

Rev. 11/2015

INSTITUTIONAL REVIEW BOARD

for the Protection of Human Subjects in Research FWA 00000078

> Research & Creative Scholarship University Hall 116 The University of Montana Missoula, MT 59812 Phone 406-243-6672 | Fax 406-243-6330

Getting Started: A Quick Overview of the IRB Review Process for Investigators

- 1. Make sure that your project will require IRB review. Read the document "Is it Human Subjects Research?" If in doubt, contact the IRB office at 243-6672 or email irb@umontana.edu.
- 2. All research team members need to complete a <u>Human Subjects Protection course</u> before the IRB application can be approved (may be waived by the IRB Chair for some exempt projects). This includes the PI, Co-PI, faculty advisor, and any research assistants. Be sure to keep the certificate of course completion, and be ready to enter the date of completion on the IRB Checklist/Application in item #2.
- 3. Fill out the IRB Checklist/Application. Follow the directions on the form.

Other considerations and documents that may be required:

- Recruitment materials (flyers/posters, etc.) these must be included with the application, and they must be approved and date-stamped by the IRB before using. See <u>Advertisement Guidance</u>.
- Informed Consent Form this must be approved and date-stamped by the IRB before using; see the ICF template.
- Minors (age 17 or younger) include a <u>parental permission form</u> and <u>minor assent form</u>; these must be approved and date-stamped by the IRB before using.
- Online surveys attach the <u>Statement of Confidentiality form</u> and a copy of the actual survey questions; use the <u>online consent template</u> and incorporate it into the beginning of the survey.
- Off-site locations (schools, reservations, parks, etc.) include a written letter (or email) of permission to conduct your research from the proper site official.
- Foreign Countries fill out and attach the <u>Foreign Site Study Appendix (RA-112)</u>.

All documents submitted by email (electronically) must be sent from your **UM email account**. Alternatively, hard copies (signed) may be submitted to the Office of the Vice President for Research in University Hall 116. Students must have their faculty supervisor sign a hard copy of the application (see last page) <u>OR</u> have them send an email with their authorization to <u>irb@umontana.edu</u>.

How long will this process take?

If no additional information or materials are needed, then approximately:

- 7 business days or less for Expedited and Exempt review (no application deadlines)
- 4 8 weeks for Full Committee review (applications due by 1st day of the month)

IRB Essentials

- The IRB review must be conducted <u>before</u> you involve human participants in your research, including any study advertisement, subject recruitment, or data collection.
- You need to have final, written IRB approval before you begin. All consent forms and flyers must be approved, date-stamped, and signed by the IRB before being used.
- If you do not have IRB approval for your research, your research project cannot be recognized by UM and, for students, may not be accepted to fulfill any academic requirements.
- Except in very limited circumstances, the IRB cannot review research that has already been conducted.

Expedited and Full Committee Reviewed Projects: Additional Requirements

- Continuing Review <u>projects reports</u> are due annually <u>before</u> the expiration date. Projects for which
 approval has expired are in non-compliance with federal regulation and UM IRB policy, and all work
 must cease.
- Closing out the Project a <u>closure report</u> must be filed when the research is completed, when analysis is continuing with de-identified data only, or if the project has been abandoned or significantly postponed.

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

Please note: The information provided here is intended to be a quick reference for PI's on how to get started with the IRB review process. It is not intended to be comprehensive, and the IRB may require additional materials. Official UM IRB policies can be found on the IRB website.