



OFFICE OF RESEARCH POLICY ON CONFLICTS OF INTEREST IN RESEARCH AND SPONSORED PROJECTS

I. BACKGROUND AND POLICY

Eastern Virginia Medical School (EVMS) is committed to promoting objectivity in research by establishing standards that provide a reasonable expectation that research/sponsored projects conducted by EVMS investigators will be free from bias resulting from the financial conflicts of interest of its investigators. In addition, the requirements listed in 42 CFR, Part 50, Subpart F (PHS Regulations) governing the Public Health Service (PHS) 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 the National Institutes of Health (NIH) and other federal regulations require disclosure of personal financial interests by those involved in the design, conduct or reporting of research/sponsored project data.

It is the Policy of EVMS that all Investigators, as defined below, regardless of funding source, must abide by this Policy on Conflicts of Interest in Research/Sponsored Projects. Specifically, each Investigator must: (a) review and receive training on EVMS Policy and federal conflicts of interest regulations; (b) disclose relationships and financial interests related to their responsibilities at EVMS; and, when required, (c) Investigators must work cooperatively with the Office of Research to develop and implement plans to manage, reduce, or eliminate conflicts of interest related to their research or sponsored projects.

II. DEFINITION OF INVESTIGATORS

“Investigators” at EVMS include **all** Key Personnel (Principal Investigator (PI), Project Director and any other person identified as senior/key personnel) listed in a grant application, contract, progress or other report, and any other individuals, regardless of title or position, who have responsibility over the design, conduct, or reporting of funded research or certain other sponsored projects, which may include research assistants, post-docs, fellows, students, collaborators or consultants.

When determining which individuals should be considered Investigators on a research/sponsored project, the PI should consider roles, not titles, of individuals and the degree of independence given, or oversight provided, to individuals who perform research/sponsored project functions.

III. RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS



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Each PI in a PHS or other sponsored project, no later than at the time of submission of an application for funding, or, for sponsored projects that do not run through EVMS Office Of Sponsored Programs, concurrent with the request for review and approval of a protocol by an EVMS regulatory committee such as the EVMS Institutional Review Board(s), Institutional Animal Care and Use Committee, and/or the EVMS Biosafety Committee, and regardless of funding source, shall complete a Proposal Approval Form or an Office of Research Grant/Contract Compliance Information Form that will identify all individuals who the PI has designated as an Investigator. PIs shall also ensure that any changes to the list of Investigators be provided to the Office of Research and shall ultimately be responsible for ensuring that Investigators:

- A. Become familiar with Financial Conflict of Interest (FCOI) regulations and EVMS Policy;
- B. Complete the required training set forth in Section X of this Policy;
- C. Provide and update disclosures in accordance with this Policy and the Policy on Disclosure of Interests;
- D. Comply with any EVMS Conflict of Interest (COI) Committee Management Plans including required annual certifications; and
- E. Comply with any retrospective review that may be required as a result of non-compliance as set forth in Section XII of this Policy.

IV. DESIGNATED INSTITUTIONAL OFFICIAL

EVMS has designated the Senior Associate Dean for Research as the Designated Institutional Official (DIO) who shall have the duty and authority to solicit and review disclosures from Investigators, determine what Significant Financial Interests (SFI) or FCOIs, as later defined, exist, facilitate management of identified FCOIs with the Conflicts of Interest Committee, and ensure that all Investigators are compliant with this Policy. Further, the DIO shall be responsible for posting this Policy on the EVMS public website and reporting FCOIs as set forth in Section IX of this Policy.

V. DISCLOSURE OF INTERESTS



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A. All Investigators, including EVMS faculty, non-faculty, or grant subrecipients who do not have a compliant financial conflict of interest policy, shall:

1. Disclose all Interests, as defined in the EVMS Policy on Disclosure of Interests, including those of Covered Family Members:

a. for the preceding 12 months, within 30 days of hire or prior to the submission of any application for funded research, whichever may come first; and

b. for the preceding calendar year, annually upon request by EVMS.

2. Update all Interests previously disclosed at least annually, as well as:

a. not later than the 30th day after acquiring a new financial interest or adding to a previously disclosed financial interest so as to make the value of such Interest a significant financial interest as defined in Section VI(B) below;

b. not later than the 30th day after discovering a Financial Interest that had not otherwise been disclosed; or

c. within 30 days from the date of any reimbursed or sponsored travel.

