

SECTION 2: DEFINITIONS

The following definitions are applicable to all sections of this document.

"Conflict of Interest:"

Growing interaction between for-profit enterprises and UNTHSC has created new possibilities for the occurrence of conflicts of interest. These conflicts arise when there are opportunities for faculty or staff members to benefit financially either from the outcome of research or from activities conducted in the course of responsibilities as an institutional research member.

UNTHSC believes that with clear guidelines and principles, in conjunction with appropriate supervision and monitoring, it is possible for interaction between industry and academic medicine to take place in a manner that is consistent with the highest traditions of medical and scientific research and in a way that energizes scientific creativity.

This Policy establishes guidelines for the appropriate structuring of relationships with industry and other outside ventures so as not to conflict with previously established responsibilities to UNTHSC. Investigators are expected to make reasonable inquiry as to whether their relationships and activities fall within the provisions of this Policy. It is not the intent of this Policy to eliminate or prohibit all situations involving a potential Conflict of Interest. This Policy is intended to enable Investigators to recognize situations that may pose a conflict of interest, to report these situations to the Conflict of Interest Committee, and to ensure that the Conflict of Interest Committee reviews these situations and, if necessary, supervises or monitors them. An integral part of this Policy is a disclosure mechanism whereby Investigators regularly review their activities. This Policy is intended to maintain the professional autonomy of scientists and physicians inherent in the self-regulation of science. This Policy should be viewed as complementing all institutional policies and procedures, including Sections 5.05 and 5.06 of UNTHSC's Personnel and Procedures Manual.

Each Investigator shall disclose all **significant financial interests:**

- (i) of the Investigator including spouse and dependent children
- (ii) that would reasonably appear to be affected by the

research, educational, or service activities funded, or proposed for vending, by an external sponsor

(iii) in entities whose financial interests would reasonably appear to be affected by such activities.

What is covered?

"Significant financial interests include:

- a. Receipt of, or the right or expectation to receive monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, payments for directorships or executive roles); equity interests (e.g. stocks, stock options, dividends or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights); or
- b. receipt of, or the right or expectation to receive other value, such as in the form of a forbearance, forgiveness, interest in real or personal property, rent, capital gain, real or personal property, or any other form of compensation, such as gifts.

The term **does not include:** interests held directly through funds such as mutual funds, pension funds, or other institutional investment fund in which the Investigator or the Investigator's Family does not control the selection of investments.

Further, the following financial interests do not rise to the level of a Significant Financial Interest:

- (1) salary, royalties, or other remuneration received from UNTHSC;
- (2) standard royalties received for published scholarly work or other professional writings;
- (3) royalties or equities received under UNTHSC royalty-sharing policies (see UNTHSC Intellectual Property Policy);
- (4) consulting fees received from an entity in which neither the Investigator, the Investigator's Family, an Associated Entity of the Investigator, nor UNTHSC have any other relationship, provided that the consulting relationship has been approved in accordance with the UNTHSC Outside Employment Policy, and subject to all other policy requirements including appropriate devotion of time to UNTHSC;
- (5) income from seminars, lectures, or teaching engagements sponsored by public entities; or
- (6) income from services on advisory committees or review panels for governmental entities.

"**DHHS**" means the Department of Health and Human Services.

"**FDA**" means the Food and Drug Administration.

"**Federal Wide Assurance (FWA)**" means a document that fulfills the requirements of 45 CFR Part 46 and is approved by the Secretary of Health and Human Services. The University of North Texas Health Science Center has an approved FWA on file with DHHS.

"**HIPAA**" is the Health Insurance and Portability and Accountability Act of 1996 (HIPAA) that protects the privacy of a research participant's health information. The three categories of IRB approval are maintained but the research protocol, and the activity conducted preparatory to the research, is required to meet additional qualifications more fully explained below.

"**Human Subject**" means a living individual about whom the investigator conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

Intervention includes both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

"**Informed Consent/authorization**" means the knowing consent/authorization of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Information

conveyed in the informed consent/authorization procedure must include all essential elements listed in Section 4 of this manual.

"Institution" means any public or private institution or agency (including Federal, State and local Government agencies).

"Key Personnel" are defined as the principal investigators, co-investigators, and others specified within each project, as having decision-making power over the investigation.


- The principal investigator is that individual with signatory power on all documents related to the research project. This person has final authority over the project. The principal investigator accepts responsibility for training all personnel associated with the study in compliance with the human subject's regulations of 45 CFR 46.
- The co-investigator is that individual who may be designated as a co-investigator in grant-related documents. The co-investigator reports to the principal investigator who is ultimately responsible for the conduct of the research.
- Others with decision-making power may include such persons as project managers, directors, trainers. These designations are not all-inclusive. Operationally, these individuals have some oversight responsibility for one or more portions of the project. Individuals in this category are determined uniquely for each project by the principal investigator.

"Legally authorized representative," means an individual or judicial or other body authorized under applicable law to consent/authorization on behalf of a prospective subject to that subject's participation in the particular activity or procedure.

"Minimal Risk" means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Please note the different definition for minimal risk for incarcerated persons: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

"OHRP" means the Office for Human Research Protections. This is an office in the Office of the Secretary of Health and Human Services that is responsible for regulatory oversight of human subject research.

"Research" means a systematic investigation, including research



development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research is defined by both the Common Rule of the Federal regulations and by the Privacy rule of HIPAA.

"Secretary" means the Secretary of Health and Human Services and/or any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.