



## IRB for Human Subjects Use Submission Procedure

To help determine if your project is research and if your research does involve human subjects as defined by the federal government please visit the compliance manager. Examples of research are surveys, interviews, observations of activities or behaviors, exercise tests, blood or other tissue collections, psychological or medical measurements or intervention and sensory responses. In addition, any research involving responses from people or access to records about people must be reviewed. Research studies involving human subjects are reviewed in one of three ways: exempt review, expedited review and full board review.

The process begins by the principal investigator accessing all application materials online from ACOM website. Once the principal investigator has assembled the application paperwork, it should be submitted to research administration office.

The IRB Chair/or designated individual, not the principal investigator, is charged with reviewing the application to determine the appropriate level of review for the research as well as assuring that all necessary documents are included. The research office will work closely with the principal investigator to ensure the appropriate forms are completed and will assist with the preparation of other items that may be needed.

### Step 1: Prepare Research Protocol

In many cases, this can be the research plan of a grant application. Literature reviews, reference lists, etc...Please submit all the required sections in the request for proposals if research is tied to a grant opportunity but for IRB the following are necessary:

- A background or literature review
- A clear research hypothesis or study aims
- Demonstration that the study design is appropriate to test the hypothesis or meet the aims
- Explanation of the risks to the subjects and how they are reasonable in relations to benefits
- Description of inclusion and exclusion criteria as well as protections in place for any subjects considered vulnerable
- Procedure outlining informed consent process
- Description of safeguards in place to ensure subject privacy and confidentiality
- Description of data collection and security

### Step 2: Complete the IRB Application Form

The IRB Application Form requires summary information from the research protocol, and lists supplemental documents that may be required for submission. In addition to the IRB Application Form, one of the following forms must be completed depending upon the level of review required:

- Full-board review request
- Expedited review request
- Exemption request

Questions on what level of review a protocol requires can be directed to the research administration office.

### Step 3: Review Requirements and Develop Informed Consent Form

Questions on guidelines on developing a consent form, as well as components of informed consent, information on assent determination and sample consent forms can be sent from the research administration office

Under certain circumstances, a waiver of informed consent is justified. Informed Consent form should be completed and included should this be applicable to the study.

### Step 4: Complete Additional Documents as Required

Additional forms and information that may be required include:

Surveys / data collection instruments

Brochure / recruitment materials

Approval letters from cooperative IRBs at other sites

### Step 5: Complete Training Requirements

All personnel involved in the research, including data analysts, lab assistants, etc., must complete and pass all CITI Protection of Human Research Subjects course. This course is comprised of different modules each with a separate test that must be taken. Once all modules have been taken and tests passed, a completion report can be printed. This report must be submitted as part of the application packet. A step by step presentation on registering on CITI is available on the Required Education page. ACOM IRB also currently accepts certifications from the NIH's Protecting Human Research Participants course in lieu of CITI certification.