B. All disclosures shall be made on a Disclosure Form provided by EVMS and shall be submitted in accordance with the EVMS Policy on Disclosure of Interests.

C. Prior to the expenditure of any funds and/or execution of any agreement or application for new, continuation, or revised grants and/or contracts for funded research (and certain other sponsored projects as determined by the Office of Research), the DIO shall ensure that:

1. The listing of Investigators provided by the PI has not changed or, if changed, has been updated; and

2. Each Investigator has a current disclosure on file with EVMS. Note that all disclosures received are also subject to the review procedures set forth in Section VI and, if applicable, management in accordance with Section VII.

VI. REVIEW OF DISCLOSURES, DETERMINING SIGNIFICANT FINANCIAL INTERESTS, AND FINANCIAL CONFLICTS OF INTEREST

A. Review by DIO. Prior to the expenditure of any funds and/or execution of any sponsored agreement for any new or continuing award or no cost extension or within 60 days of the disclosure of new Interests by a new or existing Investigator in an on-going project, the DIO shall evaluate the applicable disclosure forms to determine whether Interests disclosed are:

1. Significant Financial Interests as defined in Section VI (B) or VI(C) below;
2. Related to the research/sponsored project being proposed or conducted (in the case of renewals); and
3. An FCOI as defined in Section VII (D) below.

B. Significant Financial Interests (SFI). Except as set forth in Section C below, an SFI exists when Financial Interests of the Investigator and/or any Covered Family Member (your spouse, domestic partner, dependent children or other member of your household) consist of one or more of the following:

1. Any remuneration from a publicly traded entity in the 12 months preceding the date of disclosure that, in aggregate, exceeds \$5,000. Remuneration shall include:
 - a. salary,
 - b. non-salary payments including, but not limited to, consulting fees, honoraria, or authorship fees;
 - c. equity interest including any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. Any remuneration from a non-publicly traded entity in the 12 months preceding the date of disclosure that, in aggregate, exceeds \$5,000.
3. Any equity interest including stock, stock option, or other ownership interest of a non-publicly traded company.

4. Intellectual property rights and interests such as patents and copyrights where income related to those rights have been received (including royalties and other remuneration paid to the Investigator by EVMS).

5. Reimbursed or sponsored (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) travel related to an Investigator's institutional responsibilities, as defined in the Disclosure of Interests; provided, however, that this does not apply to travel that is reimbursed or sponsored by:

a. a federal, state, or local government agency, an institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital; or

b. a medical center or a research institute that is affiliated with an institution of higher education.

6. Note that an SFI **does not** include the following types of Financial Interests:

a. salary paid by EVMS to the Investigator if the Investigator is currently employed or otherwise appointed by EVMS;

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;

c. income from seminars, lectures, or teaching engagements sponsored by:

i. a federal, state, or local government agency; an 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 an institution of higher education; or

ii. income from service on advisory committees or review panels for a federal, state, or local government agency, an 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 an institution of higher education.

7. For National Science Foundation (NSF) Sponsored Research. SFIs shall be determined in accordance with the conflicts of interest provisions found in the NSF Award and Administration guide.

C. Financial Conflict of Interest (FCOI). An FCOI exists when:

1. The Investigator, or a Covered Family Member, has inventive or ownership interest, regardless of amount, in intellectual property that will be utilized in a project on which the Investigator is working;

2. The Investigator, or a Covered Family Member, have ownership interest, regardless of amount, in an entity that is proposed as a subcontractor, consortium member, or will otherwise be involved in the project on which the Investigator is working;

3. The Investigator, or a Covered Family Member, have other interest(s) that could directly and significantly affect the design, conduct, or reporting of a funded research/sponsored project: or

4. The DIO determines that an SFI could directly and significantly affect the design, conduct, or reporting of a funded research/sponsored project. The DIO will consider various factors such as the nature of the research/sponsored project, the nature and size of the SFI, the degree to which the conflict is related and the extent to which the SFI or the Investigator could benefit or be affected by the research/sponsored project. If for any reason, the DIO is unable to make a clear determination as to whether an SFI directly and significantly affects the research/sponsored project, all supporting documentation shall be provided to the COI Committee to establish whether such SFI is an FCOI.

VII. MANAGEMENT OF FCOI

Any FCOIs identified must be managed prior to the expenditure of any funds and/or execution of any sponsored agreement for any new, continuation, or revised grant.

