IRB Policy 17a: Investigator Conflict of Interest
Revision Date: May 15, 2007, revised October 28, 2009, revised January 27, 2011, revised April 22, 2001, revised October 13, 2011, revised November 17, 2015, revised February 24, 2016

I. Pertinent Definitions

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 $5,000 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.

II. Summary Policy

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/ Veterans Affairs Institutional Review Board (ETSU/VA IRB) is to establish procedures for reporting and managing conflict of interest as it pertains to research conducted at ETSU and James H. Quillen VAMC that involves use of human research subjects. They are based on policies set forth in the ETSU Faculty Senate Handbook 1.17. These policies are not intended to eliminate any situation of

conflict of interest, but to give an understanding of what is conflict of interest and how to report and manage it. It is the policy of the ETSU IRB and the ETSU/VA IRB that all significant financial interest, as well as other conflict of interests, be reported to the IRB for review to assure protection of the rights and welfare of participants in human subject research.

III. Study Staff Conflict of Interest

When an investigator submits a protocol, a disclosure of significant financial interest to the IRB is required for all Covered Individuals and consultants serving as study personnel involved in designing, conducting, or reporting the research presented in the protocol. For non-VA studies, the PI is required to submit this information on the New Protocol Submission xform.
For non- VA studies, the PI is responsible for obtaining this disclosure from all study staff members who are involved in designing, conducting, or reporting the research presented in the protocol (anyone with direct contact with participants or direct contact with data collection, reporting or analysis of data, i.e., anyone who could influence outcome of the data). Study staff members must disclose any personal conflict of interest as well as any conflict of an immediate family member. The PI is responsible for obtaining this disclosure from study staff by having each person complete the "Potential Conflict of Interest for Study Staff Form." The PI is responsible for keeping these completed forms with their study records. Audits of these forms may be conducted by the IRB.

The PI is responsible for providing an attestation on new protocol submissions and modifications adding study staff that written disclosures have been obtained and reviewed for any conflict of interest. This attestation is documented on the New Protocol Submission xform completed by the PI for new protocol submissions and the modification request form for modifications.

For VA studies, all research personnel are required to have a VA Conflict of Interest Form on file with the VA R&D Office. The VA Administrative Officer for Research is responsible for attesting to the IRB that those forms have been reviewed and any reported conflict disclosed to the IRB. This is applicable to both new protocol submissions and modifications adding study staff.

1) If a potential conflict of interest is present for the investigator or any Covered Individuals or consultants serving as study personnel involved in designing, conducting, or reporting the research presented in the protocol, then additional forms must be submitted as follows:

- For ETSU researchers, an ETSU Conflict of Interest Form must be completed and submitted to Vice Provost for Research
- For VA Researchers, a VA conflict of interest form must be completed and submitted to the VA R&D Office. Like all VA employees, VHA

employees conducting VA research approved by the Research and Development Committee, must comply with the Federal criminal code and the Standards of Ethical Conduct for Executive Branch Employees.

- For researchers affiliated with both institutions, both forms must be completed and submitted as noted above (two parallel pathways).

The IRB Coordinator holds the proposal until a management plan as detailed below is received in the IRB Office. The IRB Coordinator forwards a copy of the conflict of the Potential Conflict of Interest Form to the IRB Director. The IRB Director forwards copies of any disclosures of conflict of interest to the VPR and/or ACOS/Research.
Once the management plan is received, the IRB Coordinator forwards the proposal with the management plan to the convened board.

2) If the Conflict of Interest is such as to require either a VAMC or ETSU conflict management plan the approved plan must be submitted to the IRB prior to review of the protocol.
3) In addition, the investigator must submit a revised Conflict of Interest Form within ten days of any change from previous disclosures, and annually disclose any changes on the continuation review Form 107.
4) When presenting a proposal or modification to the convened IRB, the investigator and any accompanying study staff leave the room prior to the deliberation and vote.
5) The investigator must comply with all recommendations of the IRB Office to minimize conflict of interest.
6) The IRB Director will inform either the Vice Provost for Research or the ACOS/Research of the disclosed financial interest.

