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SECTION 3.1 DESIGNATION OF THE INSTITUTIONAL REVIEW BOARD

The University of North Texas Health Science Center at Fort Worth has one (1) Institutional Review Board (hereinafter referred to as the IRB) that is responsible for conducting initial and continuing reviews and providing oversight for all research activities involving the use of human subjects performed on the campus or at any location under the purview of UNTHSC. The IRB will conduct initial and continuing reviews of research activities according to the procedures outlined in this document. All review procedures will meet or exceed the requirements set forth in 45 CFR 46.

To ensure compliance with the regulations, the University of North Texas Health Science Center has adopted an internal audit and/or self-assessment procedures designed to assure proper protocol and consent document preparation, protocol submission, review and approval by the IRB, and timely monitoring of protocol implementation. One example is the use of approval date stamps on consent documents and protocols to ensure that the Federal requirement of at least annual IRB review of each protocol is met. A second example is the use of standardized language endorsed by the institution, which meets the regulatory requirements and which is customized and elaborated upon by the investigator in creating an appropriate informed consent document.

Specification of quality standards in the conduct of research is an important function of the institutional leadership. Insistence upon well-conceived and well-conducted research should be evident both in written policies and in actions of institutional officials. Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk.

SECTION 3.2 CHARGE TO THE INSTITUTIONAL REVIEW BOARD

The University of North Texas Health Science Center (UNTHSC) has established a standing committee, Institutional Review Board (IRB), of members with the experience and expertise charged with the review of research involving the participation of human subjects and the protection of their rights and welfare. The IRB is charged with the responsibility to review and approve, disapprove or require modifications in all research involving the participation of human subjects that is:

Sponsored by the UNTHSC;

Conducted by or under the direction of any employee or agent of UNTHSC in connection with his/her institutional responsibilities;

Conducted by or under the direction of any employees or agent of UNTHSC using institutional property or assets; or
Facilitated by the use of the institution's non-public information to identify or contact subjects or prospective subjects.

The IRB may also review other human subject research pursuant to formal affiliation agreements between UNTHSC and other organizations.

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of this institution.

The ethical framework for this charge consists of the ethical principles regarding all research involving humans as subjects, as set forth in the Nuremberg Code, the Declaration of Helsinki, and the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"], regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).

The IRB operates under assurance of the Office for Human Research Protection (OHRP) and in accord with the regulations of the Food and Drug Administration (FDA) and in compliance with other State and federal regulations as applicable.

Federal Wide Assurance (FWA) covers the following entities:

Texas College of Osteopathic Medicine
Graduate School of Biomedical Sciences
School of Public Health

SECTION 3.3 FACULTY BYLAWS

The IRB is a standing committee established under the Faculty Bylaws of UNTHSC. Therefore, the bylaws as a whole provide the basis and framework under which the UNTHSC bylaws operate. The IRB is addressed in Article XVI, Section H – Institutional Review Board:

1. Composition: The board shall consist of a minimum of nine members of the faculty appointed by the President of UNTHSC to serve for three years. The Chair will be elected from among the members of the Board, subject to approval of the President. The Chair may request additional faculty members to be appointed by the President as needed by increased workload. The President will appoint certain community members as mandated by federal regulations in addition to the above cited faculty members. The Associate Vice President for Research will be an ex-officio member.
2. Responsibilities: The IRB is responsible for review and approval of all research involving human subjects. Research involving human subjects cannot be conducted without the approval of the IRB. Federal guidelines for the conduct of research

involving human subjects are provided by the United States Department of Health and Human Services.

3. Minutes: Copies of the minutes of the IRB are available to all faculty members.

SECTION 3.4 COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD

The President of UNTHSC will solicit names for appointments from a variety of sources, e.g., past and present IRB members, and UNTHSC staff. The names of persons in ethics and healthcare, who have demonstrated experience and/or interest regarding the protection of the rights and welfare of human volunteers in research, will be considered for possible contact and appointment. As IRB members rotate off and new members are appointed, selections will be made to assure continuing compliance with the requirements of 45 CFR 46.107 regarding gender and diversity.

The committee must be sufficiently qualified through the maturity, experience, and expertise of their members and diversity of membership to insure respect for their advice and counsel specific to safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of proposals in terms of organizational commitments, regulations, applicable law, standards of professional conduct and practice, and community attitudes.

In addition to faculty members representing different disciplines, the IRB currently has three non-affiliated members who are deemed to represent non-scientific areas. At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols, the IRB may call upon ad hoc consultants for assistance in review for scientific merit.

Member files are kept in the IRB Services Office. They include 1) a letter of appointment, 2) a current curriculum vitae (as appropriate), and 3) documentation of a certificate that shows the member has completed the UNTHSC tutorial for IRB members and investigators.

Educational materials are generally distributed and discussed at each IRB meeting.

SECTION 3.5 CHAIRPERSON

It is the responsibility of the President to confirm the Chairperson. This appointment is made for a three-year period. In the absence of the Chair, the Vice Chair (an IRB member) has signatory authority.

SECTION 3.6 MEETINGS

The IRB shall hold one regularly scheduled meeting per month, at a time and place to be pre-determined (See Section 6 and 7 for specific details).

SECTION 3.7 CONFIDENTIALITY OF THE REVIEW PROCESS

During the process of initial or continuing review of an activity, material provided to the Institutional Review Board shall be considered privileged information and the Board shall assure the confidentiality of the data contained therein. All members of the IRB sign a Confidentiality Agreement.