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SECTION 1.1 PURPOSE AND SCOPE OF THESE POLICIES AND PROCEDURES

All research projects with human participants conducted by faculty, staff, and students associated with The University of North Texas Health Science Center at Fort Worth (hereinafter referred to as UNTHSC) must receive ethical approval before the research is begun. The information in this Policies and Procedures document is designed to assist investigators with the process of achieving this approval. For more information about the Common Federal Policy for the Protection of Human Subjects, read 45 CFR, Part 46. For more information about basic ethical questions in the conduct of research, read The Belmont Report. These documents may be found on our web site at <http://www.research.hsc.unt.edu/irb.html>.

A brief review of these documents is provided here so that investigators may better understand the reasons for ethical review of research with human participants; the primary ethical principles that govern such research; and the statutory basis or enactment of these principles. This document also contains information that should be sufficient to allow researchers to submit an acceptable application for the review of a project involving human subjects. Investigators who read this document will be informed about the National Institute of Health (NIH) rules and UNTHSC requirement of education for all individuals responsible for the design and conduct of research projects with human subjects. Investigators will also be informed about their obligation to obtain an authorization from research participants for the disclosure of protected health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); in what circumstances the authorization may be waived; and the process involved in creating de-identified information in compliance with the HIPAA privacy rule.

1.2 SECTION BACKGROUND INFORMATION

SECTION 1.2.1 ETHICAL VIOLATIONS IN RESEARCH WITH HUMAN PARTICIPANTS

Human researchers have treated other humans inhumanely and unethically. The Nuremberg trials documented the unethical behavior of Nazi physicians. American researchers from the Public Health Service studied 400 African American men with syphilis in the Tuskegee syphilis study between 1933 and 1972. These men were not asked for their informed consent/authorization to be in the study and they were, in fact, given misinformation about their treatment. After penicillin became available and was known to be effective in the treatment of syphilis, it was withheld from these subjects because the researchers were interested in the natural history of the disease. Researchers from Harvard and MIT formed a "science club" of 19 mentally impaired boys at the Fernald State School between 1946 and 1956. These boys were fed forms of radioactive iron or calcium, sometimes in their milk, to enable the

researchers to study the body's ability to digest minerals. Doctors at the Jewish Chronic Disease Hospital conducted studies of human transplant rejection using cancer cells. The subjects were not asked for informed consent/authorization and did not give written consent/authorization to participate in the study. Between 1963 and 1966, children at the Willowbrook State School, a state school for "mentally defective" youths were purposely infected with the hepatitis virus in a study of that disease. During the course of this study the institution closed its doors to new clients, claiming overcrowding. However, the wing housing the hepatitis program was willing to admit new clients if their parents agreed to allow their children to participate in the ongoing studies. (These descriptions of unethical research conduct are based on the NIH tutorial for ethical training. That training module is at <http://ohsr.od.nih.gov/cbt/>.)

Behavioral and social science researchers have exposed other humans to severe trauma and psychological stress in the name of scientific research. The participants in Milgram's "obedience" studies, conducted in the early 1960s, were told that they had to continue to participate in the study and shock another person at increasingly intense voltages. Studies supported by the Human Resources Research Office of the U.S. Army introduced severe stress to army recruits by threatening them with death from errant artillery rounds or by causing the recruits to think that they, by making a mistake in wiring an instrument, had caused the injury or death of others in their units.

SECTION 1.2.2 CODES OF RESEARCH ETHICS

Codes of research ethics have been developed, in part to address the disregard for human safety and dignity that these research projects reflect. The Nuremberg Code of 1947 was the first international code of research ethics. Its first principle is "The voluntary consent/authorization of the human subject is absolutely essential." The accompanying text made it clear that this voluntary consent/authorization should also be informed consent/authorization: "...the person involved ... should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." This principle of "free and informed consent/authorization" remains the basic foundation of ethical research with human participants.

Another early code was the Helsinki Declaration, adopted by the World Medical Assembly at its meeting in Helsinki, Finland in 1964. Its second principle, "The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor..." established the concept of ethical review.

