



1.1.002 Financial Conflict of Interest

Subject	Financial Conflict of Interest
Effective Date	September 27, 2021
Revision Date	N/A
Approvals	Executive Educational Council (EEC)
Responsible Office	Applied Technology Center™ (ATC)
Owner/Creator(s)	Dean of Applied Research

I. PURPOSE and SCOPE

It is the policy of Milwaukee School of Engineering (MSOE) to comply with Federal regulations regarding financial disclosure of potential conflict of interest in research, as made part of the 2011 revised Financial Conflict of Interest (FCOI) regulation at [42 CFR Part 50 Subpart F](#). This policy is intended to ensure that the design, conduct and reporting of research will not be biased by any conflicting financial interest of those investigators responsible for the research. This policy is supplemental to [MSOE's Conflict of Interest & Ethics Policy](#).

II. INTRODUCTION

This policy governing financial conflict of interest applies to all Investigators funded by or submitting proposals for funding to any agency of the US Public Health Service (PHS), except for Small Business Innovation Research (SBIR) Program Phase I applications. This exclusion does not apply to investigators submitting proposals to the National Institutes of Health (NIH) or National Science Foundation (NSF).

Investigators are required to disclose any external financial interests related to their MSOE responsibilities for review, and any required management, to ensure the design, conduct or reporting of the PHS research is not biased by a financial conflict of interest.

III. DEFINITIONS:

Compelling Circumstances are those facts that convince MSOE's Research Conflict of Interest (RCOI) Committee that a financially interested individual should be permitted to conduct human subjects research. When considering a request by a financially interested individual to conduct human subjects research, the circumstances that the RCOI Committee should evaluate include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be

directly and substantially affected by the research, the degree to which the interest could affect the research, and the degree of risk to the human subjects involved that is inherent in the research protocol. A material conflict of interest requires a written mitigation plan to be monitored by the RCOI Committee.

Conducting Research means, with respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

Dean of Applied Research is the individual responsible for reviewing all Significant Financial Interest disclosures; determining whether a Financial Conflict of Interest (FCOI) potentially exists and submitting potential FCOIs to the Research Conflict of Interest Committee for review and/or management. The Dean of Applied Research will chair the Research Conflict of Interest Committee and submit FCOI and other reports to applicable awarding agencies/funders.

Disclosure means a release of relevant information about significant financial interests in human subjects research to parties outside MSOE's RCOI review and management processes (e.g., to research subjects or journal editors).

Externally Funded Research means all externally funded research, including grants, contracts, and cooperative agreements. External sponsors include, but are not limited to PHS-Awarding Components (e.g., NIH), other federal funding agencies (e.g., DoD, NSF), foundations, private companies and individuals.

Family Member means any member of the Investigator's immediate family, including spouse, domestic partner, parents, siblings, and children.

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting the results of Research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Financially Interested Individual means a covered individual who holds a significant financial interest that would reasonably appear to be affected by the individual's human subject's research.

Human Subjects Research includes all research meeting the definition of "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 CFR Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of "human subjects" or "research" are modified through rulemaking, any such revisions shall apply for the purposes of this guidance.

Investigator's Institutional Responsibilities means an Investigator's professional responsibilities on behalf of MSOE, which may include, but is not limited to research, consultation, speaking engagements, teaching, professional practice, contract negotiation, clinical activities, purchasing and institutional committee memberships.

Investigator means 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, and all senior/key personnel on a project, regardless of funding.

MSOE Institutional Review Board is MSOE's institutional review board with jurisdiction over the research as specified in the federal wide assurance (FWA) for protection of human subjects that Milwaukee School of Engineering has provided to the U.S. Department of Health and Human Services.

PD/PI means a Project Director or Principal Investigator of a research project. In funded research, the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS-funded Research means all research which is sponsored by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including but not limited to the National Institutes of Health (NIH), the Center for Disease Control (CDC), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ).

Reporting means the provision of information about significant financial interests in human subjects research by a covered individual to the Dean of Applied Research and to the RCOI Committee, or the transmission of such information within institutional channels.

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

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in a grant application, progress report, or any other report submitted to a funding agency.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of the remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity 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. 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.

- 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 spouse, or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such rights and interest.
- Investigators must also 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 the institutional responsibilities; except for travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education (as defined at 20 USC 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Significant Financial Interest does not include:

- salary, royalties, or other remuneration paid by MSOE to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to MSOE 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;
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education; or

IV. RESPONSIBILITIES OF MILWAUKEE SCHOOL OF ENGINEERING (MSOE)

This is the essential statement of the policy that is posted in public places, such as the catalog, handbook, or website. Use bulleted subheadings, if necessary.

