Investigator Disclosure of Financial Conflict of Interest

PURPOSE: To define the Middle Tennessee Research Institute (MTRI) policy regarding objectivity in research and to define the procedures for reviewing potential financial conflicts of interest and addressing such identified instances.

POLICY: It is the policy of MTRI that objectivity in the conduct of research must be maintained and that there are procedures to identify potential financial conflicts of interest. If such are identified, there will be procedures for managing, mitigating, or eliminating them.

APPLICABILITY:

A. The regulations apply to all National Institutes of Health (NIH) applications and funded grants, cooperative agreements, and research contracts, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards. When a project is initiated through MTRI there is a specific investigator certification requirement regarding financial conflict of interest.

B. If potential financial conflict of interest is identified for any MTRI administered project, the procedures defined in VHA Directive 1200.13, Financial Conflicts of Interest and outside Compensation for Performance in VA Research, will be affected.

C. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing FCOI for employees. NIH FCOI Policy Statement

PURPOSE:

The intent of this document is to define policy and procedure for assuring MTRI's compliance with requirements for Promoting Objectivity in Research found at 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. The policy also applies to individuals who meet the regulatory definition of "Investigator"(as defined below) who are planning to participate in, or who participate in NIH-funded research.

The purpose of the COI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS/NIH-funded research under grants, cooperative agreements or contracts will be free from bias resulting from an Investigator's financial conflicts of interest (FCOI). This policy also serves to protect the safety of animals and human research participants, the reputation of the recipient institution and of the "investigator" who participates in PHS/NIH-funded research.

These requirements also work together to preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

The NIH Office of Extramural Research Conflict of Interest website contains helpful information and resources about the COI Regulations. See NIH COI FAQs.

The Department of Veterans Affairs is responsible for developing agency specific guidance regarding the management of financial conflict of interest in research. Because all research managed by MTRI is VA research and because employees engaged in such research hold VA paid or VA Without Compensation (WOC) appointments, the Tennessee Valley Healthcare System's (TVHS) policy on Conflict of Interest in the Conduct of Research is applicable to MTRI activities. Any project that involves human subjects research is subject to VA policy and requirements regarding financial conflict of interest in the conduct of human research.

PHS agencies including the NIH require that each investigator disclose to a designated representative of the institution (MTRI) all significant financial interests of the investigator that would reasonably appear to be related to the investigator's institutional responsibilities. Processes for disclosing and for managing any significant financial conflict of interest are described in this policy.

DEFINITIONS:

Financial conflict of interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institution for purposes of this policy means MTRI. However, by virtue of their appointments with TVHS could include that institution.

Institutional responsibilities: Professional activities an Investigator performs on behalf of MTRI (but also to include VA if relevant to a MTRI-administered award); these may include research, publication, research consultation, committee memberships or other administrative responsibilities.

Designated Official (DO): The individual designated by MTRI to oversee the financial conflict of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOSs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring staff FCOI training requirements.

Investigator: The Project Director or Principal Investigator and any other person, regardless of title or position, **who is responsible for the design, conduct, or reporting of research** funded by NIH/PHS, or proposed for such funding. This may include collaborators or consultants. MTRI will consider the individual's role, rather than the title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded research.

Research: Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test of drug). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

PHS: The Public health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS-Funded Research: Any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

NIH: The biomedical research agency of the PHS.

Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by MTRI in the grant application, progress report, or any other report submitted to the PHS/NIH by MTRI. *This term is defined only as it relates to the public accessibility requirements described under Section: PUBLIC ACCESSIBILITY OF THE FCOI POLICY AND FCOI INFORMATION HELD BY SENIOR/KEY PERSONNEL.*

Significant financial interest (SFI):

A. A domestic or foreign financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities (e.g. research, consulting, etc.) performed on behalf of MTRI.
    a. **Publicly Traded Entity**: A significant financial interest exists if the value of a remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Remuneration includes salary, consultant payments, honoraria, paid authorship; equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
    b. **Non-Publicly Traded Entity**: A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (stock, stock option, or other ownership interest).
    c. **Intellectual Property Rights and Interests**: A significant financial interest exists upon receipt of income greater than $5,000 received over the preceding months that is related to such rights and interests (patents, copyrights).

B. **Travel**: Investigators must disclose the occurrence of any reimbursed or sponsored travel that exceeds $5,000 (i.e. paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Institutional Responsibilities during the prior 12 months. Disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The disclosure requirement does not apply to travel reimbursed of sponsored by the following:

   a. A Federal, state, or local government agency located in the United States;
   b. A United States Institution of higher education;
   c. An academic teaching hospital;
   d. A medical center; or
   e. A research institute that is affiliated with a United States Institution of higher education.
   f. Travel reimbursed by MTRI is not subject to reporting requirements.

