**UNIVERSITY OF MONTANA**

Form RA-108

(Rev. 8/01/2022)

IRB Protocol No.:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Review Board (IRB)

*for the Protection of Human Subjects in Research*

**APPLICATION FOR IRB REVIEW**

At the University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects as outlined in the U.S. Department of Health and Human Services’ Office of Human Research Protections.

**Instructions:** A separate application must be submitted for each project. Email the completed form as a Word document to *IRB@umontana.edu**,* or submit a hardcopy (no staples) to the IRB office in the Interdisciplinary Science Building, room 104. Student applications must be accompanied by email authorization by the supervising faculty member or a signed hard copy. *All fields must be completed. If an item does not apply to this project, write in: N/A.* Questions? Call the IRB office at 243-6672.

1. **Administrative Information**

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| Project Title:       |
| Principal Investigator:       | UM Position:       |
| Department:        | Office location:       |
| Work Phone:       | Cell Phone:       |

**2. Human Subjects Protection Training** *(All researchers, including faculty supervisors for student projects, must be listed below and have completed a* [*self-study course on protection of human research subjects*](http://www.umt.edu/research/compliance/IRB/hspcourse.php) ***within the last three years*** *and be able to supply the “Certificate(s) of Completion” upon request. If you need to add rows for more people, use the* [*Additional Researchers Addendum*](http://www.umt.edu/research/compliance/IRB/Docs/Additional%20Researchers%20Addendum.doc)*.*

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| **All Research Team Members** (list yourself first) | **PI** | **CO-PI** | **Faculty****Supervisor** | **Research Assistant/Other** | **DATE COMPLETED IRB-approved Course mm/dd/yyyy** |
| Name:      Email:       | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Name:      Email:       | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Name:      Email:       | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Name:      Email:       | [ ]  | [ ]  | [ ]  | [ ]  |       |

**3. Project Funding** *(If federally funded, additional requirements may apply.)*

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| Is grant application currently under review at a grant funding agency? [ ] Yes *(If yes, cite sponsor on ICF if applicable)* [ ] No | Has grant proposal received approval and funding? [ ] Yes *(If yes, cite sponsor on ICF if applicable)* [ ] No |
| Agency | Grant No. | e-Prop # | Start Date | End Date | PI on grant |
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**Note to PI:**  Use any attached IRB-approved forms (signed/dated) as “masters” when preparing copies. Notify the IRB if any significant changes or unanticipated events occur. Failure to follow these directions constitutes non-compliance with UM policy.

For UM-IRB Use Only

**IRB Determination:**

\_\_\_\_\_ Not Human Subjects Research

\_\_\_\_\_ Approved by Exempt Review, Category # \_\_\_\_\_\_

\_\_\_\_\_ Approved by Expedited Review, Category #\_\_\_\_\_\_

\_\_\_\_\_ Full IRB Determination

 \_\_\_\_\_ Approved *(see* **Note to PI***)*

 \_\_\_\_\_ Conditional Approval *(see memo) -* IRB Chair Signature/Date: ­­\_\_\_\_\_\_\_\_­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ Conditions Met *(see* **Note to PI***)*

 \_\_\_\_\_ Resubmit Proposal *(see memo)* Risk Level: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_ Disapproved *(see memo)*

Final Approval by IRB Chair/Manager: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expires: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

*<In an effort to be environmentally responsible, please expand/reduce box size as needed.>*

**4. Purpose of the Research Project:**  Briefly summarize the overall intent of the study. Your target audience is a non-researcher. Include in your description a statement of the objectives and the potential benefit to the study subjects and/or the advancement of your field. **Generally** **included are literature related to the problem, hypotheses, and discussion of the problem’s importance.** Expand box as needed.

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 4.1 What do you plan to do with the results? If not discussed above, include considerations such as whether this is a class project, a project to improve a program/school system, and/or if the results will be generalized to a larger population, contribute to the general field of knowledge, and/or be published/presented in any capacity.

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| Is this part of a thesis or dissertation? [ ] No [ ] Yes If yes and other than the PI’s, then whose?       |

**5. IRB Oversight**

Is oversight required by other IRB(s) [e.g., tribal, hospital, other university] for this project? [ ] Yes [ ]  No

 If yes, please identify IRB(s):

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**6. Subject Information:**

 6.1 Human Subjects *(Describe subject population, any special characteristics, targeted age range and gender, and*

 *justification for any exclusions)*:

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6.2 How many subjects will be included in the study?

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

 If yes, specify age range:       to

6.4 Are members of a physically, psychologically, or socially vulnerable population being specifically targeted?

 [ ] Yes [ ]  No

 If yes, please explain why the subjects might be physically, psychologically or socially vulnerable:

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6.5 Are there other special considerations regarding this population? [ ] Yes [ ]  No

 If yes, please explain:

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6.6 Do subjects reside in a foreign country? [ ]  Yes *Specify country:*       [ ]  No

If yes, please fill out and attach Form RA-112, Foreign Site Study Appendix (<http://www.umt.edu/research/compliance/IRB/Docs/foreign.doc>).