Policy MSOE will maintain an up to date, written, enforced policy on financial conflicts of interest that complies with 42 CFR 50 Subpart F. The Policy applies to research that is funded by PHS. The Policy will be made publicly available via the University's public-facing website.

Training MSOE is responsible for informing each Investigator of this Policy; relevant regulations, and the Investigator's responsibility to disclose significant financial interest. Investigators are required to complete Investigator COI training before engaging in research, and at least once every four years. In addition, Investigators will be trained/re-trained immediately when:

- MSOE revises this Policy in any manner that affects the requirements of investigators;
- An Investigator is new to MSOE; or
- MSOE finds that an Investigator is not in compliance with the financial conflict of interest policy or management plan(s).

Reporting

PHS-funded Research. MSOE is obligated under 42 CFR 50 Subpart F to report to the PHS Awarding Component all related significant financial interests that are deemed financial conflicts of interest (FCOI), as defined in this Policy, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. MSOE must review, manage, mitigate, report, and when appropriate, conduct retrospective reviews of potentially conflicted projects as described in this Policy.

V. INVESTIGATOR DISCLOSURE REQUIREMENTS

Initial Disclosures. Each Investigator (as defined in this Policy – individuals responsible for the design, conduct, or reporting of research or proposed research in a funding application) is required to disclose the Investigator's Significant Financial Interests – and those of the Investigator's spouse, and dependent children – prior to submitting an application for PHS-funded research.

Disclosing Significant Financial Interests allow MSOE to determine whether a "Financial Conflict of Interest" exists, whether it is related to the research, and whether management or mitigation strategies must be implemented to ensure objectivity in research.

Investigators who are new to MSOE must disclose Significant Financial Interests before transferring any research to MSOE and before engaging in any research activities at MSOE.

Disclosures must be made, in writing, to the Dean of Applied Research in accordance with their published Investigator COI Disclosure form(s).

Subsequent Disclosures. Each Investigator who participates in research must submit an updated disclosure of significant financial interests at least once per year during the period of the award or project, to determine whether the interest, if any, is a "Financial Conflict of Interest" that is potentially related to the research.

The disclosure must include any information that was not initially disclosed to the University and shall also include updated information on any previously disclosed significant financial interests (e.g., updated value of a previously disclosed equity interest).

Additionally, Investigators must submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (through purchase, marriage, inheritance, etc.) a new significant financial interest.

Management of Subrecipients. When MSOE carries out research through a subrecipient (e.g., subcontractors), MSOE must take reasonable steps to ensure that the subrecipient Investigator(s) will comply with either the subrecipient's or MSOE's Investigator Conflict of Interest Policy.

Special Provisions for PHS-funded Subrecipients: When MSOE carries out PHS-funded research through a subrecipient (e.g., subcontractors), MSOE must take reasonable steps to ensure that the subrecipient Investigators will comply with 42 CFR 50 Subpart F by incorporating one of the following into the subcontract agreement:

- Statement that the subrecipient will comply with their own financial conflict of interest policy which complies with 42 CFR 50 Subpart F. The agreement will specify the time periods for the subrecipient to report all identified financial conflicts of interest to the awardee's institution (Milwaukee School of Engineering). Time periods for reporting to MSOE must be sufficient to allow MSOE to complete the review, management, and reporting of subrecipient Financial Conflicts of Interest which are related to PHS-funded research; or
- Statement that the subrecipient will comply with this Policy (MSOE's Investigator COI Policy) which complies with 42 CFR 50 Subpart F. The agreement will specify the time periods for the subrecipient to report all Investigator disclosures of significant financial interest to the awarded institution (Milwaukee School of Engineering). Time periods for reporting to MSOE must be sufficient to allow MSOE to complete the review, management, and reporting of subrecipient Financial Conflicts of Interest which are related to PHS-funded research.

VI. PHS FUNDING APPLICATION CERTIFICATION

In accordance with 42 CFR 50 Subpart F, MSOE will meet the following PHS expectations when applying for PHS-funding:

Certification. MSOE must certify, in each grant application for PHS-funded, that MSOE; Has in effect an up to date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS:

- Shall promote and enforce Investigator compliance with the requirements under 42 CFR 50 Subpart F including those pertaining to disclosure of significant financial interest;
- Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component;
- Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and MSOE's review of, and response to, such disclosure, whether or not the disclosure resulted in MSOE's determination of a FCOI; and
- Shall fully comply with the requirements of 42 CFR 50 Subpart F.

