



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 subject's.

Scope

All human 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

Human subject's 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 Regulatory and Ethical Mandates

The mission of the USA Human Subjects Protection Program is to ensure that:

1. the rights and welfare of human subjects are paramount in the research process;
2. the highest standards of ethical conduct are employed in all human subjects research activities;

3. research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
4. research investigators inform human subject participants fully of procedures to be followed, and the risks and benefits of participating in research; and
5. research using human subjects at USA conforms with all applicable local, state and federal laws and regulations and the officially adopted policies of the University.

The regulation of human subject's research by the U.S. Department of Health and Human Services is codified in 45 CFR 46. Because Subpart A of 45 CFR 46 has been adopted for human subjects research by many federal agencies it is known as the "Common Rule." The Common Rule requires that every institution performing federally supported human subjects research file an assurance of protection for human subjects. This research should be guided by the ethical principles adopted in the Belmont Report and, additionally, should conform to the guidance documents described below:

1.1 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 Nuremberg 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.

1.2 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: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (1964, revised 1975, 1983, 1989, 1996, 2000, 2013), *which call for* prior approval and ongoing monitoring of research by independent ethical review committees.

1.3 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).

1.4 Department of Health and Human Services (DHHS) Regulations

Federal regulations require specific protections for human subjects. 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 and 2005, 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).

1.5 Federal Policy (Common Rule) for the Protection of Human Subjects. Food and Drug Administration (FDA) Regulations at 21 CFR 50 and 56

When DHHS revised its regulations in 1981, the FDA codified almost identical informed consent regulations at 21 CFR 50 and IRB regulations at 21 CFR 56. Additional FDA regulations that are relevant to the protection of human subjects are:

- (1) Investigational New Drug Applications (IND) (21 CFR 312)
- (2) Radioactive Drugs (21 CFR 361)
- (3) Biological Products (21 CFR 600)
- (4) Investigational Device Exemptions (IDE) (21 CFR 812)
- (5) Additional Safeguards for Children (21 CFR 50, Subpart D).

1.6 **Federalwide Assurance**

The Common Rule requires that every institution engaged in federally supported human research file an "Assurance" of protection for human subjects. The University of South Alabama conducts human use research under the terms specified in its Federalwide Assurance (FWA), the legally-binding agreement to ensure that all human subject's research complies with the requirements of the governing Federal Department or Agency head and its policies. All human subject's 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 4 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.

References

[DHHS Office of Human Research Protections, Code of Federal Regulations](#)

[FDA Code of Federal Regulations](#)

HISTORY

Revisions: November 2018