404 Conflict of Interest for Externally Funded Projects

Approved by President

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Sidney A. McPhee, President

Effective Date: ________________, 2021
Responsible Division: Academic Affairs
Responsible Office: Vice Provost for Research
Responsible Officer: Vice Provost for Research

I. Purpose

This policy is predicated on the expectations that Investigators will conduct their affairs so as to avoid, mitigate, or minimize, conflicts of interest and they must respond appropriately when conflicts of interest arise in accordance with this policy and with Policy 12 Conflict of Interest. To that end, this policy informs faculty about situations that generate conflicts of interest related to research; provides mechanisms for Investigators and Middle Tennessee State University (MTSU or University) to manage those conflicts of interest; and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official. Investigators must also abide by all applicable University policies including Policy 211 Misconduct in Research and Scholarly Activity.

In addition to this policy, the National Science Foundation (NSF) and the U.S. Public Health Service (PHS) have promulgated additional regulations related to conflicts of interest that affect institutions applying for research funding. The NSF and PHS require each institution to maintain an appropriate policy to ensure that the financial interests of the employees of the institution do not compromise the objectivity of research supported with public funds. In order to comply with federal mandates and to be consistent in application, this policy shall apply to all externally funded projects.

This policy governing conflicts of interest applies to all Investigators of the University. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to University policy.
II. Definitions

A. Clinical Trial. Any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices, or medical or other clinical procedures, such as surgery.

B. Conflict of Interest. Conflicts of interest include situations in which employees may have the opportunity to influence the University's business decisions in ways that could lead to personal gain or give improper advantage to members of their families or to associates, as well as, situations of conflicts of commitment in which employees' external activities interfere or appear to interfere with their paramount obligations to students, colleagues, and the University.

C. Family Member. With regard to the Investigator, their spouse, dependent children or stepchildren, or relatives related by blood or marriage.

D. Financial Conflict of Interest. A significant financial interest (or, where the Institutional Official requires disclosure of other financial interests, a financial interest) that the University reasonably determines could directly and significantly affect the design, conduct, or reporting of institutional research.

E. Financial Interest. Anything of current or potential monetary value received or held by an Investigator or an Investigator's family member, whether or not the value is readily ascertainable, including, but not limited to, salary or other payments for services (i.e., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (i.e., stocks, stock options, or other ownership interests); or intellectual property rights and interests (i.e., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to their institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. federal, state, or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial interest does not include:

1. salary, royalties, or other remuneration from the University;

2. income from the authorship of academic or scholarly works;
3. income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. federal, state, or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

4. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

F. Significant Financial Interest (SFI). A financial interest that reasonably appears to be related to the Investigator's institutional responsibilities:

1. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve (12)-month period preceding the disclosure, and the value of any equity interest during the twelve (12)-month period preceding or as of the date of disclosure, exceeds five thousand dollars ($5,000.00); or

2. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve (12)-month period preceding the disclosure exceeds five thousand dollars ($5,000.00); or

3. if with a non-publicly-traded company, is an equity interest of any value during the twelve (12)-month period preceding or as of the date of disclosure; or

4. is income related to intellectual property rights and interests not reimbursed through the institution.

G. Institutional Official. The individual within the University who is responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's family member(s) related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Vice Provost for Research and Dean of the College of Graduate Studies (VPR) or designee.

H. Institutional Responsibilities. The Investigator's responsibilities associated with their institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal, and external professional committee service.

I. Investigator. Any individual who is responsible for the design, conduct, or reporting of PHS and other sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as Principal Investigator or co-Investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or
graduate students. The definition may also include collaborators or consultants, as appropriate.

J. Public Health Service (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 of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

K. Research. A systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (i.e., a published article, book, or book chapter) and product development (i.e., a diagnostic test or drug).

L. Research Misconduct. Misconduct in research or scholarly activity (misconduct) includes, but is not limited to: fabrication; falsification; misrepresentation; plagiarism; failure to provide periodic reporting; failure to promote, or to sustain, collegial collaboration; failure to monitor and/or manage student researchers and graduate assistants; intentional bypass of academic or scientific research procedures; self-dealing; financial conflict of interests (whether current or potential monetary value); or other practices that significantly deviate from those that are commonly accepted within the academic community for proposing, conducting, reviewing, or reporting research or other scholarly accomplishments. This does not include honest errors or honest differences in interpretations or judgments of data.

