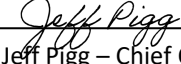




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Policy Title:	Research and Sponsored Programs Financial Conflict of Interest	
Department:	Compliance	
Origination Date:	August 31, 2021	
Approving Officer:	 Jeff Pigg – Chief Operating Officer	07/27/2023 Date
Last Date Revised/Reviewed:	July 18, 2023	
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I. Purpose

Mountain Area Health Education Center, Inc. (MAHEC) seeks to support funded project collaborations with industry, government, academia, and others such that Personal and Financial Interests 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 Financial Conflict of Interest (FCOI) that may affect Sponsored Programs 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](#).

MAHEC must be able to certify, in each application for funding, that MAHEC:

- A. Has in effect an up-to-date, written, enforced and accessible administrative policy and process to identify and manage FCOI
- B. Promotes and enforces Covered Individuals and Investigator training and compliance with the required regulation
- C. Manages Investigator Disclosures and determined FCOI along with initial and ongoing FCOI reports
- D. Maintains records and agrees to make FCOI and Significant Financial Interest (SFI) information (including related Institutional reviews and determinations) available to HHS and funders, promptly, upon request
- E. Shall fully comply with the regulation's requirements

As members of a scientific and intellectual community the fact that an individual may be determined to have a conflict does not imply that the conflict is unethical or impermissible; it means simply that the relation of the conflict to the individual's Institutional Responsibilities must be carefully examined and in some cases managed, because conflicts - real, potential or perceived - may impair performance of teaching, research, and public service, as well as jeopardize public trust and support.

II. Scope

This policy applies to all Covered Individuals and Investigators regardless of title or position, who are engaged in Public Health Service (PHS)-funded and Non PHS funded research Projects at or under the auspices of MAHEC.

Regardless of source of funding, independent contractors, sub-recipients, or consultants who are determined to be Covered Individuals and Investigators shall be covered by this Policy. [42 CFR 50.604\(g\)](#) This includes, but is not limited to, staff, faculty, residents, students, interns, and affiliates. Sub recipients (i.e., subcontractor, sub grantee, or sub awardee) at other institutions engaging in sponsored projects with MAHEC are also required to demonstrate compliance with this policy.

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III. Responsibility

The 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 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 Principal Investigator/Program Director (PI/PD) is responsible for ensuring all applicable Covered Individuals and Investigators, including sub recipients, on the Sponsored Program are in compliance with this policy. Applications for funding will only be submitted once all concerned Investigators are determined to be in compliance with this policy. Funding may not be drawn down until all Investigators are in compliance.

It is the responsibility of each Covered Individual and Investigator to understand which of the following provisions and associated required actions are applicable in the performance of Institutional Responsibilities.

IV. Definitions

- A. Conflict of Commitment (COC): A conflict of commitment arises when an employee undertakes external commitments that burden or interfere with the employee's primary obligations and commitments to MAHEC. Refer to MAHEC Policies [3.HR.1013: Outside Employment](#) & [3.CM.1001: Conflicts of Interest for Employees](#)
- B. Conflict of Interest (COI): means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the research/program when performing under a contract.
- C. Covered Individual: refers to any MAHEC employee, student, or trainee who is performing teaching, research, public service, administration, or business operations of MAHEC.
- D. Disclosure of significant financial interests: an Investigator's disclosure of significant financial interests to an institution
- E. Family: any member of the Investigator's immediate family, specifically, any dependent children and spouse or with whom one lives together in the same residence, shares responsibility for each other's welfare and shares financial obligations. Some funders expand the scope of family in those instances the expanded definition is followed.
- F. Financial Conflict Of Interest (FCOI): A financial conflict of interest exists when the institution's designated official(s) reasonably determines that an investigator's significant financial interest (SFI) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
- G. FCOI Report – an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- H. 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.

Financial Interest does NOT include:

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- 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;
 - 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
 - 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.
- J. Honoraria: payment made to an individual for services, typically offered in a volunteer capacity, in which fees are not traditionally negotiated or expected.
- K. Human Subjects Research: “research involving a living individual about whom data or bio specimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed or generated.” – National Institutes of Health Definition
- L. Institution: any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding
- M. Institutional Responsibilities - an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, 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.
- N. 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 sub recipients (i.e., subcontractor, sub grantee, or subaward) at other institutions. The term Investigator does not apply to individuals whose primary role is to provide technical support or administrative support, or whose role is solely advisory in nature and have no influence over the results of the project.
- O. IRB Administrator: an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
- P. Manage: taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- Q. Paid authorship: payment from an entity in exchange for drafting a publication (e.g., remuneration from authorship of textbooks, payments to faculty authors from publishers, payment from private entities in return for allowing Investigator’s name to be used as an author on a publication).
- R. Personal Interest: an external executive, board position, consulting, volunteer or advisory position related to an activity that involves or is related to Institutional Responsibilities. These activities may or may not be uncompensated.

