

IRB – OPHS CONFLICT OF INTEREST POLICY AND STATEMENT

The University of North Texas Health Science Center Office for the Protection of Human Subjects (OPHS) has adopted the following Conflict of Interest (COI) Policy and Statement. **Each** protocol submitted to the IRB for review must be accompanied by a COI Disclosure Statement for **each** investigator/key personnel who is directly involved in the treatment or evaluation of research subjects in the covered study.

NOTE: Each protocol must be accompanied by a COI Statement. This policy is effective May 18, 2006 and is part of the IRB protocol review process. Protocols submitted without the COI Statement will not be accepted or reviewed until all appropriate COI documents are received.

Such a Statement MUST be completed, signed and submitted with each Initial and Continuing Application for Review.

Note that this IRB – OPHS Conflict of Interest Statement is *independent* of the “Statement of Interest Form” that may be required for Sponsored Grant, Contract, or other Financial activities that need to be disclosed to other units within the University.

If you have any further questions, please call OPHS (the IRB Office) at 817-735-0409.

IRB - OPHS 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-OPHS 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 the University or an approved UNTHSC entity, for recruiting subjects.

Effective May 18, 2006

CONFLICT OF INTEREST STATEMENT

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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 IRB requires that such potential conflicts be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the 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 Statement.

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 IRB should consider.

If I have not checked any of the boxes above, or attached a letter of explanation for consideration by the 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 will be required to notify the IRB within 10 business days if I change in my disclosure status occurs.

Signature

Date