III. Disclosure of Conflicts of Interest

All Investigators are required to disclose in writing their conflicts of interest, to include any outside financial interests, to the University on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

Regardless of the disclosure requirements, the Investigator, in their own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

A. Annual Disclosures. All Investigators must disclose their significant financial interests to the University, through the Institutional Official, on an annual basis. All forms should be
submitted to the Institutional Official or designee by March 1 for the previous calendar year.

B. Ad hoc Disclosures. In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their significant financial interests to the University, through the Institutional Official, within thirty (30) days of their initial appointment or employment.

Prior to entering into sponsored projects or applications for sponsored projects where the Investigator has a significant financial interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of their significant financial interests with the outside entity. The University will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any significant financial interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the significant financial interest.

C. Travel Disclosure. Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of financial interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (i.e., the monetary value if not already disclosed) to determine whether the travel constitutes a financial conflict of interest with the Investigator's research.

IV. Review and Decision of the Institutional Official

If the disclosure form reveals a significant financial interest or a conflict of interest related to the research, it will be reviewed by the Institutional Official, and/or the University’s Conflict of Interest Committee in collaboration with the Offices of Research and Sponsored Programs, and Academic Affairs for a determination of whether it constitutes a conflict of interest. If a conflict of interest exists, the Institutional Official will take action within sixty (60) days to eliminate, reduce, mitigate or manage the conflict, as appropriate.

A conflict of interest will exist when the Institutional Official determines that the reported interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research, as well as any other externally funded research. If the Institutional Official determines that there is a conflict of interest that can be managed or mitigated, they must require and approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.
To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

V. Notification to Funding Agency of Financial Conflict of Interest

The Director of the Office of Sponsored Research will notify the funding agency of the existence of a conflict of interest and the action taken to manage, mitigate, reduce, or eliminate the conflict under the following circumstances:

A. Prior to the expenditure of funds;

B. Within sixty (60) days of identification for an Investigator who is newly participating in the project;

C. Within sixty (60) days for new, or newly identified, conflicts of interest for existing Investigators;

D. At least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the financial conflict of interest and any changes to the management plan, if applicable, until the completion of the project; or

E. Following a retrospective review to update a previously submitted report, if appropriate.

MTSU will make available to the funding agency, upon request, all conflicting interests identified and how those interests were managed, reduced, or eliminated. (42 CFR 50.604(h); 42 CFR 50.605 (b); 42 CFR 50.605 (a)(3)(ii))

VI. Financial Conflict of Interest (FCOI) Training

Public Health Services (PHS) requires that all PIs submitting proposals to PHS (such as NIH proposals) must complete FCOI training before the proposal is submitted, and at least every four (4) years thereafter. PIs must also complete the training in a reasonable period of time, if this policy is substantially amended in a manner that affects the requirements of the Investigator, or if it is determined that the PI has not complied with this policy or with a management plan related to their activities.

PIs submitting to other federal agencies will be required to take the FCOI training, if they have disclosed a financial conflict of interest. If the VPR determines that a PI has a financial conflict of interest that has not been disclosed, the Investigator will be required to complete the FCOI training.
VII. Subrecipients, Contractors, and Collaborators

Subrecipients, contractors, or collaborators who are working under subagreements from MTSU that are funded by the federal government, must comply with federal regulations (42 CFR Part 50, Subpart F, Grants and 45 CFR Part 94, Contracts).

If these subrecipient's, contractor's, or collaborator's Investigators must comply with the subrecipient's, contractor's, or collaborator's financial conflict of interest policy, the subrecipient, contractor, or collaborator shall certify as part of the written agreement that its policy complies with federal regulation (42 CFR Part 50, Subpart F). If the subrecipient, contractor, or collaborator cannot provide such certification, the agreement shall state that subrecipient, contractor, or collaborator Investigators are subject to MTSU's financial conflict of interest policy for disclosing significant financial interests that are directly related to the subrecipient's, contractor's, or collaborator's work for MTSU.

The written agreement shall specify time period(s) for the subrecipient, contractor, or collaborator to report all identified financial conflicts of interest to the VPR. Such time period(s) shall be sufficient to enable MTSU to comply timely with its review, management, and reporting obligations.

