UNIVERSITY OF SOUTH ALABAMA

IRB SOP 101
Regulatory and Ethical Mandate

Purpose

The purpose of this document is to describe the ethical principles and regulatory mandates surrounding the protection of human research subjects.

Scope

All human subjects research conducted at the University of South Alabama and those affiliates using USA IRB approval must comply with all applicable federal, state, local laws, and institutional policies.

Policy

The University of South Alabama IRB is a single part of a larger Human Research Protection Program (USA HRPP) established to ensure compliance with ethical principles and regulatory mandates surrounding the protection of human subjects research.

The mission of the USA HRPP is to ensure that:

- the rights and welfare of human subjects research participants are paramount in the research process;
- the highest standards of ethical conduct are employed in all human subjects research activities;
- research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
- research investigators inform human subjects research participants fully of procedures to be followed, and the risks and benefits of participating in research; and

- research using human participants at USA conforms with all applicable local, state and federal laws and regulations and the officially adopted policies of the University.

Human subjects research must be consistent with the basic ethical principles recognized as governing research involving human subjects. It must also comply with all applicable laws and regulations of the United States and the State in which the research is conducted.

1.0 Regulations

The following regulations have been codified into the United States Code of Federal Regulations (CFR) and must be strictly followed.

1.1. Department of Health and Human Services (DHHS)

The regulation of human subjects research by the U.S. Department of Health and Human Services is codified in 45 CFR 46. Subpart A of 45 CFR 46 has been adopted for human subjects research by many federal agencies and is known as the "Common Rule."

In May of 1974, the Department of Health, Education, and Welfare (later renamed DHHS) codified its basic human subject protection regulations at 45 CFR 46, Subpart A. Revised in 1981, 1991, 1996, 2005, and 2018, the DHHS regulations presently include additional protections for fetuses, pregnant women, and human in vitro fertilization (Subpart B), prisoners (Subpart C), and children (Subpart D). The DHHS regulations are enforced by the Office for Human Research Protections (OHRP).

The Common Rule requires that every institution performing federally supported human subjects research file an assurance of protection for human subjects. The University of South Alabama conducts human subjects research under the terms specified in its Federalwide Assurance (FWA), the legally-binding agreement to ensure that all human subjects research complies with the requirements of the governing Federal Department or Agency head and its policies. All human subjects research activities, regardless of funding source, will be guided by the ethical principles in the Belmont Report and all other appropriate ethical standards recognized by Federal Departments and Agencies which have adopted the Federal Policy for the Protection of Human Subjects. All research studies will comply with subparts of DHHS regulations as codified in Title 45 CFR Part 46 and its Subparts A, B, C, and D. The Office of Research Compliance and Assurance must renew the FWA every five years with the federal Office of Human Research Protections, even if no changes have occurred. The Common

Rule Terms of Assurance are listed on the OHRP website. USA conducts human research under FWA #00001602.

1.2. Food and Drug Administration Regulations

The Food and Drug Administration (FDA) is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. FDA regulations are published as part of chapter 21 of the Code of Federal Regulations. Research falling under the purview of the FDA must comply with FDA regulations in addition to DHHS regulations. Although the FDA regulations differ from the Common Rule, the FDA is required to harmonize with the Common Rule whenever permitted by law.

FDA regulations that are relevant to the protection of human subjects include:

- Electronic Records; Electronic Signatures (21 CFR 11)
- Protection of Human Subjects (Informed Consent) (21 CFR 50)
- Institutional Review Boards (21 CFR 56)
- Investigational New Drug Applications (IND) (21 CFR 312)
- Radioactive Drugs (21 CFR 361)
- Biological Products (21 CFR 600)
- Investigational Device Exemptions (IDE) (21 CFR 812)

2.0 Ethical Principles and Guidance Documents

All human subjects research conducted at the University of South Alabama should be guided by and conform to the ethical principles outlined in the guidance documents described below:

2.1. The Nuremberg Code

The modern history of human subject protections begins with the discovery after World War II of numerous atrocities committed by Nazi doctors in war-related human research experiments. The Nuremberg Military Tribunal developed ten principles as a means of judging their "research" practices, known as The Nuremberg Code. The significance of the Code is that it addressed the necessity of requiring the voluntary consent of the human subject and that any individual "who initiates, directs, or engages in the experiment" must bear personal responsibility for ensuring the quality of consent. Additionally, the Nuremburg Code, more than other counterparts listed here, is a recitation of participants' legal rights, and has been used as a basis for decisions made in adjudicating the cases involving human research.

2.2. The Declaration of Helsinki

Similar principles to The Nuremberg Code have been articulated and expanded in later codes, such as the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants (1964, revised 1975, 1983, 1989, 1996, 2000, 2013, 2024), *which call for* prior approval and ongoing monitoring of research by independent ethical review committees.

2.3. The Belmont Report

Revelations in the early 1970s about the 40-year United States Public Health Service Study of Untreated Syphilis in the Negro Male at Tuskegee and other ethically questionable research resulted in the 1974 legislation calling for regulations to protect human subjects and for a national commission to examine ethical issues related to human subject research (i.e., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). The Commission's final report, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, defines the ethical principles and guidelines for the protection of human subjects. Perhaps the most important contribution of *The Belmont Report* is its explanation of three basic ethical principles:

- Respect for persons (applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations);
- Beneficence (applied by weighing risks and benefits); and
- Justice (applied by the equitable selection of subjects).

References

DHHS Office of Human Research Protections, Code of Federal Regulations

FDA Code of Federal Regulations

HISTORY

Revisions: November 2018, March 2025