VII. REVIEW AND MANAGEMENT OF POTENTIAL COI

In accordance with 42 CFR 50, Subpart F, MSOE designates the Dean of Applied Research as responsible for soliciting and reviewing disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, research. Disclosures must be made, in writing, to the Dean of Applied Research prior to the submission of each application for PHS funding, in accordance with MSOE's published Investigator COI Disclosure form. MSOE will provide initial and ongoing FCOI reports to the funding agency, if any, in accordance with the funding agency's policies.

MSOE will provide guidelines consistent with 42 CFR 50, Subpart F for the Institutional Officials to determine whether an Investigator's significant financial interest is related to the research, and if so, whether the significant financial interest constitutes a "financial conflict of interest." A "financial conflict of interest" occurs when the Dean of Applied Research reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of research. MSOE may not rely solely upon an Investigator's determination to decide whether a Significant Financial Interest or Financial Conflict of Interest is related to research. The Dean of Applied Research or RCOI Committee may, however, request information and feedback from the Investigator regarding relatedness to research and/or Institutional Responsibilities.

Appeals. Any Investigator who disagrees with a final decision of the RCOI Committee may appeal in writing to the Dean of Applied Research within ten (10) calendar days of a final decision. The RCOI Committee must review and consider all appeals, and vote to either retain its original findings or to revise its recommended actions. The final decision regarding management of an actual or potential COI in research under this Policy rests with the RCOI Committee, though investigator feedback is encouraged.

VIII. COMPLIANCE, NON-COMPLIANCE AND INSTITUTIONAL ENFORCEMENT

All persons subject to this Policy are expected to comply fully and promptly. An Investigator who submits a complete and accurate COI Disclosure and complies with conditions required by the RCOI Committee shall be deemed to be in compliance with this Policy. Failure to fully and accurately disclose a Conflict of Interest or failure to comply with conditions or management plans imposed by the RCOI Committee shall constitute non-compliance with this Policy.

MSOE encourages Investigators who are aware of an unreported Conflict of Interest to bring the COI to the attention of the Dean of Applied Research who will consult with the RCOI Committee regarding possible enforcement actions to be taken. If the RCOI Committee determines that an Investigator has failed to comply with any aspect of this Policy, the RCOI Committee shall submit a report in writing to MSOE's Executive Vice President of Academics. The report shall include all material facts and recommendations for enforcement actions, if any.

The Executive Vice President of Academics shall make final decisions regarding enforcement actions, up to and including termination of employment or legal action.

MSOE will complete and document retrospective reviews within 120 days of the University's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner. Such reviews will be documented consistent with the regulation.

IX. REVIEW AND MANAGEMENT OF CONFLICTS OF INTEREST

Mitigation

For PHS-funded research, MSOE must 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, as well as MSOE's plan of action to eliminate or mitigate the effect of the bias. Thereafter, MSOE shall submit FCOI reports to the PHS Awarding Component annually. Depending on the nature of the FCOI, MSOE may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS – funded research project between the date that the FCOI or noncompliance is determined, and the completion of MSOE's retrospective review. The RCOI Committee will be responsible for generating all appropriate documentation, including when the retrospective review finds no bias, and the basis for such a finding.

X. PUBLIC ACCESSIBILITY

Prior to the expenditure of any funds under any PHS-funded research projects, MSOE will ensure public accessibility of information concerning any Financial Conflicts of Interest (FCOI) disclosed to MSOE. MSOE will ensure such accessibility by responding

to any requestors within five (5) business days of a request, or posting on MSOE's external website, when the following criteria are met:

- A Significant Financial Interest (SFI) was disclosed and is still held by the senior/key personnel as defined in 42 CFR 50, Subpart F.
- The Dean of Applied Research and/or RCOI Committee has determined that the SFI is related to the research and the RCOI Committee determines that the SFI is a FCOI.

The information that MSOE must make publicly available includes, at a minimum:

- Investigator's name
- Investigator's title and role with respect to the Externally funded project
- The name of the entity with which the significant financial interest (SFI) is held
- The nature of the SFI
- The approximate value of the SFI
- When the value of an SFI cannot be readily determined through reference to public prices or other reasonable measure of fair market value, a statement stating so.
- A statement that the information 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 Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. MSOE is not responsible for continually updating previous requests. The requestor must make a new request to obtain updated information.