If the Vice Provost for Research or the ACOS/Research has already reviewed the financial interest, the Vice Provost for Research or the ACOS/Research will inform the IRB in writing of all actions taken according to the relevant policies. Otherwise the Vice Provost for Research or the ACOS/Research will review the financial interest and inform the IRB in writing of all actions taken according to the relevant policies. The Vice Provost for Research or the ACOS/Research will use the following criteria to determine whether financial interests require management- a. Whether the financial interest will adversely affect the protection of participants in terms of the criteria for IRB approval b. whether the financial interest will adversely affect the integrity of the research. The VPR will devise a monitoring plan if management is required, and this will be included in the management plan.

7) In all cases, IRB review will be held until the Vice Provost for Research or the ACOS/Research has completed the review. The Vice Provost for Research is responsible for reporting any disclosure of conflict of

interest received by the Office of Research and Sponsored Programs on a human subject research study to the IRB.

8) All IRB members will be provided with a copy of the report of Vice Provost for Research or the ACOS/Research.
9) When presenting a proposal or modification to the convened IRB, the investigator and any accompanying study staff leave the room prior to the deliberation and vote.

IV. Managing Conflicts of Interest

A. In addition to actions taken by the Vice Provost for Research or the ACOS/Research, the IRB reviews the management (resolution) plan. The IRB may accept the plan, request modifications, or disapprove the research. The IRB uses the following criteria to determine that the management plan is adequate:
    1. Whether the financial interest will adversely affect the protection of participants in terms of the criteria for IRB approval
    2. whether the financial interest will adversely affect the integrity of the research

The IRB makes the final determination and may take the following actions to manage, reduce, or eliminate conflict of interest

1) Public disclosure of significant financial interests
2) Monitoring research through oversight/audit
3) Modify research plans and/or ICD
4) Disqualification from participating in research
5) Divestiture of significant conflict of interest or
6) Severance of relationship that create actual or potential conflicts
7) More frequent continuing review
8) Disapproval of research

B. If a conflict of interest is identified after a study has been approved or initiated, the Chair or VPR will consult with the IRB and, if appropriate, the R&D Committee to identify the impact of the conflict on the protocol and the research subjects to ensure actions are taken to decrease the impact. Corrective actions may include:

1) Modifying the protocol and ICD
2) Re-consenting subjects
3) Removing the investigator from the subject selection process
4) Supervision of the protocol by independent reviewers and/or

5) Requiring disclosure in all publications/presentations resulting from the research

C. The conflict must be managed so that it does not affect the rights and welfare of participants or the integrity of the research. Disclosure alone can not be used to manage a conflict of interest that might affect participant rights and welfare.
D. The IRB's evaluation of the management plan is documented in the IRB minutes and/or protocol file. The management plan is maintained in both the IRB protocol file and the Vice Provost for Research/ or VA Research and Development Office files. The ETSU Significant Conflict of Interest Form is maintained in the Vice-Provost for Research files. The VA Conflict of Interest Form is maintained in the VA Research and Development Office files.

E. An inability to resolve these issues will be reported to the ETSU President, and if applicable, the VA Medical Center Director, through the appropriate committees.

V. Failure to Comply with Conflict of Interest Policy

If an investigator fails to comply with this policy or with the corrective actions relating to it, the Chair will report this to the VPR, and if applicable, the Medical Center Director. The researcher will be required to attend a mandatory educational session with the VPR. Failure to comply may also result in additional conditions or restrictions including:

A. Termination of the protocol
B. Removal of the investigator from the research team
C. Revocation of the privilege to conduct research at ETSU or within the VA
D. Sanctioning by PHS, FDA (or other applicable entities)

References:
ETSU Faculty Senate Handbook
VA Conflict of Interest Policy
"Financial Conflict of Interest In Research" Memo issued by CRADO on September 13, 2005