

Quick Start Guide for Investigators

This Quick Start guide explains what investigators must do to meet the requirements of the Institutional Review Board (IRB) when conducting research projects that involve human subjects.

The purpose of IRB oversight of research is to assure the protection of the rights and welfare of human subjects.

Step 1 - Does My Study Require IRB Oversight?

The information in this section is intended to assist the Principal Investigator (PI) in understanding how the IRB determines the need for oversight of a research study.

A study requires IRB oversight if it meets both of the following definitions:

- A. It is research **and**
- B. It directly involves human subjects or private, identifiable information about or from human subjects (including biological samples, etc.).

If you are sure that your proposed project requires IRB oversight, please read Steps 2, 3, and 4.

If you believe that your project does not meet these definitions (as explained in A and B below), please submit a letter or e-mail to the IRB briefly outlining your proposed project and explaining why you believe it does not meet the definitions of research with human subjects.

If the IRB determines that your proposed project:

- Does not require IRB oversight – please read Steps 2 and 3 and keep a copy of the IRB determination in the records for your project (in case a question ever arises as to whether IRB oversight was required).
- Does require IRB oversight – please read Steps 2, 3, and 4

Graduate students planning a thesis or dissertation in a social/behavioral field will most likely require IRB oversight.

If you have any questions relating to IRB processes, please contact a Senior Grant Specialist in the IRB office at (813) 974-9343.

A. Is It Research?

According to the Code of Federal Regulations, 45 CFR 46.102 (d), **“Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Systematic investigation means an activity that may include:

- Collection of observational or qualitative data;
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups;
- Collection of data using experimental designs such as clinical trials; or
- Some demonstration and service activities.

Contributions to generalizable knowledge means public presentation of the study data through any of the following:

- Meetings, conferences, seminars, poster presentations, et al;
or
- Publications, including journal articles, papers, dissertations, and Master's Theses and Projects.

B. Are Human Subjects Involved?

According to the Code of Federal Regulations, 45 CFR 46.102 (f):

A **Human subject** is any living individual about whom an investigator obtains data

- Through observation of the individual, or
- Through intervention or interaction with the individual, or
- That is private information.

Observation includes

- Counting the frequency or otherwise recording specific behaviors of humans; or
- Audio or video tape recording the subject's behavior or interactions.

Intervention includes

- Manipulations of the subject's environment; or
- Applications of procedures or treatments, such as drugs, devices, or biologics; or
- Administration of psychological therapies or counseling to change behavior or promote well-being.

Interaction includes

- Communication with the subject; or
- Interpersonal contact with the subject; or
- Physical procedures to collect data, such as taking blood samples.

Private information must be individually identifiable and includes

- Information about behavior that the subject expects will not be observed or recorded; or
- Specific information about the individual that the individual can reasonably expect will not be made public.

Step 2 - What If My Study Is Funded?

If your study is funded, you should contact Sponsored Research (if you have not already done so) at (813) 974-2897 or <http://www.research.usf.edu/sr/> and then please go to Step 3 below.

If your study is not funded, please go to Step 3.

Step 3 – What About the HIPAA Privacy Rule?

HIPAA requirements are independent of IRB requirements.

Please refer to the [HIPAA Decision Tree](#) to find out whether or not your study must comply with HIPAA.

More information about HIPAA, including whom to contact, is available on the [HIPAA Web Page](#).

Step 4 – Yes, My Research Does Require IRB Oversight. What Next?

Please complete Steps **A** through **D** below:

A. Complete IRB education requirements.

All USF and affiliate faculty, staff, and students who are involved in research using human subjects must complete approved education in Human Subjects Protection annually and must submit a copy of the certificate of completion to the Division of Research Compliance.

Please read the [Mandatory Investigator Education Policy](#) carefully and complete the required education.

- B. Submit a current curriculum vitae or resume** (this is a one-time requirement).
- C. Complete the Investigator Responsibility Certification Form** (this is a one-time requirement).

Each Principal Investigator and Co-Principal Investigator must read and sign the [Investigator Responsibilities Certification](#) and submit it to the Division of Research Compliance. By signing and submitting this Certification, the Investigators certify that they have read the following documents and that they agree to conduct their research in accordance with these documents:

- [The Belmont Report](#). This report is a summary of the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- [Federalwide Assurance](#) - FWA00001669. This contract between USF and the Office of Human Research Protection (OHRP) of the Department of Health and Human Services assures that Investigators conducting human subject research at USF will follow the ethical principles outlined in the Belmont report.

The official listing of USF IRBs and USF Affiliate IRBs is located at [OHRP Web Page for Domestic Assurances](#).

- The Code of Federal Regulations for the Protection of Human Subjects:
[Title 45, Part 46](#)
[Title 21 CFR Part 50](#)
[Title 21 CFR Part 56](#)
<http://www.fda.gov/oc/ohrt/irbs/appendixc.html>
- [IRB Policies and Procedures Manual](#)

- D. Complete the correct application (the three types are explained below) and submit it with all supporting documents.**

Researchers proposing to use human subject participants are required to submit an application to the IRB for review and approval **before initiating each project.**

A researcher may begin a study only after receipt of a letter of approval from the IRB.

- **Exemption from Review**

If you believe your study meets the federal requirements for exemption from IRB review, please read the instructions for the *Exemption Certification Request*. If you are not sure which form to use, please call a Senior Grant Specialist in the IRB office at (813) 974-9343.

If you are sure your study qualifies for exemption or if you were directed by the IRB to do so, please submit your completed *Exemption Certification Request* to the IRB.

The link to the application and instructions is on the on the [IRB Applications and Forms Page](#).

- **Initial Expedited Review**

If you believe your study meets the criteria for expedited review, please read the instructions for the *Application for Initial Expedited Review* (which includes the *Expedited Certification Form*). If you are not sure which form to use, please call a Senior Grant Specialist in the IRB office at (813) 974-9343.

If you are sure your study qualifies for expedited review or if the IRB has directed you to do so, please submit your completed *Application for Initial Expedited Review* to the IRB.

The link to the application and instructions is on the on the [IRB Applications and Forms Page](#).

- **Initial Full Review**

If you are sure your study requires full board review or if the IRB has directed you to do so, please read the instructions and submit your completed *Application for Initial Full Review* to the IRB. If you are not sure which form to use, please call a Senior Grant Specialist in the IRB office at (813) 974-9343.

The link to the application and instructions is on the on the [IRB Applications and Forms Page](#).