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- S. PHS Awarding Component: the organizational unit of PHS that funds the research.
- T. Principal Investigator/Program Director: the individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/Pis) who share the authority and responsibility for leading and directing the project, intellectually and logistically.
- U. Project: any funded research, testing, evaluation, training, and/or instructional plan conducted at or under the auspices of MAHEC. MAHEC Administrative Leadership Team has the authority to require projects without external funding to also have to follow this policy.
- V. 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.
- W. Research: means 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 (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).
- X. Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution
- Y. 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:

Publicly traded entity: If the value of any remuneration received from the entity in the 12 months preceding the disclosure and/or the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. This includes:

- Salary
- Any payment for services not otherwise identified as salary
- Consulting fees
- Honoraria
- Paid authorship
- Equity interest (e.g., stock, stock option, or other ownership interest)

For all Non-Publicly Traded Entities: If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated exceeds \$5,000, or when the Investigator holds any equity interest

Reimbursed or Sponsored Travel: Investigators also must disclose the occurrence of 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.

Intellectual Property (IP) Right and Interests: Investigators must disclose, upon receipt of income related to such rights and interests (e.g., patents, copyrights).

- Z. Sponsored Programs: are defined as an activity that is sponsored, or funded, by an external organization, such as a federal, state, or private organization or agency. Sponsored programs typically include basic or applied research, scholarly activity, training, instruction, instructional design, public

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service, and other quality improvement projects. MAHEC Administrative Leadership Team has the authority to deem projects without external funding as a Sponsored Program.

V. General

A. Training

Training is required of all Covered Individuals and Investigators prior to involvement in any Project and at least every four years thereafter and immediately when any of the following circumstances apply:

1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to an Institution; or
3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

Such training will inform the Covered Individuals and Investigators of the Policy, and an Investigator's disclosure responsibilities under the Policy and applicable federal regulations on Financial Conflict of Interest (FCOI). [42 CFR 50.604\(b\)](#)

All Covered Individuals and Investigators involved in a Project must complete the COI training modules through the [NIH COI Training Tutorial](#). Training completion will be reflected in the MAHEC's COI Tracking system. Funding for any sponsored Project may not proceed until all of the Investigators involved in these activities have completed the COI training and Disclosure.

Investigators are also subject to re-training within a reasonable period of time as determined by the Compliance Officer if/when

1. This policy is substantively amended in a manner that affects the requirements of Investigators
2. It is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Alternative training options for Investigators with special circumstances may be proposed by a principal investigator and approved on a case-by-case basis by the Compliance Officer with support from the Office of Sponsored Programs (OSP).

B. Disclosure

All Investigators involved in any Project are required to disclose their and/or Family Personal and Financial Interests, related to the Investigator's Institutional Responsibilities that meets or exceeds the definition of Personal and Financial Interests to the MAHEC Compliance Officer through MAHEC's Conflict of Interest Attestation and Disclosure form. [42 CFR 50.604\(e\)\(1-3\)](#); [42 CFR 50.603](#). Disclosure must include any Personal or Financial Interest, regardless of level or type of compensation. All Investigators

1. Must complete the Conflict-of-Interest Attestation and Disclosure prior to the start of any design, conduct, reporting, or funding of a Project.
2. New to MAHEC must complete the applicable Conflict of Interest Disclosure form within 30 days of their initial employment.
3. Must complete disclosure at least annually during the period of an award. Such disclosure shall include any information that was not disclosed initially to the Institution or in a subsequent disclosure of significant financial interests and shall include updated information regarding any previously disclosed significant financial interest. [42 CFR 50.604\(e\)\(2\)](#)
4. Must submit an ad hoc disclosure of any Personal or Financial Interest they acquire during the course of the project to the Compliance Officer within thirty (30) days. [42 CFR 50.604\(e\)\(3\)](#)

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5. With their own best interest, are 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.