6.7 How will the subjects be selected or recruited? Include a bulleted list of inclusion/exclusion criteria. ***(Attach copies of all flyers, advertisements, etc,. that will be used in the recruitment process as these require UM-IRB approval)***

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 6.8 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

*(Secure written [e.g., ICF] or verbal permission to identify; if risk exists, create a confidentiality plan.)*

 [ ]  Confidentiality Plan

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

 [ ]  Never know participant’s identity

*(An ICF may be unnecessary [e.g, anonymous survey, paper or online]* ***unless*** *project is sensitive or involves a vulnerable population.)*

 6.9 Describe the means by which the human subject’s personal privacy is to be protected, and the confidentiality of information maintained. If you are using a Confidentiality Plan (as checked above), include in your description a plan for the destruction of materials that could allow identification of individual subjects or the justification for preserving identifiers.

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6.9a Will subject(s) receive an explanation of the research – separate from the informed consent form (if applicable) – before and/or after the project? [ ]  Yes *(attach copy and explain when given)* [ ]  No

**7. Information to be Compiled**

 7.1 Explain where the study will take place *(physical location not geographic). If permission is required to conduct the*

 *research at the location or to use any of the facilities, indicate those arrangements and attach copies of written permission:*

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 7.2 Will you be working with infectious materials, ionizing radiation, or hazardous materials? Please specify. *(Do not*

 *include here standard biological samples, such as blood, buccal cells, or urine; specify those in #7.6.)*

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

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 7.4 Activities the subjects will perform and how the subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. **Provide enough detail** so the IRB will be able to evaluate the intrusion from the subject’s perspective (expand box as needed):

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7.5 Is information on any of the following included? *(check all that apply)*:

 [ ]  Sexual behavior [ ]  Drug use/abuse

 [ ]  Alcohol use/abuse [ ]  Illegal conduct

 [ ]  Information about the subject that, if it became known outside the research, could reasonably place the

 subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or

 employability.

 7.6 Means of obtaining the information *(check all that apply).* **Attach questionnaire or survey instrument**, if used:

[ ]  Field/Laboratory observation [ ]  In-person interviews/survey

[ ]  Blood/Tissue/Urine/Feces/Semen/Saliva [ ]  Telephone interviews/survey

 Sampling *(IBC Application must be submitted)* [ ]  On-site survey

 [ ]  Medical records *(require HIPAA form)* [ ]  Mail survey

 [ ]  Measurement of motions/actions [ ]  Online survey *(attach* [*Statement of Confidentiality*](http://www.umt.edu/research/compliance/IRB/Docs/Online%20Survey%20Confidentiality.doc)  *and*

 *see* [*Guidance for Online Survey Research)*](https://www.umt.edu/research/compliance/IRB/Docs/guidance-for-online-survey-research.pdf)

 [ ]  Use of standard educational tests, etc. [ ]  Examine public documents, records, data, etc.

 [ ]  Other means *(specify)*:      [ ]  Examine private documents, records, data, etc.

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

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

 *(securing an additional signature is recommended on consent/assent/permission forms)*

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

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7.8 Discuss the benefits (does not include payment for participation) of the research, if any, to the human subjects and to scientific knowledge *(if the subjects will not benefit from their participation, so state)*:

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7.9 Cite any payment for participation (payment is not considered a benefit). Include incentives of monetary value. If grant funding is not indicated in item #2, please specify the source of the funding and in what form it is to be dispersed.

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7.9a Outline, **in detail**, the risks and discomforts, if any, to which the human subjects will be exposed *(Such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. As a result, one can never guarantee that there are no risks – use “minimal.” Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified)*:

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 7.9b Describe, **in detail**, the means taken to minimize each such deleterious effect or violation::

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**8. Informed Consent**

An informed consent form (ICF) is usually required, unless subjects remain anonymous or a waiver is otherwise justified below. *(Templates and examples of* *Informed Consent, Parental Permission, and Child’s Assent Forms are available at* [*http://www.umt.edu/research/compliance/IRB/forms.php*](http://www.umt.edu/research/compliance/IRB/forms.php)).

