

Potential Conflict of Interest Form for Study Staff

The thresholds of ownership described below apply to the aggregate ownership of an individual study staff member, his/her spouse, domestic partner and dependent children (e.g., if a study staff member, his/her spouse, domestic partner and dependent children own together \$5,000 or 5% worth of equities in the sponsor, it should be reported below).

Please choose the applicable box(s).

- ☐ financial interest in the research with value that can not be readily determined
- ☐ financial interest in the research with value that exceeds the specified monetary threshold (\$5,000) or 5% ownership
- ☐ has received or will receive compensation whose value could be affected by the study outcome.
- ☐ has a proprietary interest in the research included but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.
- ☐ has received payments from the sponsor that exceed the specified monetary threshold (\$5,000) in the past year.
- ☐ is executive or director of the agency or company sponsoring the research
- ☐ Equity interest of less than \$5,000 when that value could not be determined through reference to public prices or other reasonable measures of fair market value
- ☐ None of the above

If your answer is NOT "none of the above", you must follow the additional reporting/management requirements in IRB Policy 17a.

Attestation:

I agree to submit a revised Conflict of Interest Form to the PI and IRB within ten days of any change from previous disclosures.

Typed/Printed Name

Signature and Date

Protocol(s)

Revision date 11/23/15, 4/30/18

- A. **Conflict of interest** refers to instances when there is a convergence between an individual's personal financial, relational, or other interests and his/her professional obligations to East Tennessee State University (ETSU) or the James H. Quillen Veterans Affairs Medical Center (VAMC) such that an independent observer might reasonably determine that the individual's professional actions or decisions are adversely affected, distorted or otherwise compromised by the individual's personal interest. The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research and for the purposes of this policy includes conflicts that may arise in review and approval of protocols submitted to the IRB when an IRB member is part of the team designing, conducting, or reporting the research presented in the protocol, or has an immediate family members involved in the design, conducting or reporting the research presented in the protocol.
- B. **Financial Interest Related to the Research: means financial interest in the sponsor, product or service being tested**
- C. **Covered individual** includes any faculty or staff member (whether fully-, partially-, or non-salaried), student, fellow, trainee, administrator or other employee who is involved in research for which the ETSU or the VAMC is responsible, or who, pursuant to the review and approval of the ETSU/VA or ETSU Institutional Review Board (IRB), conducts or engages in research involving human subjects, or is otherwise identified as involved in research by a principal investigator, chair or unit head, or other University administrative officer responsible for research activities.
- D. **Immediate Family Members** includes spouse, domestic partner, and dependent children.
- E. **Significant Financial Interest**
- 1) Includes, but is not limited to, any economic or monetary interest of the types listed in "(a)" through "(e)" below, that is held by a covered individual (or by his/her immediate family member), and that to an independent observer would reasonably appear to affect or be affected by research in which the individual is involved, or that is held by any entity in which a covered individual (or his/her immediate family member) has a financial or fiduciary interest the financial interests of which entity would reasonably appear to an independent observer to affect or be affected by the research (e.g. stock values, etc). (Such an entity may be a financially interested entity):
 - a) **"Compensation interest,"** meaning salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 (twelve) months exceeded \$5,000, or are expected to exceed that amount in the next twelve months;
 - b) **"Equity interest,"** meaning i) any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds \$5,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same) whether or not financial value can be determined through reference to public prices;
 - c) **"Intellectual property interest"** meaning i) royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or ii) any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right where the research is directly related to the interest;
 - d) **"Extraneous research payments,"** meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested entity or from the institution;
 - e) **"Fiduciary relationship,"** meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.
 - f) **"Compensation affected by the outcome of the research"** meaning compensation of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
 - 2) **Exclusions.** Significant financial interest excludes, and therefore is not meant to refer to, the following types or categories of economic or monetary interest:
 - a) **"Mutual fund interests,"** meaning interests of any amount in publicly traded, diversified mutual funds;
 - b) **"De minimis equity interests,"** meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or his or her immediate family members) meets both the following tests: it does not exceed \$10,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;
 - c) **"Outside payments,"** meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her immediate family members), over the next 12 months, are not expected to exceed \$5,000;
 - d) **"Regular research payments,"** meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;
 - e) **"University compensation,"** meaning salary, royalties, and other remuneration for services from the University;
 - f) **"Public or non-profit income,"** meaning income for service on advisory committees or review panels for public or non-profit entities, or from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.