



Human Subjects at Florida State University

Definitions:

Human Subjects: Living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

Research: As defined by DHHS 45.CFR 46.102 (d), a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.

Protocol: The formal design or plan of an experiment or research activity.

The protocol is submitted through the [HSRS \(Online System\)](#) and includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects, the treatment regimen, and the proposed methods of analysis that will be performed on the collected data.

Institutional Review Board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of the human subjects recruited to participate in biomedical or behavioral research - also known as the "IRB" or Human Subjects Committee.

Research on Human Subjects is Regulated by:

- 45 CFR 46 (DHHS - Office of Human Research Protections(OHRP))
- 21 CFR 50, 21 CFR 56 (FDA)

IRB Authority

- Approve research
- Require modification (conditional approval)
- Disapproval
- Conduct continuing review of approved research
- Suspend or terminate previously approved research not in compliance with IRB's requirements or federal regulations, or associated with unanticipated serious harm to subjects.

Types of IRB Review (the IRB determines type of review needed)

- Full Committee -vulnerable populations, greater than minimal risk (see website for meeting dates and deadlines)
- Expedited - no more than minimal risks, criteria described in regulations
- Exempt - no more than minimal risks, criteria described in regulations

Human Subjects Committee

Physical Address:

2010 Levy Avenue Building B,
Suite 276
Tallahassee, FL 32310

Mailing Address:

Florida State University
Human Subjects Committee
Tallahassee, FL 32306-2742
Campus Mail Code: 2742
Phone: (850) 644-7900
Fax:(850) 644-4392

Investigator Responsibilities (PI)

- Has primary duty for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Assurance
- Conducts all research according to the IRB-approved protocol and complies with all IRB determinations
- Ensures that each potential subject understands the nature of the research, participation, and the consent process
- Provides a copy of the IRB-approved informed consent document to each subject at the time of consent
- Retains all signed consent documents for at least 3 years beyond completion of the research
- Reports proposed changes/amendments to IRB for review and approval
- Reports progress of research as required by IRB, not less than once per year
- Promptly reports to IRB any unanticipated problems involving risks to subjects or others

Institutional Responsibilities (FSU)

- Full legal responsibility pursuant to Assurance (FWA #00000168)
 - FSU's Assurance commits the University regardless of sponsorship
- Designates IRB to review and approve research (IRB # 00000446)
- Sets the tone for an institutional culture of respect for human subjects

Consequences of Noncompliance with Federal Regulations

- Suspension/shut down of research and funding
- Investigation, reporting, increased oversight
- Overhaul and reorganization of institutional reporting structure, offices, etc.
- Massive expenditures and lost efforts
- Initiation of legal actions by federal government, research subjects
- Payment of fines, penalties, damages, findings of liability for negligence and other malfeasance

<http://www.research.fsu.edu/humansubjects/>