The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972, which has been updated effective June, 2003. The bases for these principles were critical incidents. Psychologists were asked to submit examples of research that they deemed unethical or of questionable ethics. The committee charged with developing ethical standards for psychological research then developed principles that would guide the conduct of researchers when conducting research that could pose ethical problems. The American Psychological Association's principles were the first to recognize the principle of confidentiality. Principle 10 states: "Information obtained about the research participants during the course of an investigation is confidential. When the possibility exists that others may obtain access to such information, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to the participants as a part of the procedure for obtaining informed consent/authorization." Most professional organizations have ethical codes, and most require authors of manuscripts submitted

to the journals of these organizations to state that they have followed these ethical principles in their research.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971, which were codified into Federal Regulations in 1974. However, the primary impetus for current government ethical regulation began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the aegis of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report because it was based on deliberations held at the Smithsonian Institution's Belmont Conference Center, was published in 1978. The Belmont Report identified three basic ethical principles. They are:

(1) Respect for Persons (autonomy): This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent/authorization from all potential research subjects (or their legally authorized representatives).

(2) Beneficence: This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.

(3) Justice: This principle requires the equitable selection and recruitment and fair treatment of research subjects.

These three principles were the underpinnings of both an early (1980) version of a Common Federal Policy for the Protection of Human Research Subjects and the current version of that policy. The current version has been adopted by sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, the Department of Education, and the Central Intelligence Agency. The Food and Drug Administration (FDA) has concurred with the Federal Policy and has made changes in its IRB and informed consent/authorization regulations so that they correspond to the Federal Policy. This Federal Policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991. It is referred to as 45 CFR 46 and its regulations underlie the decisions of IRBs. The regulations further require that each 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. This institution's agreement to abide by the Belmont Report and by 45 CFR 46 (called a Federal Wide Assurance or FWA) is approved by the federal agency that oversees ethical issues in human research. Because UNTHSC has an FWA, UNTHSC can establish an IRB that can review all research projects involving human subjects.

SECTION 1.2.3 ADMINISTRATION OF RESEARCH ETHICS - FEDERAL

The audits conducted by the federal department responsible for human subject protection, now known as the Office for Human Research Protections (OHRP), of the performance of IRBs and the conduct of research with human participants at several medical schools have resulted in temporary injunctions of research with humans at those schools. The death of a participant in a gene therapy research study suggested a lapse of oversight at the site of that study. News reports of clinical trials have suggested that doctors may receive financial benefits by enrolling their patients in such trials and that the patients may not benefit or may be at risk.

SECTION 1.2.4 ADMINISTRATION OF RESEARCH ETHICS - THE UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER AT FORT WORTH

The Office of the Senior Vice President for Research is responsible for the administration of research ethics at UNTHSC. That office oversees the functioning of the Institutional Review Board (IRB), the University committee that reviews proposals for research with human participants. The IRB itself works out of the Office of IRB Services.

If there are questions about the rules or procedures for ethical review or the applicability of the information in this manual to a proposal, first contact the Departmental Chair. Chairs serve as the liaison between the IRB and the faculty, staff, and students in the departments and colleges where research is conducted with human participants. If the Chair cannot answer the questions, contact:

Brian Gladue, Ph.D. (Director, Office for the Protection of Human Subjects) [bgladue@hsc.unt.edu]
Phone: 817-735-5083
Fax: 817-735-0375

Debbie Ceron (Administrator – Biomedical Protocols) [dceron@hsc.unt.edu]
Phone: 817-735-5483
Fax: 817-735-0375

Sharon Tobola (Administrator – Behavioral and Social Science Protocols) [stobola@hsc.unt.edu]
Phone: 817-735-5457
Fax: 817-735-0375

Jerry McGill, Ph.D., Chair, UNTHCS IRB (jmcgill@hsc.unt.edu)
Department of Manipulative Medicine
UNTHSC
3500 Camp Bowie Blvd.
Fort Worth, TX 76107-2699
Phone: 817-735-5483
Fax: 817-735-0375

SECTION 1.3 REVISION AND MAINTENANCE OF THE POLICIES AND PROCEDURES

All new or revised materials will be placed on the IRB web page by the Office of Research.