Collaborators, sub awardees or independent contractors who are determined to be Investigators also must comply with this Policy. If they are not covered by a collaborating or contracting institution's own FCOI Policy that meets the sponsoring organization's requirements they must follow the MAHEC FCOI Policy. An assurance signed by an Authorized Official at their own organization indicating policy coverage must be provided along with a copy of the organization's COI policy to determine whether it meets the sponsoring organization's COI standards. [42 CFR 50.604\(c\)](#)

The Principal Investigator on each Project is responsible for ensuring that all Covered Individuals and Investigators have completed training and each individual considered an Investigator completes a Conflict of Interest Disclosure and Attestation form at least annually and as needed as required under this Policy. The Office of Sponsored Programs (OSP) and Compliance Officer will provide reports to the Principal Investigator, Chairs and Administrative Leaders of impacted departments of the Covered Individuals and Investigators FCOI training and disclosure status.

PHS-funded Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities, as defined above in the definition of Financial Interest through the FCOI Attestation and Disclosure form. 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 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. The travel disclosure should be submitted prior to the travel but no later than 30 days after the occurrence of the travel.

PHS-funded Investigators must disclose any income received from any paid authorship. Disclosure for paid authorship can be submitted on any applicable Conflict of Interest Disclosure form, and must be submitted no less than annually.

C. **Review and Monitoring**

Conflict of Interest Disclosure forms are solicited from Investigators, including sub-recipient Investigators, and submitted through MAHEC's OSP to MAHEC Risk and Compliance where they will be processed and reviewed by the Compliance Officer prior to the expenditure of funds. [42 CFR 50.604\(d\)](#)

Prior to Expenditure of Funds MAHEC's Compliance Officer, or designee, will

1. Review all disclosures of Personal or Financial Interest of the Investigators and Family related to an Investigator's Institutional Responsibilities;
2. Determine if any SFIs relate to PHS funded research;
3. Determine if an FCOI exists (that could directly and significantly affect the design, conduct, or reporting of the funded research); and
4. Develop and implement management plans that specifies actions that have been and shall be taken, as needed to manage FCOIs. [42 CFR 50.605\(a\)\(1\)](#)

The review and determination of COI Disclosure will include an analysis of the Investigator's Personal and Financial Interests and relatedness to Institutional Responsibilities and the nature of the activities potentially affected by the disclosed Personal or Financial Interest. Specific review will be conducted to determine if the disclosed interests meet the federal definition of being an FCOI. The Investigator will be contacted at key stages of the process to indicate the status of the review. Any Conflict of Interest Disclosure form submitted by an Investigator will be processed as specified in the [3.CM.1001: Conflicts of Interest for Employees](#). In addition, MAHEC uses the following guidelines to make a COI determination:

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1. Where an Investigator proposes to be engaged in the design, conduct or reporting of a Sponsored Program or Project other than Human Subjects Research, the Conflict of Interest or FCOI may be allowed with approval and appropriate management.
2. Where an Investigator proposes to be involved in the design, conduct or reporting of Human Subjects Research, they may not have a Personal or Financial Interest of any level or value reasonably judged to be significantly and directly related to the outcomes of such research, absent a showing by the Investigator of compelling circumstances justifying continuation of involvement. Compelling circumstances are those facts that convince the reviewer that an Investigator who has a Personal or Financial Interest judged to be significantly and directly related to the research should be permitted to conduct Human Subjects Research, taking into account the following factors:
 - a. the nature of the research,
 - b. the magnitude of the interest and the degree to which it is related to the research,
 - c. the extent to which the Financial Interest could be directly and substantially affected by the research,
 - d. the degree of risk to the human subjects involved that is inherent in the research protocol,
 - e. the extent to which the Investigator is uniquely qualified to perform a research study with important public benefit, and
 - f. the extent to which the Personal or Financial Interest is amenable to effective oversight and management.

The training experience and academic progress of students and trainees must not be subordinated to the Personal or Financial interest of an Investigator or commercial interests of Sponsored Programs.

Where a Conflict of Interest or FCOI poses the risk that MAHEC activities may be inappropriately affected, the conflict must be managed, reduced or eliminated.

An Investigator's Significant Financial Interest (SFI) is related to PHS-funded research when the Compliance Officer reasonably determines that the SFI: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. MAHEC may involve the Investigator in the determination of whether a SFI is related to the PHS-funded research.

A financial conflict of interest exists when MAHEC's Compliance Officer reasonably determines the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. [42 CFR 50.604\(f\)](#)

The Compliance Officer will take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a sub recipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report. If the Compliance Officer determines an existing FCOI can be managed, a written management plan must be developed and approved before the expenditure of funds and/or any related project goes forward.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to

1. Public disclosure of FCOI (e.g., when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of FCOI directly to participants;
3. 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;
4. Modification of the research plan;

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5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest)
7. Severance of relationships that create financial conflicts. [42 CFR 50.605\(a\)\(1\)](#).