VIII. Investigation of Non-Compliance

In compliance with NSF and PHS, as well as in compliance with research funding from the National Institutes of Health (NIH) as provided in 42 CFR § 93.108, the University will comply with its written policies and procedures for investigating and responding to allegations of research misconduct and will carry out such investigation and responses with extra care in maintaining the confidentiality of any research subjects, as well as respondents and complainants. For NIH funded research projects and grants, the University will additionally protect the scientific integrity of the research project during any investigation of research misconduct, including the protection of human participants, live vertebrate animals, and the environment, to the extent possible, and will provide reports to the Department of Health and Human Services Office or Research Integrity (ORI), when applicable.

IX. Investigator Non-Compliance

A. Institutional Response to Non-compliance. In the event of an Investigator's failure to comply with this policy, the Institutional Official may suspend all relevant activities until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented. The Investigator may also be subject to disciplinary action due to non-compliance.

The action(s) taken by the Institutional Official will be described in a written explanation of the decision and provided to the Investigator, the Provost, and the Investigator's Dean and Department Chair, and, where applicable, the Institutional Review Board.
(IRB), and will notify the Investigator of the right to appeal the decision. The Investigator may appeal the decision by submitting, in writing, a request to appeal, listing the reasons for an appeal, within thirty (30) days of receipt of the Institutional Official’s decision. If appealed, the Institutional Official will convene an ad hoc Appeals Committee consisting of the respective Dean and Department Chair, one (1) other faculty member from a department other than the Investigator’s, and the IRB chair, if the project is research involving human subjects, or the IACUC chair, if the project is research involving vertebrate animals. The Appeals Committee will review the appeal and respond within thirty (30) days of the receipt of the appeal. The decision will be sent to the Investigator, the VPR, the Provost, the Dean and the Department Chair. The Provost may determine that disciplinary action is appropriate and, if so, will notify the Institutional Official of the disciplinary steps being taken.

The Institutional Official shall notify the funding agency of any disciplinary steps being taken within one hundred twenty (120) days of the Institutional Official’s decision to take action.

B. Retrospective Review. In addition, if the Institutional Official determines that a financial conflict of interest was not identified or managed in a timely manner, including, but not limited to, an Investigator’s failure to disclose a significant financial interest that is determined to be a financial conflict of interest, or failure by an Investigator to materially comply with a management plan for a financial conflict of interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator’s activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the financial conflict of interest, name of the entity with which the Investigator has the financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review. Such review shall be completed within one hundred twenty (120) days of the Institutional Official’s determination of noncompliance.

The Institutional Official will update any previously submitted report to the funding agency relating to the research, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

C. Clinical Research Involving Drugs, Medical Devices, or Treatments. If the Department of Health and Human Services determines that a PHS-funded clinical research project,
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 the University as required by the regulations, the Institutional Officer shall require the Investigator involved to:

1. Disclose the financial conflict of interest in each presentation of the results of the research, or

2. Require an addendum to previously published presentations.

The Investigator shall submit documentation confirming that the disclosure of the financial conflict of interest has been made in each presentation of the results. The Institutional Officer will forward the documentation to PHS in an updated report.

X. Maintenance of Records

The University will maintain records of all disclosures and of all actions taken to resolve conflicts of interest for three (3) years from the date the final expenditure report is submitted (or as otherwise specified in 45 CFR 74.53(b) or 45 CFR 92.42(b)), or until the resolution of any action taken by the funding agency involving those records, whichever is longer.

XI. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the University may make such information available to an agency funding research of the faculty member; to a requestor of information concerning a financial conflict of interest related to PHS external funding; to the ORI for any NIH related research grant or funding; or to the primary entity who made the funding available to the Institution, if requested or required. If the University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

XII. Public Accessibility

Prior to the expenditure of funds, the University will publish on a publicly-accessible website, information concerning any significant financial interest that meets the following criteria:

A. The significant financial interest was disclosed and is still held by the Investigator;

B. A determination has been made that the significant financial interest is related to the externally funded research; and
C. A determination has been made that the significant financial interest is a financial conflict of interest.

The information to be made available shall be consistent with the requirements of the PHS policy. Requests for access to or copies of research records must also comply with Policy 120 Public Records – Inspecting and Copying.

XIII. Regulatory Authority

This policy implements the regulatory requirements of 42 CFR 50 and 45 CFR 94. Where there are substantive differences between this policy and the requirements, the regulatory requirements shall take precedence.

Forms:

Disclosure Form

Revisions: June 5, 2017 (original); __________, 2021.

Last Reviewed: __________ 2021.