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Policy Title:	Research and Sponsored Programs Financial Conflict of Interest
Department:	Compliance
Origination Date:	August 31, 2021
Approving Officer:	 Daniel J. Frayne, MD - President <u>8/31/21</u> Date
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Board Approval:	

**I. Purpose**

Mountain Area Health Education Center, Inc. (MAHEC) seeks to support funded project collaborations with industry, government, academia, and others such that financial conflicts of interest (FCOI) do not jeopardize the validity of the results, or the safety those participating in research and evaluation activities.

The purpose of this policy is to ensure the highest ethical standards of objectivity by identifying, evaluating, and mitigating FCOI that may affect funded research and evaluation projects at MAHEC. Additionally, this policy is intended to comply with the requirements of the Federal regulations set forth in 42 CFR Part 50: Objectivity in Research, and 45 CFR Part 94.

**II. Scope**

This policy applies to all individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of Public Health Service (PHS)-funded and Non PHS funded research and evaluation projects at or under the auspices of MAHEC. This includes, but is not limited to, staff, faculty, residents, students, interns, and affiliates. Subrecipients (i.e., subcontractor, subgrantee, or subawardee) at other institutions engaging in sponsored projects with MAHEC are also required to demonstrate compliance with this policy.

Subrecipients: For all funded projects involving a subrecipient (i.e., subcontractor, subgrantee or subawardee) at another institution, MAHEC requires a written agreement from the subrecipient that establishes whether MAHEC’s FCOI policy or the subrecipient’s FCOI policy shall apply to the subrecipient’s Investigators. In all cases, MAHEC must report to the PHS-funding agency any subrecipient FCOI (as defined below) prior to the execution of the subcontract, or within 60 days of identification of a new FCOI that arises during the term of the subcontract.

If the subrecipient’s policy is used, the subrecipient must certify that its FCOI policy is compliant with 42 CFR Part 50 and 45 CFR Part 94, and that they will be responsible for ensuring that the subrecipient Institution and its Investigators comply with federal regulations. Subrecipients must report to MAHEC, as the awardee Institution, any identified FCOI within 10 business days of the management plan agreement with the subrecipient’s Investigator, but no later than 45 days after identification of the FCOI by the subrecipient. The details of the FCOI will be reported to the funding agency as required under applicable regulations or policies.

If MAHEC’s FCOI policy is used, the subrecipient must ensure that its Investigators disclose to MAHEC all Significant Financial Interests as defined below, that are directly related to the subrecipient’s work for MAHEC at the time of submission of the application by MAHEC or at the time the subrecipient signs an institutional letter of support if during an on-going award grant or contract.

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### III. Responsibility

The Research Compliance Officer is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Research Compliance Officer is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

The MAHEC site Principal Investigator is responsible for ensuring all applicable Investigators, including subrecipients, on their project team are in compliance with this policy, as well as any Investigator who joins the project team after the project starts. Applications for funding will only be submitted once all concerned Investigators are determined to be in compliance with this policy.

### IV. Definitions

- A. Conflict of Interest Committee (COI Committee): the individuals that review conflict of interest matters. The committee consists of at least the Research Compliance Officer and the Director of the Division of Research, as applicable.
- B. Family: any member of the Investigator's immediate family, specifically, any dependent children and spouse.
- C. Financial Interest: anything of monetary value received or held by an Investigator or their Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.
  1. Financial Interest does NOT include:
    - a. Salary, royalties, or other remuneration paid by MAHEC to the Investigator if the Investigator is currently employed or otherwise appointed by MAHEC, including intellectual property rights assigned to MAHEC and agreements to share in 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; and
    - c. Income from seminars, lectures, teaching engagements or service on advisory committees or review panels that are sponsored by a federal, state, or local government agency within the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education
  2. Significant Financial Interest: any financial interests (i.e., anything of monetary value) consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children), within the previous 12 months, that reasonably appears to be related to the Investigator's Institutional Responsibilities:
    - a. For all Publicly Traded Entities
      - 1) Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds \$5,000;
      - 2) Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity that exceeds \$5,000; or

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3) Any remaining remuneration and equity from an Entity that, when added together, exceeds \$5,000 in value.

b. For all Non-Publicly Traded Entities

1) Remuneration (e.g., salary, income, consulting fees, honoraria, paid authorship or any other payment) from an Entity that exceeds \$5,000;

2) Any equity interest (e.g., stock, stock option, or other ownership interest) in the Entity regardless of value; or

3) Any remaining remuneration and equity from an Entity that, when added together, exceeds \$5,000 in value.

c. Intellectual Property (IP) Right and Interests

Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

d. For PHS-Funded Research Investigators Only: Reimbursed or Sponsored Travel

Travel reimbursed or sponsored by an Entity other than the Investigator's current institution (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), and related to their institutional responsibilities that exceeds \$5,000 in value (in aggregate for a single Entity).

