, explain:

**8. Project Type:**  [ ] Faculty Research [ ] Thesis/Capstone

 [ ] Class Project, name:

 [ ] Other, explain:

**9. Funding Source** (*if applicable*):

**10. Collaborative Effort** -Are any other institutions involved the in the proposed project?[ ] No [ ] Yes

* If yes, give name and nature of the collaborative relationship:

**11. Other Approval** - Has another IRB [e.g. tribal, other university] approved the research study? [ ] No [ ] Yes

* If yes, explain and include a copy of the approval form:

**12. Project Description** - Provide a concise but thorough description of the steps to be undertaken in the proposed activity and address the involvement of human participants:

**13. Objectives** - Briefly state what you hope to find or observe in this study:

**14. Procedures**

**14.1** Location(s) of study:

**14.2** Do you have approval to be in this location? [ ]  No [ ]  Yes [ ]  Not applicable

* If yes, attach a letter from a representative of the location (on letterhead), authorizing you to utilize the space
* If you answered no or not applicable, please explain:

**14.3** Does your study include sensitive data obtained from the MSUB Registrar (ex: student emails from Banner) or Institutional Research? [ ] No [ ] Yes

- If yes, do you have permission to use this information? [ ] No [ ] Yes

- If yes, please attach permission letter. If not, explain why not:

**14.4** Subject matter or kind(s) of information to be compiled from/about subjects:

**14.5** Means of obtaining the information (check all that apply). **Must attach questionnaire or survey instrument if used**.

[ ] Field/Lab observation [ ] In-person interview/survey

 [ ] Blood/Tissue/Urine/etc. (*must submit IBC*) [ ] Telephone interview/survey

 [ ] Medical records (*requires HIPPA form*) [ ] On-site survey

 [ ] Measure of motions/actions [ ] Mail survey

 [ ] Use of standard educational tests, etc. [ ]  Online survey

 [ ] Examine public documents, records, etc. [ ]  Examine private documents, records, etc.

 [ ] Other, explain:

**14.6** Will subjects be (*check all that apply*):

[ ] Videotaped [ ] Audio-taped [ ] Photographed [ ] N/A

Explain how the above media will be used, who will transcribe, and how/when destroyed:

**14.7** Mark if the project involves any of the following:

1. Deception of participants [ ]
2. Any form of punishment [ ]
3. Questions about any kind of illegal or illicit activity [ ]
4. Purposeful creation of anxiety [ ]
5. Any procedures that might be viewed as an invasion of privacy [ ]
6. Physical exercise or stress [ ]
7. Administration of any substance (e.g., food, drugs) [ ]
8. Exposure to materials that might be considered offensive [ ]
9. Inducements for participation (including course credit) [ ]

For each item marked above, please explain:

**15. Source of participants**

**15.1** Number of participants:

**15.2** Are minors included (under age 18, per Montana law)? [ ] No [ ] Yes

 If yes, specify age range: to

**15.3** Mark if the project targetsparticipants from any of the following groups:

1. Individuals over the age of 65 [ ]
2. Individuals who are educationally or economically disadvantaged [ ]
3. Individuals who are unable to provide their own legal informed consent [ ]
4. Individuals who are in institutions, e.g., prisons, nursing homes [ ]
5. Individuals who have physical or mental disabilities [ ]
6. Individuals who are part of a specific ethnic, racial, religious, etc. group of people [ ]

For each item marked above, please explain:

**15.4** Mark if the project incidentally includesparticipants from any of the following groups:

1. Individuals over the age of 65 [ ]
2. Individuals who are educationally or economically disadvantaged [ ]
3. Individuals who are unable to provide their own legal informed consent [ ]
4. Individuals who are in institutions, e.g., prisons, nursing homes [ ]
5. Individuals who have physical or mental disabilities [ ]
6. Individuals who are part of a specific ethnic, racial, religious, etc. group of people [ ]

For each item marked above, please explain:

**15.5** Characteristics of participants other than those above:

**15.6** Recruitment procedures to be used (attach all copies of flyers, advertisements, etc., that will be used in the recruitment process as these require IRB approval):

**16. Risks and Protection**

**16.1** Identify any foreseeable inconveniences or physical, psychological, social, or legal risks for participants (do not answer “None”):

