

1. BACKGROUND OF CPHS AT UH

All research projects with human subjects conducted by faculty, staff and students associated with the University of Houston must receive approval from the Committees for the Protection of Human Subjects (CPHS). CPHS is the name for the two institutional review boards at the University of Houston, responsible for reviewing and monitoring human subject research and its compliance with the Office of Human Research Protections (OHRP).

For more information about basic ethical questions in the conduct of research, you are encouraged to read the Belmont Report [<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>].

A brief review of relevant documents is provided here to help investigators better understand the reason for ethical review of research involving human participants, the primary ethical principles that govern such research, and the statutory basis for enactment of these principles. This manual contains information that should assist UH researchers in the preparation of an acceptable application for review of a project that involves human subjects.

1.1 Historical Significance of Human Subject Research

The history of research involving human participants includes multiple instances of inhumane and unethical treatment. The Nuremberg trial documents one such episode involving the unethical behavior of German doctors and scientists during World War II.

The United States possesses its own unique history of abuse. The worst example of human subject violations in the United States was the Syphilis Study conducted in Tuskegee, Alabama by the U.S. Public Health Service from 1932 to 1972. Approximately 400 poor and uneducated African American men were enrolled in a study designed to follow the natural course of syphilis. There was no informed consent process. In fact, at no time were they informed that they had the disease nor were they offered any treatment after penicillin was found to be effective in the mid 1940's. In another example, children at the Willowbrook State School, a New York state school for "mentally defective" youths, were purposely infected with the hepatitis virus between 1963 and 1966. During this time, the school claimed that they were overcrowded and closed the school to enrollment of new clients. Parents were allowed to enroll their child only if they agreed to allow their child to participate in the research project.

Also, behavioral and social science researchers have exposed other humans to severe trauma and psychological stress in the name of scientific research. The participants in Stanley Milgram's studies on obedience in the early 1960s were told that continued participation in the study required that they shock another person at increasingly intense voltages. Participants were unaware that the third party was actually a collaborator who was "faking" a reaction to electrical shock.

1.2 Codes of Research Ethics

Codes of research ethics have been developed to address the disregard for human safety and dignity reflected in the aforementioned projects. The Nuremberg Code of 1947 was the first international code of research ethics. The first principle established that "The voluntary consent of the human subject is absolutely essential." The code clarified that the potential subject should "...have the legal capacity to give consent" and "...should have sufficient knowledge and comprehension ... to make an understanding and enlightened decision." This basic concept continues to serve as the foundation for ethical research involving human participants. [<http://www.hhs.gov/ohrp/references/nurcode.htm>]

Other codes followed. In 1964, the World Medical Association adopted the Declaration of Helsinki. This code established the concept of ethical review by an independent board. It also recognized a distinction between therapeutic and non-therapeutic research. [<http://www.wma.net/e/policy/b3.htm>] The American Psychological Association established the first ethical code addressing social and behavioral research in the U.S. in 1972. Based on examples of unethical or questionable behavior, the APA developed ten basic principles for human subjects research. These principles were the first to recognize the principle of confidentiality. Today, most professional organizations have ethical codes that provide guidance on human subject research. Also, many journals now require that authors state adherence to appropriate ethical principles and guidelines in their research.

The U.S. Department of Health, Education and Welfare (DHEW) issued ethical guidelines in 1971 through the National Institutes of Health. In 1973, an ad hoc advisory panel issued the final report of the Tuskegee Syphilis study. This report concluded that, "Society can no longer afford to leave the balancing of individual rights against scientific progress to the scientific community." The following year, Congress passed the National Research Act and codified the DHEW guidelines into federal regulations at 45 Code of Federal Regulations (CFR) 46 (also known as the Common Rule) [<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>]. The Act also established the National Commission for the Protection of Human Subjects to identify the basic ethical principles that now underlie the conduct of biomedical and behavioral research involving human subjects. Known as the Belmont Report, the report was published in 1979 and identified three basic ethical principles:

- **Respect for Persons** (autonomy) – This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from all potential research subjects (or their legally authorized representatives).
- **Beneficence** – This principle requires the investigator to maximize the benefits and minimize the harms or risks associated with the research. Research-related risks must be reasonable in light of expected benefits.
- **Justice** – This principle requires equitable selection, recruitment and fair treatment of human research subjects.

The three principles were the underpinnings of the Common Federal Policy for the Protection of Human Subjects. Sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, The Department of Education, and the Department of Energy, have adopted the current version. The current version was published in 1991 and guides the decisions of CPHS. The regulations further require that every institution at which federally funded research is conducted adhere to the principles of the Belmont Report and set forth in writing its ethical principles, policies, and procedures. The University of Houston's agreement to abide by the Belmont Report and by 45 CFR 46 (called a Federalwide Assurance) is approved by the federal agency that oversees ethical issues in human research. **The University of Houston is committed to following and complying with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.**

1.3 Administration of Research Ethics – Federal

The Office for Human Research Protection (OHRP) is the federal office responsible for the oversight of research involving human participants and is part of the Department of Health and Human Services. Audits conducted by OHRP at several institutions have resulted in the temporary suspension of all research activities involving human subjects. Additional information about this agency is available at [<http://www.hhs.gov/ohrp/>].

1.4 Administration of Research Ethics – University of Houston

The key institutional leader responsible for oversight and management of all aspects of University of Houston research is the Vice Chancellor and Vice President for Research. The Office of the Vice Chancellor and Vice President for Research has been given the authority and responsibility to establish, maintain and oversee the protection of human subjects by the President of the University of Houston and is the designated institutional official for human research protection in UH's Federalwide Assurance with the DHHS. The primary administrative responsibility for the day-to-day operation for the protection of human subjects lies with the Executive Director of Research Services and the Director of Research Compliance, which are part of the Office of Research Policies, Compliance and Committees (ORPCC). The Office of the Vice President for Research is responsible for the administration of research ethics at the University of Houston. The office oversees the Office of Research Policies, Compliance and Committees, which includes the two Committees for the Protection of Human Subjects.CPHS. For additional information, visit our web site at www.research.uh.edu, click on "Human Subjects."

1.5 Committees for the Protection of Human Subjects Authority

The CPHS plays a primary role in protecting human subjects involved in research at University of Houston by:

1. reviewing new and continuing human subject research protocols through the evaluation of risks and benefits to the human subjects,
2. reviewing the adequacy of the informed consent document, particularly as to its description of the risks and benefits,
3. observing and monitoring ongoing research as is necessary to protect human subjects;
4. investigating and acting on allegations of non-compliance and
5. suspending or terminating approval of previously approved research when necessary.

Although the Vice President of Research, deans, department chairs and other University officials may have the authority to disapprove research activities approved by the CPHS or to set more stringent requirements on research protocols, research disapproved by the CPHS cannot be conducted.