

Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

Applies to: faculty staff students student employees visitors contractors

Effective Date of This Revision: December 15, 2016

Contact for More Information: Office of Research and Graduate Studies

Board Policy Administrative Policy Procedure Guideline

BACKGROUND:

On August 25, 2011, the Department of Health and Human Services issued the final regulations related to managing individual conflicts of interest in Public Health Service (PHS) funded research. These regulations aim to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-funded research will be biased by any Investigator conflict of interest. Before it can receive funds from a PHS-awarding component, Central Michigan University must have an enforced policy on financial conflicts of interest related to PHS-funded research in place, and that policy must conform to the Department of Health and Human Service's regulations.

PURPOSE:

Central Michigan University seeks to ensure that research conducted with the support of PHS-funds is not biased by an Investigator's financial conflict of interest. This policy is an effort not only to satisfy federal regulatory requirements, but also to promote objectivity and integrity in PHS-funded research at Central Michigan University.

DEFINITIONS:

- A. Conflict Review Committee - This committee consists of the Vice President for Research/Dean of Graduate Studies, Assistant Vice President for Academic Administration and the Director of Contracting & Purchasing Services, advised by the University Counsel. In the event that the committee determines that additional expertise is necessary, it reserves the right to invite persons with such expertise to participate in its discussions.
- B. Family/Household- This includes the Investigator's immediate family (spouse, parents and children), significant other, and persons living at the same residence as the Investigator, except their tenants or employees.
- C. Institutional Responsibilities - an Investigator's professional responsibilities on behalf of Central Michigan University, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Authority: George Ross, President

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Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

- D. 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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. Financial Conflict of Interest - A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- E. PHS-Awarding Component - the organizational unit of the PHS that funds research.
- F. Senior/Key Personnel - The Project Director or Principal Investigator and any other person identified as senior/key personnel in Central Michigan University's grant application, progress report, or any other report submitted to the PHS by Central Michigan University.
- G. Significant Financial Interest - A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's family/household) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - 1. With regard to any 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 and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, 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;
 - 2. With regard to any 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 family/household) holds any equity interest (e.g., stock, stock option, or other ownership interest);
 - 3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - 4. Any reimbursed or sponsored travel (i.e., that which is 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - 5. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Central Michigan University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or

Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

POLICY:

Central Michigan University requires all Investigators participating in PHS-funded research to disclose significant financial interests related to their institutional responsibilities. Once a significant financial interest is disclosed to the Office of Sponsored Programs (OSP), it will attempt to determine, at the initial disclosure review stage, whether the significant financial interest is related to PHS-research, and if so, whether the significant financial interest represents a financial conflict of interest. If a financial conflict of interest is determined to exist, OSP will attempt to manage, reduce, or eliminate the conflict.

If OSP is unable to determine whether a significant financial interest is related to PHS-funded research, whether a significant financial interest creates a financial conflict of interest, or is unable to manage, reduce, or eliminate a conflict at the initial disclosure review stage, it will refer the disclosure to the Conflict Review Committee so that it may review the disclosure and manage, reduce, or eliminate the conflict of interest.

Once a financial conflict of interest has been managed, reduced, or eliminated, OSP will submit the necessary reports to the PHS-awarding component.

PROCEDURE:

The following Procedures will apply when evaluating a potential conflict of interest in a PHS funded research Project:

I. Disclosure Requirements

- A. Investigators participating in a PHS-funded research project must disclose significant financial interests related to his/her institutional responsibilities:
 - 1. Prior to the submission of the grant/award application; and
 - 2. Prior to engaging in the research if added to an ongoing sponsored research project; and
 - 3. Annually, after the initial disclosure, for the duration of the award; and
 - 4. Within 30 days of discovering or acquiring a new significant financial interest.
- B. When disclosing incidents of sponsored travel, Investigators must provide, at a minimum, the following information:
 - 1. The purpose of the trip; and
 - 2. The identity of the sponsor/organizer; and
 - 3. The destination; and
 - 4. The duration of the trip.