C. **Significant Financial Interest does not include**:

   a. Salary, royalties, or other remuneration paid by the MTRI or the VA to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to MTRI or the VA and agreements to share royalties related to such rights;
   b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
   c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a domestic institution of higher education and/or its affiliated research institute, a domestic academic teaching hospital or a domestic medical center;
   d. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a domestic institution of higher education and/or its affiliated research institute, a domestic academic teaching hospital or a domestic medical center.
   e. **NOTE**: Exclusions above do not apply to Foreign Financial Interests.

SIGNIFICANT FINANCIAL INTEREST INVESTIGATOR DISCLOSURE :

Investigators will disclose their SFIs that are related to their "*institutional responsibilities"* as defined in the policy.

The disclosure will not be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.

The Investigator SFI Disclosures will be retained by the Institution as part of the record maintenance requirements.

Investigators will disclose their SFIs at the following times:

- **Initial Proposal and Annual Report Related Submissions and Review**: The Principal Investigator and all other individuals who meet the definition of "Investigator" must complete the Tennessee Valley Healthcare System's (TVHS) Conflict of Interest Disclosure Form: TVHS COI Disclosure at initial PHS-funded proposal submission for new award applications and annually in conjunction with submission of PHS-funded non-competing continuation awards. The VA Conflict of Interest Administrator reviews the form to determine if any conflict exists. Any new Investigator who, after applying for NIH funding or during the course of the research project, plans to participate in the project must similarly disclose their SFIs prior to participation in the project.

- **Ad Hoc Basis – New SFIs During the Award:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure or reimbursed or sponsored travel within thirty (30) days of each occurrence.

GUIDELINES FOR DETERMINING "RELATEDNESS" OF SFI TO PHS/NIH-FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST

The Designated Official will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

- **Relatedness Test:** An Investigator's SFI is related to the research when the Designated Official reasonably determines the SFI:
  1) Could be affected by the PHS/NIH-funded research; or
  2) Is in an entity whose financial interest could be affected by the PHS/NIH- funded research.

  Investigator Involvement: The designated official(s) may involve the Investigator in determining whether an SFI is related to the NIH-funded research.

- **FCOI Determination**: A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.

MANAGEMENT OF SFIs THAT POSE FCOI

If a Significant Financial Interest that reasonably appears to be related to an Investigator's Institutional Responsibilities is disclosed that information along with supporting documentation shall be forwarded to MTRI's Executive Director. In coordination with VA and COI Managers and relevant policies or procedures, a determination as to whether any of the disclosed Significant Financial Interests of the Investigator are related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project (a FCOI) will be made. If there is an FCOI it will be either eliminated, reduced or

managed depending on the specific case. If managed, a management plan will be developed in conjunction with VA and appropriate notifications will be reported to PHS.

Notice of Change in Investigator's Significant Financial Interests OR Addition of Investigator with Significant Financial Interest Submissions and Review: If at any point there is the addition of an Investigator new to the project who might have a Significant Financial Interest or a change in an existing Investigator's financial situation that meets the threshold for SFI disclosure and review of significant financial interest the Principal Investigator must disclose that change within thirty (30) days of addition of the new Investigator or of discovering or acquiring a new SFI. That is accomplished through the use of the Disclosure of Financial Interests form for review and processing as described above.

MANAGEMENT OF FCOI:

Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in the portion of the NIH funded research that would be affected by significant financial interests
- Reduction or divestiture of significant financial interests (e.g., sale of an equity interest)
- Severance of relationships that create conflicts.

Enforcement mechanisms and sanctions will be managed in coordination with applicable MTRI and VA policies.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of the Policy and has agreed, in writing, to comply with any plans determined by the Designated Official necessary to manage the Financial Conflict of Interest. The FCOI Designated Official of MTRI will submit the FCOI report to NIH via the eRA Commons FCOI module.

MONITORING INVESTIGATOR COMPLIANCE

MTRI will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the

Investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official which will serve as documentation for compliance with the management plan.

PUBLIC ACCESSIBILITY OF THE FCOI POLICY AND FCOI INFORMATION HELD BY SENIOR/KEY PERSONNEL

Public Accessibility: Per NIH requirements, this policy is posted on the MTRI website: Middle Tennessee Research Institute

Identified FCOIs held by Senior/Key Personnel: Prior to the expenditure of any funds under an NIH award, MTRI will ensure public accessibility by providing a written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel;
2. MTRI has determined that the SFI is related to the research funded through an award; and
3. MTRI has determined that the SFI is a financial conflict of interest.

The information made available via the public website or in a written response will include, at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges:
   $0-$4,999; $5,000- $9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the Institution's identification of a new FCOI which should be requested subsequently by the requestor.