A. Interim Management by the DIO. Whenever a new or existing Investigator on an ongoing research project discloses an Interest that is deemed to be an FCOI or whenever the DIO identifies an FCOI that was not previously or timely disclosed for any reason, and the DIO determines that

management of the FCOI cannot practicably be implemented by the COI Committee within 60 days, the DIO shall implement an interim management plan that shall specify the actions that have been, and will be, taken to manage such FCOI until such time as COI Committee completes its review.

B. COI Committee. The COI Committee is tasked with evaluating each FCOI and developing and implementing management plans, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

C. Management Plans.

1. The COI Committee shall develop and implement management plans to mitigate or eliminate identified FCOIs. Within 60 days of any new or updated FCOI being disclosed, the COI Committee will develop a Management Plan in conjunction with input from the Investigator. The Investigator shall cooperate with the development of the Management Plan and shall provide any additional information that may be required or requested by the DIO for development of the Management Plan. Options for the management of FCOIs include, but are not necessarily limited to the following:

- a. public disclosure and notification of affected entities; monitoring of the research, education or clinical trial activity by independent reviewers;
- b. modification of the research/activity plan;
- c. disqualification of Investigator(s) from participation in some or all portions of the project; or
- d. divestiture of Significant Financial Interests or Personal Interests; severance of relationships that create actual or potential conflicts; informing the Financially Interested Company that the proposal or protocol has been withdrawn by EVMS

2. The decision of the COI Committee is final and shall be committed to writing in the form of a COI MOU, which shall be signed by the Investigator, the Investigator's Chair and approved by the Principal Investigator of the project.



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3. Any Investigator that is subject to a Management Plan shall be monitored for and shall certify compliance with the Management Plan, at the request of the COI Committee or Office of Research, for the life of the project.

4. If for any reason a Management Plan is later deemed to have biased the design, conduct or reporting of PHS funded research, the DIO shall notify the PHS funding agency immediately and advise of the corrective action taken, or to be taken.

D. Special Provisions for Human Subjects Research. In any case where an Investigator is involved in a project where the purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment or behavioral evaluation, the identified FCOI and any subsequent Management Plan shall be provided to the IRB. The IRB, at its discretion, may also set additional conditions for the research.

VIII. SUBRECIPIENTS

A. PHS Funded Projects. U.S. based and International subrecipients (i.e. subcontractors or consortium members) to be utilized by an EVMS PI shall, through the EVMS Office of Sponsored programs, certify and enter into a written agreement with EVMS to disclose whether this Policy or the financial conflicts of interest policy of the subrecipient shall apply to the subrecipient's researchers and:

1. That the subrecipient has a Policy that is consistent with the requirements of the PHS Regulations. In such event, the agreement with EVMS shall state time periods for the subrecipient to report identified FCOIs to EVMS; or

2. That the subrecipient does not have a COI Policy that is consistent with the requirements of the PHS Regulations. In such event, the agreement with EVMS shall state that the researchers of the subrecipient shall be considered "Investigators" who shall be subject to all terms and conditions of this Policy. In addition, the agreement shall specify the time periods for the subrecipient's researchers to submit a financial interest disclosure statement to EVMS, which must be sufficient for EVMS to comply with its review, management, and reporting obligations under federal regulation.

B. Non-PHS Funded Projects. The subrecipient requirements of this section shall not apply



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to Non-PHS funded research/projects unless mandated by the research/project sponsor.

C. Vendors. The subrecipient requirements of this section shall not apply to vendors. Determinations of subrecipient vs. vendor relationships with EVMS shall be determined by the Office of Research.

D. EVMS as the Subrecipient. If an EVMS researcher shall be utilized by an awardee institution as a subrecipient, the EVMS Office of Sponsored Programs shall certify that the EVMS Policy on Conflicts of Interest in Research and Sponsored Projects shall apply.

IX. REPORTING

A. Public Accessibility. All FCOIs held by Senior/Key personnel shall, prior to the expenditure of any sponsored research funds or within 60 days after the identification of a new FCOI, be accessible to the public via a written response to any requestor within 5 business days of a request or it shall be posted on a publicly accessible website through the Office of Research. If publicly posted on a website, such posting shall be updated at least annually, and within 60 days of any newly identified FCOI. All information made available, whether through a response or public posting on a website shall include

1. The Investigator's name;
2. The Investigator's title and role/duties with respect to the project;
3. The name of the entity in which the SFI is held;
4. The nature of the SFI that constitutes an FCOI; and
5. The approximate value of the SFI by range as follows:
 - a. \$0 - \$4,999;
 - b. \$5,000 - \$9,999;
 - c. \$10,000 - \$19,999;

- d. amounts between \$20,000 - \$100,000 by increments of \$20,000;
- e. amounts above \$100,000 by increments of \$50,000; or
- f. if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.

