

Frequently Asked Questions

COMPLIANCE – HUMAN SUBJECTS RESEARCH (IRB)

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What is "Human Subjects Research"?

Human Subjects Research includes ANY data gathering on humans for scientific purposes. Data gathering for purely administrative or pedagogical purposes is not included.

Why does UM-St. Louis review research involving human subjects?

Review of Human Subjects Research is mandated by the National Research Act (Public Law 93-348) and implemented by [Federal Regulations \(45 CFR 46\)](#). A university not in compliance with the law could lose all federal funding of its programs, including student programs. From an ethical standpoint, such review is useful because even the most moral scientist may not fully consider the perspective of the research subject.

Whose research is reviewed?

The research of faculty, staff and students of UM-St. Louis that involves human subjects requires review.

Who reviews the research?

The Institutional Review Board (IRB) reviews Human Subjects Research at UM-St. Louis. Members of the committee come from a variety of disciplines, including at least one member whose primary concerns are nonscientific and one member who is not affiliated with the university.

Does the entire committee review all research activities on campus?

The IRB can exempt certain projects from full review. A principal investigator must apply for this exemption. The application form, which can be downloaded from the ORA web site FORMS page, will help you determine which parts you must complete.

What subject groups require special protection?

Federal regulations require special protection for Human Subjects Research involving prisoners, the cognitively impaired, fetuses, pregnant women, or human in vitro fertilization. Studies of these groups cannot be granted an exemption from full review and such exemption for minors (children under 18) is limited.

What are consent and assent forms?

In most studies, the subject or a person responsible for the subject must sign a **consent form** before the research can proceed. The consent form must fully inform the subject about the research in which they are about to participate. A subject who is a minor must sign an **assent form** and his or her guardian must sign a **consent form**. You can download consent and assent form templates on the ORA web site FORMS page.

What are the requirements for confidentiality?

The investigator must ensure that others are not privy to the identity of subjects or to identifiable information about them without their consent. How confidentiality is maintained must be described in detail on the application form and in plain English on the consent form. Any limitations on the investigator's ability to maintain confidentiality must also be stated (e.g. many professionals are legally required to report cases of child abuse).

Maintaining confidentiality is especially important when the research concerns criminal activity or uses prisoners. State law makes certain communications to specific professionals such as physicians, clinical psychologists, ministers and rabbis "privileged," meaning that the professional may not testify about those communications unless the client consents. This type of privilege does not extend to researchers, and researchers may be ordered by court to produce information obtained in their research.

How are risks assessed?

When you apply for human subjects review, you will be asked to assess the risks of your research. Human research almost always involves risk that may be social, psychological, financial, or even physical. For example, a seemingly innocuous survey question about test anxiety might bring back truly traumatic memories. Others, in addition to the participant, may be at risk, including persons discussed in the study, the investigator, society at large, and UM-St. Louis. The IRB does not expect research to be free from risk, but it does expect the investigator to be aware of the risks, to minimize risk when possible, and to take appropriate precautions whenever necessary. For the proposed research, the benefits should outweigh the risks.

What precautions must I take if my research involves deception?

The investigator must show that the research could not be accomplished without using deception and describe how the degree of deception has been minimized. An investigator should debrief subjects after the deception and include the debriefing statement in the application.

Where can I get more information?

This FAQs sheet is only an introduction to the terminology and procedures for Human Subjects Research; there are many other issues and statutory requirements that may apply to your particular projects. Links to the federal regulations, informational guides, the University Assurance document, issues such as informed consent and confidentiality, and all necessary forms can be found on the ORA web site. Contact John Hancock (hancockjc@umsl.edu) if you have questions.