D. Investigator: any individual who is responsible for the design, conduct, or reporting of a sponsored project, 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 faculty, residents, senior scientists, technical staff regardless of classification, or graduate students. This definition also includes subrecipients (i.e., subcontractor, subgrantee, or subawardee) at other institutions.

E. 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.

F. Project: any funded research, testing, evaluation, training, and/or instructional plan conducted at or under the auspices of MAHEC.

## V. General

### A. Conflict of Interest

This policy is predicated on the expectation that Investigators should conduct their affairs to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest, provides mechanisms for Investigators and the institution to manage those conflicts of interest that arise, 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 Research Compliance Officer.

### B. Disclosure of Financial Interests

1. All Investigators are required to disclose their outside financial interests to the Institution prior to submitting any application for funding and on an ad hoc basis, as described below. The Research Compliance Officer is responsible for the distribution, receipt, processing, review and retention of disclosure forms. Applications for funding will only be submitted once all concerned Investigators are determined to be in compliance with this policy.

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2. Regardless of the disclosure requirements, the Investigator, in his or her 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.

#### C. Ad hoc Disclosures

1. Certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Research Compliance Officer, within 30 days of their initial appointment or employment.
2. Prior to entering into sponsored projects or applications for sponsored projects where the Investigator has a Significant Financial Interest, the Investigator must submit an ad hoc updated disclosure of their Significant Financial Interests to the Research Compliance Officer. The Institution will not submit a proposal unless the Investigator(s) have submitted such ad hoc disclosures.
3. In addition, all Investigators must submit an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year to the Research Compliance Officer within thirty (30) days of discovering or acquiring the Significant Financial Interest.

#### D. Travel

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 Research Compliance Officer will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's sponsored project.

#### E. Review and Decision of the Research Compliance Officer

1. Significant Financial Interests will be reviewed by the Research Compliance Officer, or designee, for a determination of whether it constitutes a Financial Conflict of Interest. If an FCOI exists, the Research Compliance Officer will take action to eliminate, reduce, or manage the conflict, as appropriate.
2. A Significant Financial Interest that directly and significantly affecting the design, conduct, or reporting of a funded project constitutes an FCOI. If the Research Compliance Officer determines an existing FCOI can be managed, a written management plan must be approved before any related project goes forward. The affected Investigator, in partnership with the FCOI Committee, is responsible for developing and submitting a proposed management plan, in consultation with the Research Compliance Officer.
3. To address complex situations, oversight committees may be established by the Research Compliance Officer 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 project findings, and to otherwise oversee compliance with the management plan.

#### F. Reporting To PHS or other Funders

1. Should any reported conflict or non-compliance require reporting to PHS, the Research Compliance Officer will report in accordance with PHS regulations. If the funding for the project is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS. Necessary reporting to non-PHS funders will be reviewed by the Research Compliance Officer and handled accordingly.

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#### G. Investigator Non-Compliance

##### 1. Disciplinary Action

- a. In the event of an Investigator's failure to comply with this policy, the Research Compliance Officer may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Research Compliance Officer is implemented.
- b. A Research Compliance Officer's decision to impose sanctions on an Investigator because of failure to comply with this policy, or failure to comply with the decision of the Research Compliance Officer, will be described in a written explanation of the decision to the investigator as well as the investigator's immediate supervisor and appropriate other administrators.

#### H. Retrospective Review

1. In addition, if the Research Compliance Officer determines that an FCOI 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 an FCOI, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Research Compliance Officer will complete a retrospective review of the Investigator's activities and the project to determine whether the activities conducted during the period of non-compliance was biased in the design, conduct or reporting of the project.
2. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the FCOI, 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.
3. The Research Compliance Officer will update any previously submitted report to the PHS, non-PHS funder, or the prime PHS-awardee relating to the project, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the Funder's regulations or requirements, including a description of the impact of the bias on the project and the plan of action to eliminate or mitigate the effect of the bias.

#### I. Training

Each Investigator must complete training on this policy prior to starting a funded project, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Research Compliance Officer in the event that this policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Training: [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

#### J. Record Retention

The Research Compliance Officer will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the funder.

#### K. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the institution may make such information available to an agency funding a project, to a requestor of information concerning financial conflict of interest or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms,

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conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

L. Public Accessibility to PHS-Related Disclosures

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

1. The Significant Financial Interest was disclosed and is still held by the Investigator;
2. A determination has been made that the Significant Financial Interest is related to the PHS funded project; and
3. Determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.
4. The information to be made available shall be consistent with the requirements of the PHS policy.

Adapted from: Policy on Individual conflicts of Interest and Commitment, University of North Carolina at Chapel Hill; Investigator Financial Conflicts of Interest Policy for Research, Boston University