All SFI disclosures from Investigators, new to MAHEC or sub-recipients, will be reviewed by the Compliance Officer within (60) sixty days of the disclosure. The Compliance Officer will determine whether it is related to PHS-funded research and whether a financial conflict of interest exists. If an FCOI exists, the Compliance Officer will implement a management plan that specifies the actions that have been, and will be, taken to manage such financial conflict of interest. The Compliance Officer may determine interim measures with regard to the Investigator's participation in the PHS-funded project between the date of disclosure and completion of institutional review. [42 CFR 50.605\(a\)\(2\)](#)

If an SFI was not disclosed in a timely manner by an Investigator or not previously reviewed by the Compliance Officer, the Compliance Officer will review the SFI disclosure, make a determination regarding FCOI, and implement a management plan, if needed, within 60 days identifying the SFI. [42 CFR 50.605\(a\)\(3\) and \(i\)-\(iii\)](#)

In addition, whenever a FCOI is not identified or managed in a timely manner including:

1. failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a financial conflict of interest,
2. failure by the Institution to review or manage such a FCOI, or
3. failure by the Investigator to comply with a FCOI management plan;

within 120 days of the determination of noncompliance, MAHEC will 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 time period of the noncompliance, was biased in the design, conduct, or reporting of such research. MAHEC will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, MAHEC shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, MAHEC is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of

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whether the research project is salvageable). MAHEC will then submit FCOI reports annually. Depending on the nature of the financial conflict of interest, it may be determined that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review. [42 CFR 50.605\(a\)](#)

In addition, the Compliance Officer will take actions as necessary to manage FCOIs, including any financial conflicts of a sub-recipient Investigator, if applicable, and monitor Investigator compliance with management plans until the completion of the project. [42 CFR 50.604\(g\)](#); [42 CFR 50.506\(a\)\(4\)](#)

Whenever MAHEC implements a management plan it will be monitored, documented and recorded by MAHEC Risk and Compliance Office to ensure Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. [42 CFR 50.605\(a\)\(4\)](#)

To address complex situations, oversight committees may be established by the Compliance Officer to periodically review the ongoing activity, to monitor the conduct of the activity, to ensure open and timely dissemination of the project findings, and to otherwise oversee compliance with the management plan.

D. Reporting

MAHEC will send initial, annual, and revised FCOI reports including all reporting elements for MAHEC and its sub recipients, as required under applicable federal regulations, if applicable. As federal agencies may have differing requirements, reporting will be determined by the standards and guidelines set by each agency. [42 CFR 50.604\(h\)](#)

Reporting Elements include at a minimum:

1. Project Number
2. PD/PI or Contact PD/PI if multiple PD/PI model is used
3. Name of the Investigator with the FCOI
4. Name of the entity with which the Investigator has a the FCOI
5. Nature of the Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
6. Value of the Financial Interest, or a statement that the interest is one whose valued cannot be readily determined through reference to public prices or other reasonable measure of fair market value
7. A description of how the Financial Interest relates to the PHS-funded research and the basis for the determination that the Financial Interest conflicts with such research
8. A description of key elements of the Management Plan including:
 - a. Role and principal duties of the conflicted Investigator
 - b. How the Management Plan is designed to safeguard objectivity in the research Project
 - c. Confirmation of the Investigator's agreement to the Management Plan
 - d. How the Management Plan will be monitored to ensure Investigator compliance
 - e. Other information as needed or requested by the funding agency

FCOI reports will be submitted

1. Prior to the expenditure of funds;
2. Within 60 days of identification for an Investigator who is newly participating in the project;
3. Within 60 days for new, or newly identified FCOIs for existing Investigators;
4. At least annually to provide the status of the FCOI and any changes to the management plan, if applicable until the completion of the project; and
5. Following a retrospective review to update a previously submitted report, if appropriate. [42 CFR 50.605\(b\)](#); [42 CFR 50.605\(a\)\(3\)\(iii\)](#)

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Necessary reporting to non-PHS funders will be reviewed by the Compliance Officer and handled accordingly.

