IRB CONFLICT OF INTEREST POLICY AND STATEMENT

For the protection of human subjects, the North Texas Regional Institutional Review Board (IRB) has adopted the following Conflict of Interest (COI) Policy and Statement. **Each** protocol submitted to North Texas Regional Institional Review Board (IRB) for review must be accompanied by a COI Disclosure Statement for **each** person who is directly involved in research activities and/or interacting with research subjects in the covered study.

NOTE: Each protocol must be accompanied by all appropriate COI Statements. This policy is effective May 8, 2015 and is part of the IRB protocol review process. Protocols submitted without the appropriate COI Statements will not be accepted or reviewed until all appropriate COI documents are received.

COI Statements MUST be completed, signed and submitted with each Initial and Continuing Application for IRB Review.

Note that this North Texas Regional IRB Conflict of Interest Statement is *independent* of the UNTHSC Research Conflict of Interest requirement. Other forms may be required for other units within the university (e.g., Grants and Contracts / Sponsored Programs) and other insititutions. These are <u>all separate</u> documents/processes.

If you have any further questions, please call the Office of Research Compliance (ORC) - North Texas Regional IRB at 817-735-0409.

IRB CONFLICT OF INTEREST POLICY

PURPOSE - Public trust in the research enterprise and the legitimacy of its powerful role in society require a constant amenability to public scrutiny. Consequently, it is necessary at all times to assure the continued confidence of the public in the judgment of scholars and clinicians and in the dedication of academic research institutions to the integrity of the research enterprise. The strength of this assurance is based on the assumption that scholars are honest and conduct their research with the highest standards and integrity.

This policy is intended to serve subjects of human research. This policy is not intended to eliminate all situations of conflict of interest, but rather to enable individuals to recognize situations that may be subject to question and resolve them so as to avoid conflicts of interest. Thus an integral part of the policy is disclosure whereby individuals regularly review their professional activities.

THE POLICY - Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. Conflicts involving the IRB itself or conflicts involving the institution must be managed. In order to manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

IMPLEMENTATION:

A. Researchers who have completed Financial Disclosure forms required by the FDA to be submitted to a sponsor of the research may submit a copy of that form to the IRB.

B. Researchers who have not completed the form required by the FDA must complete and submit the IRB Form attached to this policy.

C. Based on the information submitted by the researcher for review, the IRB may determine that:
   1. no conflict exists, or
   2. a conflict exists and must be disclosed to the subjects in the informed consent statement, or
   3. a conflict exists and the researcher must resolve the conflict before the research can be approved.

EXAMPLES OF REPORTABLE AND NON-REPORTABLE ACTIVITIES

1. Non-Reportable Activities

The following activities and relationships do not need to be reported and do not represent a conflict of interest because they have been generally accepted practices and do not violate fundamental ethical principles.

a. Receiving royalties for published scholarly works and other writings.
b. Accepting honoraria for commissioned papers and occasional lectures.
c. Receiving payment for reasonable travel and lodging expenses related to presentations of scholarly work or to a person's academic endeavor.
d. Investing in mutual funds.
e. Participating in a University approved practice corporation.
f. Payments for clinical research to an approved practice corporation or to a department fund for salary or other expenses of conducting clinical trials.

2. Reportable Activities

a. Conducting research in applied and/or clinical research on a technology developed by the investigator or a member of his/her immediate family (spouse, children, parent, in-laws, siblings).
b. The financial relationship of an investigator or his/her immediate family member with the sponsor of his/her research (acting as scientific advisor or consultant, or receiving honoraria exceeding $5,000 annually, or acting as director or other executive).
c. Conducting applied and/or clinical research on a technology owned by a business in which the investigator or a member of his/her immediate family holds 5% or more of the outstanding stock or stock options.
d. Receiving royalties under institutional royalty-sharing policies from marketing the drug, device or procedures that is the subject of the research.
e. Receiving payments directly from the sponsor, rather than through John Peter Smith, the University or an approved UNTHSC entity, for recruiting subjects.

Effective May 8, 2015

CONFLICT OF INTEREST STATEMENT

For the protection of human subjects, the North Texas Regional Institutional Review Board (IRB) requires that **each** protocol submitted to the IRB for review must be accompanied by a Conflict of Interest (COI) Disclosure Statement for **each** investigator/key personnel who is involved in the research activities and/or interacting with research subjects in the covered study. COI Disclosure Statements must be completed, signed and submitted with each Initial and Continuing Application for IRB Review.

Protocol Principal Investigator: _____

Title of Protocol: _____

Name of Person (Investigator/Key Personnel) completing this statement:

_____

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, the North Texas Regional IRB requires that such potential conflicts be disclosed. If the North Texas Regional IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the North Texas Regional IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the subject in the Informed Consent document.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a financial interest in either a public or private company whose drug, procedure, technique, device, or software is used or tested in this study, please indicate the following:

☐ Yes ☐ No I own equity in the company (stock ownership equal to or greater than 5%, Stock Options, Real Estate, or other ownership interest in any amount) whose drug, procedure, technique, device, or software I am testing.

☐ Yes ☐ No The company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).

☐ Yes ☐ No I or a member of my immediate family hold(s) a position of senior management officer, or director of the company whose drug, procedure, technique, device, or software I am testing.

☐ Yes ☐ No I am a scientific advisor or consultant to the company and I receive honoraria exceeding $5,000 annually.

☐ Yes ☐ No I am aware that if a device, technique, software, or procedure involved in the research is marketed, I or a member of my immediate family will get royalty income or other income from the sale of the product.

☐ Yes ☐ No Any other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

Please include a separate letter of explanation if there is further information that the North Texas Regional IRB should consider.

If I have not checked any of the boxes above, or attached a letter of explanation for consideration by the North Texas Regional IRB, my signature below is my representation that I have no financial or other conflict of interest that could adversely affect a subject in this study.

I acknowledge that I am required to notify the North Texas Regional IRB within 10 business days if a change in my disclosure status occurs.

_____ _____

Signature Date