B. Reporting to Funding Agency. EVMS will report initial and ongoing FCOI reports to granting agencies as required by law, rules, or regulations. For PHS funded research, such initial reporting shall be made prior to the expenditure of any funds or, in the case of an FCOI identified subsequent to the initial reporting or for an Investigator that is new to the project, within 60 days. Ongoing FCOI reports shall be submitted annually at the same time EVMS is required to submit the annual progress report, multi-year progress report, or at the time of extension for the project. FCOI reports shall include all of the information in Section IX(A) above, plus:

- 1. the Project Number;
- 2. the PI or contact;
- 3. a description of how the SFI relates to the funded research and the basis for EVMS' determination that the SFI was a conflict;
- 4. a description of the key elements and the conditions of the Management Plan;
- 5. confirmation of the Investigator's agreement to the Management Plan;
- 6. how the Management Plan will be monitored to ensure compliance; and
- 7. any other information as needed.

X. POLICY TRAINING

All Investigators must complete training on the PHS Regulations and this Policy prior to engaging in a sponsored project, immediately upon any material change to this Policy or when an Investigator is new to EVMS, and then no less than every 4 years thereafter. Further, any Investigator who is found to be non-compliant with this Policy or any COI Management Plan shall,



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be required to complete additional training upon request by the DIO.

XI. NON-COMPLIANCE

A. Any noncompliance or violation of this Policy shall be subject to disciplinary procedures, including sanctions, suspension, or dismissal in accordance with EVMS Policy. Additionally, employees in violation of this Policy who have received financial benefit shall be liable for repayment of any and all financial benefits that resulted from such violation.

B. In addition to any disciplinary action or sanction in accordance with Section A above, whenever an Investigator involved in PHS funded research is noncompliant with this Policy, or an FCOI for a PHS funded project was not identified or managed in a timely manner for any reason, including when EVMS identifies that a disclosure was not timely made by an Investigator or, for whatever reason was not previously reviewed by EVMS, the DIO shall:

1. Notify the PHS funding agency of the Investigator's noncompliance, and advise what corrective action has or will be taken;
2. Within 60 days, review the disclosure in accordance with Section VI(A) of this Policy and determine if it is an FCOI in accordance with Section VI(D); and
3. If an FCOI is identified, the DIO shall deem the Investigator non-compliant with this Policy and shall:
 - a. manage such FCOI in accordance Section VII;
 - b. update any previously submitted FCOI as needed; and
 - c. within 120 days of the DIO's determination that the Investigator is non-compliant, conduct a retrospective review of the project to determine whether the Investigator's participation in the project created bias in the design, conduct or reporting of the project. If bias is found, EVMS must report same to the PHS awarding component and will promptly develop and submit a mitigation report. All retrospective reviews shall be documented and shall contain the following key elements:



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- i. project title;
 - ii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - iii. name of the Investigator with the FCOI;
 - iv. name of the entity with which the Investigator has an FCOI;
 - v. reason(s) for the retrospective review;
 - vi. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - vii. findings of the review; and
 - viii. conclusions of the review.
- d. for any PHS funded project whose purpose is to evaluate the safety or effectiveness of any drug, medical device or treatment, require the Investigator to:
- i. disclose the FCOI in each public presentation of the results of the research/sponsored project; and
 - ii. request an addendum to previously published presentations.
4. If bias with the design, conduct or reporting is found, EVMS shall notify the PHS funding agency immediately and shall submit a mitigation report, that shall include all of key elements from the retrospective review in Section XI(B)(3)(c) above, and a description of the impact of the bias on the project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias. The mitigation report shall be reviewed and approved by the DIO and the EVMS Office of Compliance.

XII. DOCUMENTATION/RECORDS RETENTION

All records relating to this Policy, including disclosures by Investigators, records relating to the review of disclosures by the DIO, management by the Conflicts of Interest Committee and all



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remedial or other actions under this Policy or any retrospective review, as applicable, shall be maintained by the Office of Research for at least 3 years from the final expenditures report or such other dates as specified in 45 CFR 74.53(b) and 92.42(b) as applicable. In addition any FCOIs that are reported via the public website in accordance with Section IX(b), shall remain available on the Internet for three years after its most recent update.