If necessary, Central Michigan University may request more information regarding any incidence of sponsored travel (e.g. the value of the travel) in order to determine whether the travel constitutes a financial conflict of interest.

II. Reviewing Disclosures and Managing Conflicts of Interests

- A. Following the disclosure of a significant financial interest and prior to the expenditure of any funds under a PHS-funded research project, either OSP or the Conflict Review Committee will determine whether or not the significant financial interest is related to PHS-funded research. A significant financial interest is related to PHS-funded research if OSP or the Conflict Review Committee reasonably determines that the significant financial interest:
 - 1. Could be affected by the PHS-funded research; or
 - 2. Is in an entity whose financial interest could be affected by the PHS-funded research.

OSP and the Conflict Review Committee may involve the Investigator with the significant financial interest in the determination of whether or not the interest is related to PHS-funded research.

Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

- B. If either OSP or the Conflict Review Committee reasonably determines that a significant financial interest is related to PHS-funded research, then it must determine whether the significant financial interest creates a financial conflict of interest. A financial conflict of interest exists when either OSP or the Conflict Review Committee reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- C. If either OSP or the Conflict Review Committee reasonably determines that a significant financial interest creates a conflict of interest, it must create and implement a plan that manages, reduces, or eliminates the conflict of interest prior to the expenditure of PHS-funds. Possible management plans include but are not limited to:
1. Public disclosure of the significant financial interest,
 2. Making suitable modifications to the research plan,
 3. Arranging to have the Investigator's research monitored by independent reviewers,
 4. Divestiture by the Investigator of significant financial interests,
 5. The assignment of a different Investigator without a financial interest to take responsibility for the sponsored project, or
 6. The severance of any relationship that creates an actual, perceived, or potential conflict of interest on the part of the Investigator or his/her family/ household.
- D. In the event that an Investigator is added to an ongoing PHS-funded research project or an existing Investigator discloses a newly acquired significant financial interest, OSP or the Conflict Review Committee will have 60 days to review the significant financial interest, determine whether it is related to PHS-funded research, and if so, whether it creates a financial conflict of interest. If a financial conflict of interest is determined to exist, either OSP or the Conflict Review Committee must create and implement a plan that manages, reduces, or eliminates the financial conflict of interest.
- E. In the event that a financial conflict of interest is not identified or managed in a timely manner, for whatever reason (e.g., failure by an Investigator to disclose a significant financial interest, failure of the OSP or the Conflict Review Committee to manage the conflict), OSP or the Conflict Review Committee must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance, was biased in its design, conduct, or reporting. This review must be documented and include, at a minimum, the following key elements:
1. The project number;
 2. The project title;
 3. The name of the Project Director/Principal Investigator;
 4. The name of the individual with the financial conflict of interest;
 5. The reasons for the retrospective review;
 6. A detailed explanation of the methodology used for the retrospective review; and
 7. Findings and conclusions of the review.

After the completion of a retrospective review, OSP will revise any previously submitted financial conflict of interest report and will describe the actions that will be taken to manage, reduce, or eliminate the financial conflict of interest prospectively.

If bias is found in the design, conduct, or reporting of PHS-funded research, a mitigation report must be filed with the PHS-awarding component and must include all of the information required in the retrospective review, and, additionally:

8. A description of the bias on the research project;
9. OSP's or the Conflict Review Committee's plan of action or actions to eliminate or mitigate the effect of the bias.

Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

- F. If the PHS-funded research involves human subjects, the Executive Director of OSP or the chair of the Conflict Review Committee will inform the IRB in writing of any determination regarding a disclosed financial interest as well as any plan to manage a conflict of interest. The IRB will consider the determination and the management plan in a convened meeting and determine by vote whether the financial interest and the management plan allow the research to be approved. The IRB has the final authority to determine whether a management plan is satisfactory.