**16.2** Describe the measures that will be taken to minimize these risks or to protect participants from potential risks:

**17. Benefits**

Describe any reasonably expected benefits for research participants:

**18. Confidentiality and Anonymity**

**18.1** How will you be presenting/publishing your research (i.e., conference presentation, published article, class presentation, etc.)? Please describe:

**18.2** How will subjects be identified in your personal notes, work papers or publications (may check more than one):

[ ] Identified by name and/or address or other identifying information

*(Secure written permission to identify. If identifying subjects comes with extra risks, create a confidentiality plan.)*

[ ] Confidentiality Plan

*(Identity of the subjects linked to research, but not specific data [e.g., individuals identified in the informed consent form but not included in publications]; identification key kept separate from data; or, data collected by third party [e.g., Survey Monkey, etc.] and identifiers not received with data.)*

[ ] Anonymous: never know the participant’s identity

*(A signed, informed consent form may be unnecessary [e.g., anonymous online survey]* ***unless*** *project is sensitive or involves a vulnerable population. You will still need to introduce your survey with a statement of consent and provide the script with your application materials.)*

**18.3** Explain the procedures used to protect the subject’s personal privacy. If you are using a Confidentiality Plan, include a plan for the gathering, maintenance, storage, and ultimately archival or destruction of materials:

*(Please note: You as the PI are responsible for retaining signed consent documents, IRB correspondence, and research records for at least* ***three years*** *after the completion of the research activity.)*

**18.4** Will information relevant to their participation be provided to subjects after the project? [ ] No [ ] Yes

* If yes, explain the contexts and nature of anticipated future contacts. (If a debriefing is planning, this is where you should describe the procedure and provide the script.):

**19. Informed Consent**

Important Information about Informed Consent:

* An informed consent form is required of all studies unless subjects remain anonymous or a waiver is justified. A signed copy of the consent/assent/permission form(s) must be offered to all subjects.
* Minor participants must have written parental or custodian permission. All minors from 10 to 17 are required to give written assent.
* For minors under 10 and individuals with delayed cognitive function, efforts must be taken to obtain verbal assent, and a script, written at a level appropriate for subjects’ understanding, must be included. The researcher will make a good faith effort to assess the actual level of competence of participants from these groups where there is doubt.
* All forms must be written at a level that can be understood by the participants.

**19.1** If your data collection instrument is electronic (i.e. survey through Qualtrics, SurveyMonkey, etc.), will an introductory consent opt-out be used? [ ]  Yes (*attach copy*) [ ]  No [ ]  Not Applicable

* If no, explain why it would be an impractical step in the process of gathering data. Is it foreseeable that the rights or welfare of any subjects are likely to be adversely affected by waiving informed consent? If yes, explain the nature of the adversity and the steps to be taken to minimize the effects:

**19.2** Will a written consent form be used with adult participants? [ ] Yes (*attach copy*) [ ] No

* If no, explain why it would be an impractical step in the process of gathering data. Is it foreseeable that the rights or welfare of any subjects are likely to be adversely affected by waiving informed consent? If yes, explain the nature of the adversity and the steps to be taken to minimize the effects:

 **19.3** Will a written parental permission form be used? [ ]  Yes (*attach copy*) [ ]  No [ ]  Not Applicable

* If no, explain why it would be an impractical step in the process of gathering data. Is it foreseeable that the rights or welfare of any subjects are likely to be adversely affected by waiving informed consent? If yes, explain the nature of the adversity and the steps to be taken to minimize the effects:

**19.4** Will a written minor assent form be used? [ ] Yes (*attach copy*) [ ] No [ ]  Not Applicable

* If no, explain why it would be an impractical step in the process of gathering data. Is it foreseeable that the rights or welfare of any subjects are likely to be adversely affected by waiving informed consent? If yes, explain the nature of the adversity and the steps to be taken to minimize the effects:

**ATTENTION**

**DO NOT SUBMIT WITHOUT SIGNATURES**

To obtain signature page, please use the IRB application’s DocuSign form (link found on the ORC website). You will need to have email addresses handy for your faculty sponsor and various co-PIs, where applicable.

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