Information concerning conflicts for which the above criteria are met must be available to written requestors for at least 3 years from the date that the information was last updated.

XI. REPORTING TO PHS AWARDING COMPONENTS

For PHS-funded research, MSOE will provide the PHS Awarding Component with a FCOI report regarding any Investigator's significant financial interest found to constitute FCOI, and to ensure that MSOE has implemented a management plan in accordance with 45 CFR 94.

All FCOI reports to PHS Awarding Components must include sufficient information to enable the PHS to understand the nature and extent of the financial conflict, and to

assess the appropriateness of MSOE's management plan. The FCOI report shall include, but is not limited to:

- Project number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Nature of the financial interest (e.g., equity, travel reimbursement, honoraria)
- Value of the interest (ranges are allowed as cited in the Public Accessibility section of this Policy)
- A description of key elements of MSOE's management plan, including:
 - Role and principal duties of the conflict Investigator in the research project
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the Investigator's agreement to the management plan
 - How the management plan will be monitored to ensure Investigator compliance, and
 - Other information as needed.

For any FCOI previously reported by MSOE with regard to an ongoing PHS-funded project, MSOE will provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCI and any changes to the management plan. This reporting shall continue throughout the period of funding in the time and manner specified by the PHS Awarding Component. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

Maintenance of records. MSOE shall maintain records regarding Investigator COI Disclosures, and MSOE's review of, and response to, such disclosures (whether or not the disclosure resulted in the Dean of Applied Research's determination of a financial conflict of interest related to research) and all actions relating to elimination, management, mitigation, and retrospective reviews (if applicable) for at least three (3) years after final payment on any Externally-funded project to which the potential or actual COI relates; or three years after the resolution of any funding agency action involving those actions, whichever is longer.

Research Conflict of Interest Committee (RCOIC)

The RCOI Committee membership shall consist of:

- the Dean of Applied Research,
- the Director of Human Resources
- the IRB Administrator and
- a representative from the Academic Research Misconduct Policy Committee
- Minutes shall be taken at each committee meeting and maintained by the Dean of Applied Research.

The conflicts committee will:

- Determine if there are compelling circumstances which are sufficient to allow the research to continue in the face of the conflict.
- Determine the appropriate strategies to properly oversee and manage potential conflict(s), taking into consideration the possible remedies as outlined below.
- Inform the investigator and the IRB of the actions taken and decisions made by the committee.
- For research that is permitted to go-forward by the RCOI committee, the IRB will be informed of the nature of the conflict, and any recommendations made to manage the conflict by the RCOI Committee. The recommendations and actions will become a part of the research application and continue for the duration of the research study.

The RCOI Committee responsibilities include the following:

1. Review of any request by a financially interested individual to rebut the presumption that he or she may not conduct human subject's research.
2. Documentation of the Committee's findings and the bases for any recommendation to permit or to recommend against permitting a financially interested individual to conduct human subjects research. In either case the RCOI Committee will prepare a summary report describing the nature and amount of the financial interest and the Committee's recommendations. This summary report shall be made available to MSOE's IRB. When the RCOI Committee has recommended that a financially interested individual be permitted to conduct human subject's research and MSOE's IRB has approved the research and the individual's participation, the summary report should be provided to research subjects or the public, upon request.
3. The RCOI Committee shall encourage the financially interested individual to minimize the potential for conflict of interest by reducing or eliminating the interest or the individual's direct involvement in the research. The RCOI Committee should specify the monitoring procedures or other conditions to be imposed when a financially interested individual will be permitted to conduct human subject's research. Such procedures may include: (i) public disclosure of the researcher's conflict, (ii) monitoring of a study, (iii) disqualification of a researcher from taking part in research, (iv) compelled divestiture of a researcher's ownership interest in an outside firm or corporation, or (v) severance of a researcher's business relationship with an outside firm or corporation. Mitigation plans will be monitored by the RCOI Committee and others as designated by Dean of Applied Research.

4. The RCOI Committee shall notify each researcher within ten (10) business days of its findings with regard to the existence of a conflict of interest and the action it deems appropriate to manage, eliminate, or reduce the conflict of interest.
5. The RCOI Committee will communicate summary information about the nature and amount of any significant financial interest in human subjects research, along with the Committee's findings and recommendations concerning requests by financially interested individuals to conduct such research to MSOE's IRB, and to MSOE Officials.

Process.