III. Reporting to the PHS-Awarding Component

- A. Once OSP or the Conflict Review Committee creates and implements a management plan, OSP will submit a financial conflict of interest report to the PHS-awarding component. These reports must be submitted:
1. Prior to the expenditure of PHS-funds;
 2. Within 60 days of identifying a newly discovered or acquired Investigator financial conflict of interest;
 3. Annually for the duration of the award period, including any funded or non-funded extensions of the award period. The annual reports submitted after the initial report must include:
 - i. The status of the financial conflict of interest;
 - ii. Information about changes that have occurred in the management plan;
 - iii. Information about whether the conflict of interest is still being managed, and if not, why the conflict of interest no longer exists.
- B. Conflicts of interest that are eliminated prior to the expenditure of PHS-funds do not need to be reported to the PHS-awarding component.
- C. The reports to the PHS-awarding component must include, at a minimum:
1. The project number;
 2. The Project Director or Principal Investigator or contact Project Director or Principal Investigator if a multiple PD/PI model is used;
 3. The name of the Investigator with the financial conflict of interest;
 4. The name of the entity with which the Investigator has a financial conflict of interest;
 5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 6. The value of the financial interest (dollar ranges are permissible: \$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 references to public prices or other reasonable measures of fair market value.
 7. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
 8. A description of the key elements of OSP's or the Conflict Review Committee's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the research project;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the Investigator's agreement to the plan;
 - v. How the management plan will be monitored to ensure Investigator compliance;
 - vi. And any other information that the OSP or Conflict Review Committee deems necessary.
- D. If OSP or the Conflict Review Committee conducts a retrospective review, OSP must update any previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the financial conflict of interest prospectively. If, during the retrospective review, a bias is found, OSP must timely notify the PHS-awarding component and provide a mitigation report which must include the information detailed in section (III)(E) of this policy.

Title/Subject: **MANAGING CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED RESEARCH PROJECTS**

IV. Training

- A. Central Michigan University requires all Investigators to complete training prior to engaging in PHS-funded research so that they possess an understanding of this policy, their responsibilities regarding disclosure of significant financial interests, and the regulations that form the basis of this policy. This training must be completed:
1. Every four years;
 2. Whenever an Investigator is new to a research project and has not yet completed the training;
 3. Whenever it is discovered that the Investigator is not in compliance with this policy;
 4. Whenever this policy undergoes alterations that affect the responsibilities of Investigators.

V. Public Accessibility

- A. Information meeting the following criteria regarding the significant financial interests held by a PHS-funded research project's senior/key personnel must be made available upon a written request for such information within five business days of the request.
1. The significant financial interest was disclosed and is still held by the senior/key personnel;
 2. Either OSP or the Conflict Review Committee has determined that the significant financial interest is related to the PHS-funded research;
 3. The Institution determines that the significant financial interest is a financial conflict of interest.
- B. The information available to requestors must include:
1. The name of the Investigator with the significant financial interest that represents a financial conflict of interest;
 2. The Investigator's title and role with respect to the research project;
 3. The entity in which the significant financial interest is held;
 4. The nature of the significant financial interest (consulting relationship, ownership interest, salary, etc.);
 5. The approximate dollar value of the significant financial interest 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.
 6. Any other information that OSP or the Conflict Review Committee deems necessary.

This information must remain available to written requests for at least three years from the date that the information was most recently updated

VII. Subrecipients

If any portion of PHS-funded research is performed by a subrecipient (subawardee, subcontractor), the subrecipient must provide a written assurance that it and its Investigators will adhere to the requirements set forth in this policy. Subrecipient agreements must specify time periods for the subrecipient to submit all Investigator disclosures of significant financial interests to OSP. The time periods established for subrecipient disclosure submissions must provide enough time to allow OSP and the Conflict Review Committee to review the disclosures and report any financial conflicts of interest to the PHS-awarding component.

Central Michigan University reserves the right to make exceptions to, modify or eliminate this policy and or its content. This document supersedes all previous policies, procedures or guidelines relative to this subject.