

ATTACHMENT A

Protocol for Managing Research Related Conflicts of Interest

Before [INSERT ENTITY NAME] or an employed provider of UMMS may spend any funds under a PHS-funded research project, the Conflict of Interest Officer shall determine whether there are any Financial Conflict(s) of Interest.

The Conflicts of Interest Officer at [INSERT ENTITY NAME] is [INSERT ROLE NAME].

- A. In consultation with the Research Compliance Committee, on an annual basis, the Conflicts of Interest Officer will ensure that Conflicts of Interest information is requested and received from Principal Investigators and related research staff.
- B. The Conflicts of Interest Officer will review any positive disclosure of Financial Interests responses and consult with the Office of General Counsel and the Corporate Compliance and Business Ethics Group to review the regulatory requirements and determine whether Public Health Services “PHS” reporting and/or other steps are required.
- C. Reporting to PHS:
 1. Prior to Expenditures. Before spending any PHS funds, a Financial Conflicts of Interest report must be provided to PHS by the Conflicts of Interest Officer, or designee.
 2. Eliminated Financial Conflict of Interest. If a Financial Conflict of Interest is eliminated before the expenditure of PHS funds, a Financial Conflict of Interest report is not required.
 3. Supplemental Reporting. If a Financial Conflict of Interest is identified after the initial Financial Conflict of Interest report is completed but while the PHS funded research project is still ongoing, the Conflicts of Interest Officer shall provide a Financial Conflicts of Interest report consistent with the requirements of the rule to the appropriate Public Health Services department and ensure the implementation of the management plan.
 4. Minimum PHS Reporting Elements. Minimum elements of the Financial Conflicts of Interest report submitted to PHS are:
 - i. Project number;
 - ii. Principal investigators;
 - iii. Name of the Investigator with the Financial Conflict of Interest;
 - iv. Name of the entity with which the Investigator has the Financial Conflict of Interest;
 - v. Nature of the Financial Conflict of Interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
 - vi. Value of the 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;
 - vii. Description of how the financial interest relates to the PHS-funded research and basis for the determination that the financial interest conflicts with such research; and
 - viii. A description of the key elements of the management plan; including:

- a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance; and
 - f. Other information as needed.
- A. Annual Financial Conflicts of Interest. The Conflicts of Interest Officer shall annually report to PHS and to the Research Compliance Committee the status of any previously reported financial conflict of interest with regard to an ongoing PHS-funded research project. The annual report shall specify whether the financial conflict is still being managed or explain why the financial conflict no longer exists.
- B. Immediate training. Require each investigator to complete training on the financial conflicts of interest immediately if:
- a. There is a revision in the financial conflicts of interest policies that affects the requirements of Investigators
 - b. The Investigator is new to the Affiliate or
 - c. If the Investigator is not compliant with the financial conflict of interest policy or management plan.
- C. Policy Accessibility. Ensure that this policy is available on the internet.
- D. Routine training. Require each Investigator to complete training regarding the financial conflicts of interest prior to engaging in research and at least every four years. Ensure that this policy is enforced.
- E. Confirm Exceptions. If the Affiliate believes that this policy or portions of this policy do not apply, confirm with Office of Research Compliance annually.
- F. Communicate. Inform each Investigator of this policy.
- G. Enforce Compliance. Promote and enforce compliance with the requirements of this policy.
- H. Certify. As needed, certify, as appropriate, in contract proposals that [insert entity name] complies with requirements.
- I. Cooperate in Investigations. Make information available, promptly upon request, to the Health and Human Services relating to any Investigator disclosure of financial interests and the review of, and response to, such disclosure, whether or not the disclosure resulted in the determination of a financial conflict of interest.
- J. Responding to New or Not Previously Reviewed Disclosures. For Significant Financial Interests not timely disclosed or previously reviewed during an ongoing PHS-funded research project, within 60 days, the Conflicts of Interest Officer must review the Significant Financial interest; determine whether it is related to PHS-funded research; and determine whether a Financial Conflict of Interest exists. If a Financial Conflict of Interest exists, a management plan or interim management plan must be implemented.
- K. Corrective Actions. If a Financial Conflict of Interest was not identified or managed in a timely manner for any reason (e.g. not identified in a timely manner by

Investigator or failure to review/manage the Financial Conflict of Interest), within 120 days of determining noncompliance, a retrospective review of the Investigator's activities and the PHS funded project will be completed to determine whether any PHS funded research conducted in the time of noncompliance was biased in the design, conduct, or reporting of such research. This retrospective review must be documented with the following information:

- a. Project number;
- b. Project title;
- c. Principal Investigator;
- d. Name of the Investigator with the Financial Conflict of Interest;
- e. Name of the Entity with which the Investigator has a Financial Conflict of Interest;
- f. Reason for the retrospective review;
- g. Detailed methodology used for the retrospective review (e.g. methodology of review process, composition of review panel, documents reviewed);
- h. Findings of the Review; and
- i. Conclusions of the Review.

If appropriate, the previously submitted Financial Conflicts of Interest report must be updated with specifications of the actions that will be taken to manage the Financial Conflicts of Interest. If bias was found, the Conflict of Interest Officer must notify and submit a mitigation report to the appropriate PHS department.

- L. Publicly Accessible. If any person requests, in writing, information concerning any disclosed Significant Financial Interest, the Conflicts of Interest Officer must respond within five days with information responding to the request if:
- a. The Significant Financial Interest was disclosed.
 - b. The Significant Financial Interest is still held.
 - c. The Significant Financial Interest is related to PHS-funded research.
 - d. The Conflicts of Interest Officer has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The response must include, at minimum: Investigator name; Investigator title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; the approximate dollar value of the Significant Financial Interest (dollar ranges are permissible) 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; a statement 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 identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

- M. Record Retention. The Conflicts of Interest Officer must retain records relating to all Investigator disclosures of financial interests and the review of, and response to, such disclosures for at least three years.