1. MSOE's IRB and responsible institutional officials shall be alerted whenever a financially interested individual proposes to conduct human subject's research;
2. At the time of continuing review, the IRB Administrator will report the ongoing status of the continuing review process to the Dean of Applied Research prior to IRB review.
3. Prior to MSOE's IRB final approval (whether initial or continuing approval) of human subjects research, the RCOI Committee shall inform MSOE's IRB and responsible institutional officials of any significant financial interests held by financially interested individuals who will conduct the research, as well as the RCOI Committee's findings and recommendations concerning the same;
4. When financially interested individuals are permitted to conduct human subject's research, the financial interests in question shall be disclosed in accordance with MSOE's COI policies.
5. The RCOI Committee shall maintain records of all financial disclosures and all actions taken by the institution with respect to any conflict of interest for at least three years from the date of submission of the final expenditures report (for each cited project).

Rebuttable Presumption that Financially Interested Individuals May Not Conduct Human Subjects Research. This policy establishes the presumption that, in the absence of compelling circumstances, a financially interested individual may not conduct human subject's research. This presumption should be rebuttable when compelling circumstances exist.

1. This policy allows the RCOI Committee, after it reviews the relevant facts and circumstances and documents the compelling circumstances, to recommend that a financially interested individual be permitted to conduct the research, and to make recommendations for appropriate monitoring and oversight.

2. A summary report indicating the nature and amount of the financial interest and RCOI Committee recommendations shall be transmitted to MSOE's IRB and to responsible institutional officials.

Monitoring. Procedures for internal, and, when deemed necessary, external monitoring when a financially interested individual is permitted to conduct human subjects research, include (but are not limited to):

1. The Dean of Applied Research and the IRB Administrator will conduct audits of billing records and research records every 6 months and report summary findings to the RCOI Committee and to the IRB at time of continuing review.

Continuing Review of Studies. When an industry sponsored research proposal is submitted to MSOE's IRB for continuing review, each covered individual who will conduct the research shall submit the COI Questionnaire to MSOE's IRB with the continuing review form. The IRB Administrator will report the ongoing status of the continuing review process to the Dean of Applied Research prior to IRB review. MSOE's IRB shall forward any information that it receives concerning a significant financial interest in human subject's research to the RCOI Committee. The RCOI Committee will make a determination regarding the status of the research and will forward that information to the IRB prior to the IRB meeting.

Disclosure of Significant Financial Interests.

1. This policy shall require disclosure of the existence of significant financial interests in human subjects research as follows: to federal agencies when applicable, as required by statute or regulation; to research funders or sponsors; to the editors of any publication to which a covered individual submits a manuscript concerning the research; and in any substantive public communication of the research results, whether oral or written.
2. Research consent forms should, as a matter of MSOE's COI policy, disclose the existence of any significant financial interest held by a covered individual who is conducting the human subject's research. The precise wording of disclosure in the consent form will be determined by MSOE's IRB.

Prohibition on Payments for Results. This policy prohibits payments from MSOE or the research sponsor to a covered individual, if such payments are conditioned upon a particular research result or are tied to successful research outcomes.

Process of Review and Non-Compliance. The investigator must agree in writing to follow the mitigation plan outlined by the RCOI Committee. The Dean of Applied Research and IRB Administrator will conduct audits every 6 months for compliance with the research plan. Findings will be reported to the IRB and RCOI Committee if not in compliance with the mitigation plan. Information will be reported to the RCOI Committee for review to determine if the research can continue.

XII. ASSOCIATED REGULATIONS/ACCREDITATION STANDARD

- 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought
- 45 CFR 94, Section 94.4 Institutional Responsibility Regarding Conflicting Interest of Investigators
- 45 CFR 46, U.S. Department of Health & Human Services protections of human subjects in research including The Common Rule
- Higher Learning Commission (HLC) Core Component 2.E

XIII. LIFECYCLE

Reviewed annually

XIV. APPENDICES

- A. SFI Disclosure Form-Approval
- B. SFI Disclosure Form-Investigator

This section to be completed by the Records Manager		
Related Policies	Conflict of Interest, Research with Human Participants	
Date Due for Review	Summer 2022	
Public Location(s)	MSOE Policy Library	
Record Manager	Dr. Melodie Fox, Assistant VP of Curriculum & Knowledge Management	
University Archivist	Denise Gergetz, eResources Librarian & Archivist	
Version History		
Date approved	Amendment Summary	Date(s) cross locations updated and past version provided to University Archivist
EEC: September 27, 2021	Initial approval	