* A signed copy of the consent/assent/permission form **must be offered to all subjects**, including parents/guardians of subjects less than 18 years of age (minors).
* Use of minors
	+ All minor subjects (under the age of 18) must have written parental or custodial permission (45 CFR 46.116(b)).
	+ All minors from 10 to 17 years of age are required to give written assent ([IRB Child Subjects policy](https://www.umt.edu/research/compliance/IRB/Docs/childsubjects.pdf)).
	+ Assent by minor subjects: All minor subjects are to be given a clear and complete picture of the research they are being asked to engage in, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand.
	+ Minors less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage.
		- Good faith efforts must be made to assess the actual level of competence of minor subjects where there is doubt.
		- The Minor Assent Form must be written at a level that can be understood by the minor, and/or read to them at an age-appropriate level in order to secure verbal assent.
* Is a **written** informed consent form being used? [ ]  Yes *(attach copy)* [ ]  No (*justify below)*
* *Written consent means that physical, handwritten signatures will be obtained on the informed consent forms.*

To waive the requirement for written informed consent (45 CFR 46.117), describe your justification:

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* Is a written parental permission form being used? [ ]  Yes *(attach copy)* [ ]  No

*(If yes, will likely require minor assent form)*

* Is a written minor assent form being used? [ ]  Yes *(attach copy)* [ ]  No

 *(If yes, will likely require parental permission form)*

**Principal Investigator’s Statement**

*By signing below, the Principal Investigator agrees to comply with all requirements of the University of Montana IRB, the U.S. Department of Health and Human Services Office of Human Research Protection Guidelines, and NIH Guidelines. The PI agrees to ensure all members of his/her team are familiar with the requirements and risks of this project, and has completed the Human Subject Protection Course available at* [*http://www.umt.edu/research/compliance/IRB/hspcourse.php*](http://www.umt.edu/research/compliance/IRB/hspcourse.php).

I certify that the statements made in this application are accurate and complete. I also agree to the following:

* I will not begin work on the procedures described in this protocol, including any subject recruitment or data collection, until I receive final notice of approval from the IRB.
* I agree to inform the IRB in writing of any adverse or unanticipated problems using the appropriate form. I further agree not to proceed with the project until the problems have been resolved.
* I will not make any changes to the protocol written herein without first submitting a written **Amendment Request** to the IRB using form RA-110, and I will not undertake such changes until the IRB has reviewed and approved them.
* It is my responsibility to ensure that every person working with the human subjects is appropriately trained.
* All consent forms and recruitment flyers must be approved and date-stamped by the IRB before they can be used. The forms will be provided back to the PI in PDF format with the IRB approval email. Copies must be made from the date-stamped version. All consent forms given to subjects must display the IRB approval date-stamp.
* I will keep a copy of this protocol (including all consent forms, questionnaires, and recruitment flyers) and all subsequent correspondence with the IRB.
* I understand that failure to comply with UM and federal policy, including failure to promptly respond to IRB requests, constitutes **non-compliance** and may have serious consequences impacting my project and my standing at the University of Montana.

Signature of Principal Investigator: Date:

 *(Type for electronic submission; sign for hard copy)*

**NOTE:** Electronic submission of this form must be sent from your University of Montana email account.

**Do not leave the above line blank. Unsigned applications will not be accepted.**

**Attention Students: If you are submitting your application by hard copy (paper), please have your faculty supervisor sign the statement below. If you are submitting your application electronically (by email), then you must have your faculty supervisor send a separate email to the IRB affirming the statements below.**

As the student’s **faculty supervisor** on this project, I confirm that:

1. I have read the IRB Application and attachments.
2. I agree that it accurately represents the planned research.
3. I will supervise this research project.

Faculty Supervisor:

  *(Type or print name)*

Faculty Supervisor Signature:  Date:

 *(Sign for hard copy)*

Department:       Phone:

*Please read the following before submitting your application.*

**Top reasons that IRB applications are returned for revisions:**

1. Not using the most current version of the forms and templates by downloading them directly from the IRB website.
2. The instructions on the forms were not followed.
3. All items on the checklist/application were not completed.
4. The completion date(s) for the human subjects protection course for each team member, including the faculty supervisor, is missing or outdated, in which case the course needs to be re-taken. Certificates are valid for 3 years.
5. The current Informed Consent Form template was not followed, and required elements were not included.
6. Student did not obtain the signature of (or initiate email from) his/her faculty supervisor.
7. Required attachments were not provided, such as the informed consent form, any survey instruments, questionnaires, interview questions, advertisement materials (flyers), online Statement of Confidentiality form, Foreign Site Study Appendix, etc.
8. A letter of permission from external sites was not obtained or included (especially from school or government officials).
9. Contradictory or inconsistent information within the checklist and/or consent form (or between them).
10. Poor English grammar and spelling, especially in the consent form.
11. Not writing the consent form in the 2nd voice (except the very last paragraph).
12. Incomplete grant or funding information.
13. Not signing and dating the last page of the application. If submitting by email, this information may be typed-in. Do not leave this section blank.
14. Having questions, but not contacting the IRB office to get them resolved before submitting the application.

Need assistance?  Please contact the IRB office at 243-6672 or email IRB@umontana.edu.