The information will be posted on MTRI's publicly accessible website to meet this requirement, and will be updated at least annually and within 60 days of:

1. Receiving or identifying an additional SFI of Senior/Key personnel related to the NIH-funded research that was not previously disclosed, or
2. A new SFI being disclosed by Senior/Key personnel joining the project and determined by the designated official to be related to the research and an FCOI.

Information on SFIs subject to the public accessibility requirement will remain

available for at least three years from the most recent update.

REPORTING OF IDENTIFIED FINANCIAL CONFLICTS OF INTEREST:

MTRI will assign an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award – no FCOI and no FCOI – no FCOI report). The FCOI Module User Guide is available at NIH FCOI User Guide to assist in submitting reports to the NIH.

Initial or Original FCOI Report: The Original FCOI report will include the following information:

1. NIH grant number;
2. PD/PI or contact PD/PI;
3. Name of Investigator with the FCOI;
4. Name of the entity with which the Investigator has an FCOI;
5. Nature of FCOI, e.g. equity, consulting fees, travel reimbursement, honoraria;
6. Value of the financial interest (in pre-specified dollar ranges) or a statement that a value cannot be readily determined;
7. A description of how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
8. Key elements of the Institution's management plan including:
    - role and principal duties of the conflicted Investigator in the research project;
    - conditions of the management plan;
    - how the management plan is designed to safeguard objectivity in the research project;
    - confirmation of the Investigator's agreement to the management plan;
    - how the management plan will be monitored to ensure Investigator compliance;
    - other information as needed.

Prior to the Expenditure of Funds under a new award: When an FCOI is identified upon the issuance of a new NIH award the FCOI SO will submit an Original report prior to the expenditure of any funds under an NIH award.

Identification of a new FCOI During Award Period: When an FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator, or upon the participation of a new Investigator), MTRI will provide NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the financial conflict of interest.

Annual FCOI Reports: While the award is ongoing (including any extensions with or without funds), MTRI will provide annual FCOI reports that address the status of the previously reported FCOI (i.e., whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

The Annual FCOI report will be submitted at the same time as when the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if

applicable, according to the NIH guidance. The NIH will send an annual report email notification to MTRI when an annual report is due. Annual FCOI reports are not submitted as part of grant closeout.

Revision (or Mitigation) FCOI Reports: Following the completion of a retrospective review, MTRI will provide NIH with a Revision if new information is discovered or a Mitigation Report if bias is found.

OTHER REQUIREMENTS:

Investigator Training: Prior to engaging in research related to any PHS-funded grant, each Investigator must have completed the MTRI Power Point training or the Collaborative Institutional Training Initiative (CITI) web-based program http://citiprogram.org. The required modules are 1) Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COl Rules and 2) Institutional Responsibilities as They Affect Investigators.

This training must be completed at least every four years after initial training. It must be completed immediately if: a) there is a revision to the MTRI FCOI policy that affects requirements of investigators, b) an Investigator is new to MTRI, or c) an Investigator is not in compliance with the policy or management plan. The training will be tracked through the MTRI Administration office.

Clinical Research Requirements: If the Department of Health and Human Services determines that one of its funded clinical research projects, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by MTRI, MTRI shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Requirements: A subrecipient relationship is established when federal funds flow down from or through MTRI to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to MTRI for programmatic outcomes and compliance matters. Subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to MTRI's terms and conditions. MTRI will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

MTRI will incorporate, as part of a written agreement with the subrecipient, terms that establish MTRI's' FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 for reference.

- **If the subrecipient's FCOI policy applies**: The subrecipient institution will certify as part of the agreement with MTRI that its policy is in compliance with the federal FCOI regulation. The agreement shall specify the time period for the subrecipient to

report all identified FCOIs to MTRI (e.g., within 55 days of identification to allow MTRI to report within 60 days) to enable MTRI to provide timely FCOI reports to the PHS/NIH as required by regulation. The MTRI assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.

- **If the subrecipient cannot provide certification**: The agreement shall state that the subrecipient Investigator is subject to MTRI's FCOI Policy for disclosing SFI(s) that are directly related to the subrecipient's work for MTRI. MTRI will require the submission of all Investigator disclosures of SFIs to MTRI. The agreement will include sufficient time period(s) to enable MTRI to comply timely with its review, management, and reporting obligations under the regulations. When an FCOI is identified, MTRI will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module.

Maintenance of Records: MTRI will keep all records of all Investigator disclosures of financial interests and MTRI's review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest), and all actions under this policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 2 C.F.R. 200.334 for different situations. MTRI will retain records for each competitive segment as provided in the regulation. Management plans will be retained as part of the MTRI records.

In addition, the Institution will make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to such disclosure whether or not the disclosure resulted in the Institution's determination of an FCOI per the regulation 42 CFR 50.606(b).

Enforcement Actions When an Investigator Fails to Comply with This Policy: Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply with this policy are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.