Spring 2013

IRB hopes to provide two newsletters each academic year. If you have suggestions for what you might like to see, please let me know (irb@mnsu.edu).

We hope to provide information that you might find useful when you prepare your documents for IRB to review. As always, please do not spend hours looking for something. Give me a call (5102) or e-mail (irb@mnsu.edu) if you cannot find something, find mistakes on our web site, or need help.

I am available to come to your classes and give presentations regarding any IRB issue you would like. I can come to your office to help with IRBnet. We can chat on the phone. This semester I will also be available in ML 88 on Tuesday afternoons from 1:00 PM until 2:00 PM. Come see me there.

Remember that IRB is always happy to receive suggestions for how to make things easier.

Mary Hadley, IRB Coordinator

Reviews

Common Mistakes

Remember you must submit and sign your submission before IRB can review it.

Remind your students that they must give you, the PI, access to the submission so you can sign it. IRB cannot review submission with students as the PI or if the PI has not signed the submission. A student signature is not sufficient.

Please remember that the people assigned to review the document may not be familiar with your area of expertise. Write your application and consent form in language understandable by someone in grade eight.

General Information

The application form underwent significant changes when we moved to IRBNet and some modifications have been made to the new form. It is clear to IRB that parts of the form are not clear, and it appears that we ask for the same information in more than one place. We are working on revisions to simplify and clarify the form. Suggestions are welcomed.

Outside Agency

In the application form you are told, “*If data will be collected off campus, upload with this application a signed letter indicating permission from the institution/organization (on official letterhead) to allow the data to be collected at that location.*”

Please do not obtain this letter until your proposal is approved. How can you tell an outside agency what you are doing if the research has not yet been approved?
Some Definitions

**Amendment:** when IRB requires changes in an as yet to be approved protocol.

**Revision:** when you would like to make minor changes to an approved protocol.

**Continuation:** Level II and III research is approved for one year less a day. If you wish to continue collecting data past the approved today you will request a continuation.

**Closure:** When you have completed your data collection, you ask IRB to close the project.

If changes are requested by IRB after your project is reviewed, you will receive a letter with a request to make amendments/ modifications. The direction for doing so are included in the letter.

If you wish to request a Revision, Continuation, or Closure, please contact me and I will forward the direction.

IRB is in the process of re-modeling its web site. The directions for how to submit these documents will be included in the re-modeled web site.

For IRB purposes

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:
- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart reviews

Investigations designed to develop or contribute to generalizable knowledge are those designed to:
- draw general conclusions
- inform policy, or
- generalize findings beyond a single individual or an internal program (e.g., publications or presentations.)

Results do not have to be published or presented to qualify the experiment as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research.

Participants in research studies deserve protection whether or not the research is published.

Source: http://www.virginia.edu/vpr/irb/hsr/human_subject_research_definition.html