In addition, MAHEC must promptly submit an updated/amended FCOI Report within sixty (60) days of

1. The identification of any new or newly identified FCOIs,
2. The identification of an Investigator who is newly participating in the project or following a retrospective review. [42 CFR 50.605\(a\)\(3\)\(iii\)](#); [42 CFR 50.605\(b\)](#)

If bias is found with the design, conduct or reporting of PHS funded research MAHEC will submit a Mitigation Report in accordance with the regulation. [42 CFR 50.605\(a\)\(3\)\(iii\)](#)

If an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded research MAHEC will notify the PHS Awarding Component promptly. The PHS Awarding Component may take appropriate action or refer the matter to the institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity. [42 CFR 50.606\(a\)](#)

For any previous FCOI Reports, MAHEC shall provide an Annual FCOI Report that addresses

1. The current status of the FCOI and
2. Any changes to the FCOI management plan.

These Annual Reports will be submitted for the duration of the Project and according to the timeline outlined by the PHS awarding component.

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.

E. Maintenance of Records

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. Only individuals holding responsibility for review as well as other MAHEC offices with a business purpose should access this information. The institution may make such information available to a funding agency, to a requestor of information concerning FCOI or to the primary entity who made the funding available, if requested or required. If MAHEC is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

The Compliance Officer will maintain all FCOI-related records that meet or exceed the regulatory requirements for a period of three years from the date the final expenditure report is submitted to the funder and other dates specified in [45 CFR 75.361](#) where applicable. [42 CFR 50.604\(l\)](#)

F. Enforcement Mechanisms and Remedies for Noncompliance

The Compliance Officer is responsible for ensuring implementation of this policy and may suspend all relevant activities until the decision regarding a FCOI is resolved or other action deemed appropriate by the Compliance Officer is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to the policy. [42 CFR 50.604\(i\)](#)

The MAHEC Principal Investigator is responsible for ensuring all applicable Investigators, including sub recipients, on their project team are in compliance with this policy. Applications for funding or drawing down of funds will only occur once all concerned Investigators are determined to be in compliance with this policy.

Any time the Compliance Officer becomes aware of a potential violation of the Policy or of any other situation where Sponsored Programs and Research may have been affected inappropriately by a

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Conflict of Interest, the Compliance Officer shall conduct a preliminary investigation to determine whether the concerns appear to be warranted.

On receipt of such a report, the Compliance Officer shall notify the Administrative Leadership Team. In consultation with those persons, the Compliance Officer may:

1. Investigate the matter and make a written memorandum of his or her conclusions;
2. Request that the person or committee assigned to monitor the activity conduct an investigation and file a written report of the results of that investigation; or
3. Appoint another faculty member or a committee of faculty members to conduct an investigation and file a written report of the results of that investigation.

Any such investigation should, at a minimum, include a personal interview with the person bringing forth the allegations or concerns, if known, and a personal interview with the Covered Individual/Investigator, who should be informed with specificity of the allegations or concerns that have arisen.

Upon determination that a violation of this Policy has occurred or of the existence of a situation that could have been affected inappropriately by a Conflict of Interest, the Compliance Officer should take any steps necessary to correct the situation, including and up to disapproval of the conflict of interest being managed. In addition, where appropriate the Compliance Officer must consider recommending to the Administrative Leadership Team the imposition of disciplinary or other action under other appropriate policies. The Compliance Officer, in consultation with the Administrative Leadership Team shall have the authority to direct that the Project activities of the Covered Individual/Investigator affected by the COI be suspended pending conclusion of an investigation or, on conclusion of an investigation, that the Project be suspended pending amelioration of the Policy violation.

Possible sanctions for violation of this Policy can range from administrative intervention to termination of employment, all in accordance with applicable MAHEC policies. Violations may include but are not limited to:

1. Blatant disregard of this Policy while participating on a Project
2. Failure to disclose timely Personal or Financial Interests as required,
3. Providing incomplete or knowingly inaccurate information,
4. Failure to respond to requests for additional information,
5. Failure to neutralize conflicts; and
6. Failure to comply with mutually agreed up management/monitoring plan. [42 CFR 50.604\(i\)](#)

A Compliance Officer's decision to impose sanctions because of failure to comply with this policy, or failure to comply with the decision of the Compliance Officer, will be provided to Talent Management and described in a written explanation of the decision to the Covered Individual/Investigator, their immediate supervisor and appropriate other administrators. A decision to suspend activities or take other action will be described in a written explanation of the decision to the Investigator and will notify the individual of the right to appeal the decision. The Compliance Officer will promptly notify the PHS funding agency of action taken or to be taken.

All materials generated in the course of such investigation should be placed with the Covered Individual's personnel file.

MAHEC will make this policy available on its website and as part of the policies and procedures.

