

Research with Human Subjects

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Definition of Human Subject

- “...an individual about whom an investigator conducting research obtains data through intervention or interaction, OR identifiable private information.”
- Includes information gathered by means of:
 - private records (i.e. medical, scholastic, etc.)
 - experiments,
 - surveys & questionnaires,
 - observation techniques (ethnographic, audio, and/or video)
 - interviews (live, phone, and/or electronic)

Why?

- Began in 1947 with the Nuremberg Code to judge the human experimentation conducted by the Nazis.
- A series of highly publicized abuses in research led to the enactment of the 1974 National Research Act (Public Law 93-348) designed to protect human subjects.
- According to Federal Law 45 CFR 46 (CFR = Code of Federal Regulations):
 - All institutions that receive federal funding for research are required to comply with specific regulations regarding the [ethical] treatment of people in research activities.

Where to Begin?

- All investigators (faculty, staff and students) are **REQUIRED** to complete the Collaborative Institutional Training Initiative (CITI) training in human subjects protection prior to conducting research using human subjects.
- To begin the CITI program go to <http://www.citiprogram.org>
- [CLICK HERE](#) for detailed instructions on how to register.

Completing an IRB Application

- AFTER:
 - successful completion of CITI training.
- PRIOR TO:
 - conducting ANY/ALL research involving human subjects
- EXCEPTIONS
 - Pilot a survey for content/construct validity
 - data collected as a result of the pilot survey can not be used without consent
 - Action Research
 - What a classroom teacher uses to assess learning in order to make informed decisions about planning. As with pilot survey, data can not be used without consent.

IRB Application part 2

- All research applications and protocols are managed online at www.IRBnet.org
- **STEP 1:** find a faculty member who will be “Principal Investigator”
 - MUST have CITI training
 - SHOULD be familiar with the process
 - Does NOT have to be your dissertation chair
- **STEP 2:** create a user profile
- **STEP 3:** Download and complete application with your PI
- **STEP 4:** Submit application
- **STEP 5:** Await Board Action, make revisions to app as needed.
- **STEP 6:** Begin research

Additional Resources

- [FAQs involving Human Subjects](#)
- [Glossary of Human Subjects and IRB Related Terms](#)
- [INSTRUCTIONS for CITI Training](#)
- [INSTRUCTIONS for Downloading IRB Application](#)
- [IRB Meeting Schedule \(GMU\)](#)