Guidelines for Master's Theses and Projects Involving Human Subjects

Tips for Form Completion (continued)

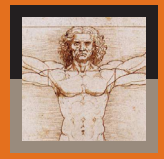
- Risks and benefits
  - Remember that no study is "no risk"
  - Minimal risk is defined as risk not greater than that encountered in everyday life
- Confidentiality
  - Data are to be protected with "two locks." This means that data must be both deidentified and securely stored in a locked cabinet or office.
  - Any electronic data must be password protected
  - Any electronic data that is unable to be deidentified (such as a video) must be password protected and encrypted
  - Protocol must note that all data are to be retained for a minimum of three years in compliance with regulations
- Consent form
  - Parental consent is required for those under 18
  - Parents will want to know
    - What their children will be doing
    - Is this a part of regular coursework
    - Will their children be singled out
    - Voluntariness
    - Confidentiality
    - Contact for IRB and for researcher
  - All children who are old enough to choose to participate must also give their assent to participate. This should be written at the child's reading and comprehension level.
  - If working with a school or other outside agency or group, the IRB must receive a letter indicating permission to collect data at the agency

Where can I get more information?

Researchers should refer to the Research Compliance section of the Research Foundation website at **www.rf.buffalostate.edu**. The Investigator's Guide to Research with Human Participants, the forms for human subjects applications, and other useful handouts and tools can be downloaded from that site.

Institutional Review Board for Human Subjects Protection

Guidelines for Master's Theses and Projects Involving Human Subjects



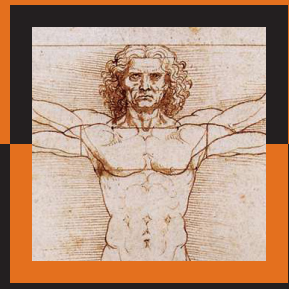
Researchers may also contact Gina Game, Institutional Review Board Administrator, via e-mail at **gina@rf.buffalostate.edu** or by phone at **716-878-6700**.

www.rf.buffalostate.edu

Buffalo State™
State University of New York

Institutional Review Board for Human Subjects Protection

Guidelines for Master's Theses and Projects Involving Human Subjects



Buffalo State™
State University of New York

Institutional Review Board for Human Subjects Protection

Guidelines for Master's Theses and Projects Involving Human Subjects

Does my research need to be reviewed by the IRB or its representative?

If your research involves humans, the answer is yes. This includes research in which you use a database of information that someone else collected. As long as you are doing research that involves living humans, your research requires some level of review.

Why do I need to do this?

Review of all research involving human participants is required by an agreement, called a Federal-Wide Assurance, signed by Buffalo State and the federal Office of Human Research Protection. This assurance is designed to protect the rights of participants. By protecting the participants, this oversight also protects the researcher and the College. Failure to follow the federal regulations, including failing to submit a protocol for research, can have serious consequences for both the researcher and the College.

What do I need to do first?

The first step is to determine what level of review is required. The different levels of review correspond to different levels of risk involved in the research. The riskier the research, the greater the level of review that is required. Many of the master's research projects at Buffalo State are found in our education programs and involve children. Because children are a vulnerable population, there are special protections in place for them. Once you have identified the appropriate level of review, you will need to download the correct form from the Research Compliance link on the Research Foundation's website (www.rf.buffalostate.edu).

How do I know what level of review my research requires?

1 LEVEL 1: Department Level Review

Student research that may be reviewed at the Department Level includes laboratory projects, educational exercises and class projects, and action research within a classroom with performance or grades as the sole outcome measure. In order to qualify for Department Level Review, the research must be disseminated only within the Buffalo State campus.

2 LEVEL 2: Exempt or Limited Review

The federal government uses the term "Exempt" to indicate that a protocol is exempt from the higher levels of review because of its low risk for harm. This does not mean that the research is exempt from oversight. Exempt research simply requires less paperwork and may be reviewed by a designee of the IRB. Research that qualifies for Exempt or Limited Review includes, but is not limited to, action research in the classroom with syllabus-related outcomes, including syllabus-related attitude questions, surveys on innocuous topics completed by adults, anonymous surveys (even on more controversial topics) completed by adults, and research using existing publicly available or deidentified databases.

3 LEVEL 3: Expedited

Research that is more intrusive than exempt research or that requires the participation of children (aside from action research as noted in Levels 1 and 2) may qualify for Expedited Review. In this case, the protocol is similar to that of the Full-Board Review, but the research is reviewed by one designated member of the IRB. The designee may approve the research, request additional information, or submit the proposal to the IRB for Full-Board Review and approval. Some examples of Expedited Review include educational research that goes beyond syllabus-related outcomes, research on individual or group behavior of normal adults where there is no intervention or deception, and all research conducted outside of the United States.

4 LEVEL 4: Full-Board Review

Full-Board Review is the highest level of review for human subjects protocols and is designed for research that is sensitive in nature. The review is conducted at the next convened meeting of the IRB. Any research that might put participants at increased risk of harm must be reviewed at this level.

Do I need ethics training?

All faculty members conducting human subjects research or supervising student research need to complete ethics training, as specified by the federal regulations. All students conducting human subjects research also need to complete this training. Although researchers may complete other federally-approved training programs to satisfy this requirement, we encourage researchers to complete the CITI program, for which the campus has a site license. To access this training, visit the CITI website www.citiprogram.org. A link to the CITI directions is located on the Research Foundation's website www.rf.buffalostate.edu/research-compliance/human-participants.html.

Tips for Form Completion

Review of protocols generally takes just a few weeks. After an initial review, we will contact the researcher with any questions or concerns. No further review will occur until the missing information has been submitted. This is the most frequent cause of delay in review. To prevent this, here are some tips:

- Purpose and background may be brief
  - About a page is generally fine for straightforward research
  - Identify concisely what study will accomplish
- Characteristics of subject population
  - Target of study may not be family members
  - Estimate somewhat larger number than you expect. This will prevent you from having to submit a request for changes to your study if you end up recruiting more participants.
- Be specific about how participants will be recruited
- Describe the study design in detail. For example…
  - How many sessions will you complete?
  - How long is each session?
  - Over what period of time will sessions be conducted?
  - What measures will be used? Attach all questionnaires.
  - If this is in a school setting, are any of these measures part of regular instruction that all students will do regardless of the study? What will nonparticipating students do during the study? How will they not be singled out?

Buffalo State™
State University of New York