If the 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

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for a Financial Conflict of Interest, a committee appointed by the Compliance Officer will complete and document 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 consistent with federal regulation with 120 days. [42 CFR 50.605\(a\)\(3\)](#)

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.

The Compliance Officer will promptly 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. [42 CFR 50.605\(a\)\(3\)\(iii\)](#)

In a situation in which the U.S. Department of Health and Human Services determines that a PHS-funded research project of clinical research 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 FCOI that was not managed or reported by MAHEC as required by the federal regulations, MAHEC shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations. [42 CFR 50.606\(c\)](#)

MAHEC will be responsive to any inquiries from or requirements by the PHS awarding agency regarding FCOI management, in order to maintain the objectivity of the research. If, in addition to MAHEC's management of an FCOI, PHS determines that further corrective action is needed to mitigate potential bias or if MAHEC has not managed the FCOI in accordance with PHS regulations, PHS may determine that imposition of specific award conditions under [45 CFR 75.207](#), or suspension of funding.

G. Subcontracts

For all funded projects involving a sub recipient, (i.e., subcontractor, sub grantee or sub awardee) at another institution, MAHEC will take reasonable steps to ensure that any sub recipient Investigator complies with this policy. MAHEC requires a written agreement from the sub recipient that establishes whether MAHEC's FCOI policy or the sub recipient's FCOI policy shall apply to the sub recipient's Investigators. In all cases, MAHEC must report to the PHS-funding agency any sub-recipient FCOI 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. [42 CFR 50.604\(c\)](#); [42 CFR 50.604\(c\)\(1\)\(i\)-\(iii\)](#)

If the sub recipient's policy is used, the sub recipient must certify that its FCOI policy is compliant with [42 CFR Part 50](#) and [45 CFR Part 94](#), supply a copy of the policy to MAHEC, be responsible for ensuring Investigator and organizational compliance with federal regulations. If the sub recipient cannot provide such certification, the agreement shall state that the sub recipient Investigators are subject to MAHEC's FCOI policy for disclosing significant financial interests that are directly related to the sub recipient's work for MAHEC. Sub recipients must report to MAHEC, as the awardee Institution, any identified FCOI within 30 business days of the management plan agreement with the sub recipient's Investigator, but no later than 60 days after identification of the FCOI by the sub recipient.

The sub-recipient will provide the following information to MAHEC for any FCOI of sub-recipient Investigators:

1. Sub-recipient contract number;
2. Name of the sub-recipient Investigator with the FCOI;
3. Name of the entity with which the Investigator has an FCOI;
4. Nature of the Financial Interest (e.g., equity, consulting, etc.);

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5. Value of the Financial Interest;
6. A description of how the Financial Interest relates to the PHS-funded research and the basis for the sub-recipient's determination that the Financial Interest conflicts with the PHS-funded research; and
7. A description of the management plan.

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 sub recipient must ensure that its Investigators disclose to MAHEC all Significant Financial Interests as defined in this policy, that are directly related to the sub recipient's work for MAHEC at the time of submission of the application or at the time the sub recipient signs an institutional letter of support if doing an on-going award or grant contract.

If additional Investigators are identified by the sub recipient at the time of the sub-award contract, these Investigators must also complete MAHEC's Conflict of Interest Attestation and Disclosure form and training before the sub-award agreement can be executed or they can begin work on the Project.

MAHEC will report the sub recipient FCOIs to PHS in the same manner as it reports FCOIs of MAHEC Investigators.

The Compliance Officer will take actions as necessary to manage FCOIs, including any financial conflicts of a sub recipient Investigator, if applicable, and monitor Investigator compliance with management plans until the completion of the project. [42 CFR 50.604\(g\)](#); [42 CFR 50.506\(a\)\(4\)](#)

H. Public Accessibility to PHS-Related Disclosures

The Compliance Officer or designee will ensure MAHEC's FCOI policy is publicly available via MAHEC's public website. [42CFR 50.604\(a\)](#)

Prior to the expenditure of funds and in accordance with federal regulations, MAHEC will publish on a publicly-accessible website or respond to any requestor within five calendar days of the request, information concerning any FCOIs held by an Investigator 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. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall

1. Include the minimum elements as provided in the regulation [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#);
2. Be posted on a Public Website or made available within 5 calendar days of written request FCOI (written request should include the updated information);
3. Be updated at least annually;
4. Be updated within 60 days of a newly identified FCOI; and
5. Remain available for three years from the date the information was most recently updated.