

AMERICAN BOARD OF FAMILY MEDICINE, INC.

Research Financial Conflicts of Interest Policy

Effective April 19, 2023

The American Board of Family Medicine (“ABFM”) has established a policy in compliance with [42 CFR 50 Subpart E](#), which promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator’s financial conflicts of interest.

As an Investigator, it is important that you understand the need to maintain the confidentiality of many of the materials utilized by the ABFM. It is equally important that you avoid any potential conflicts of interest between your responsibilities as an Investigator and the work you undertake on your own behalf or on behalf of other individuals or entities with which you may be affiliated and declare dualities of interest. In order to maintain the integrity of the ABFM, and to prevent any misunderstandings, it is required that you annually review the following policies and agree that you will adhere to them.

Please read through the following paragraphs, and electronically sign the enclosed certification and disclosure statement and return to:

Research Integrity Committee
American Board of Family Medicine, Inc.
1648 McGrathiana Parkway, Suite 550
Lexington, Kentucky 40511

1. Definitions:

- *Financial Conflict of Interest (“FCOI”)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.
- *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.
- *PHS* means 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 the National Institutes of Health (NIH).
- *Significant Financial Interest (“SFI”)* means:
 1. 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:

- a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity 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. For purposes of this definition, 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;
 - b. With regard to any non-publicly traded entity, a SFI 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
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities, including 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. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
 3. The term SFI *does not* include the following types of financial interests:
 - a. Salary or consulting fees paid by ABFM to the Investigator if the Investigator is currently employed or otherwise appointed by the ABFM.
 - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
 - d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
1. **Policy.** Each year any Investigator who conducts research on any ABFM project must disclose all SFIs that are relevant to an Investigator's institutional research responsibilities, or within 30 days after he/she becomes aware of new SFI or after a FCOI has been eliminated. Investigators are required to complete the annual disclosure form even if they have no financial interest to report.

To that end, each Investigator must disclose the following for both direct and indirect (e.g., spouse, domestic partner, child, or trust or estate in which you have a substantial beneficial interest or serve as trustee) relationships:

- a. Is a research investigator who receives financial/grant support (including salary support and other expenses) from a pharmaceutical, biotechnical, or medical device/medical instrument company or for-profit educational company;

- b. Is a research investigator who receives financial/grant support (including salary support and other expenses) from a governmental or not-for-profit foundation, including the ABFM Foundation, where the research interests of the Applicable Person are relevant to their ABFM activities;
- c. Is paid travel expenses and/or honoraria for service on a research-related expert panel or advisory board related to the Applicable Person's ABFM activities; or
- d. is consulting on the design of new drugs or devices, clinical trials, or the use of specific agents designed to be used in clinical care.

If you have business, professional, or personal relationships that are not of a commercial nature but which you believe potentially represent an actual or apparent conflict with your duties as an Investigator, or a duality of interest, you are required to disclose those relationships as well.

2. ***FCOI Training.*** PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed as soon as reasonably possible under the following circumstances:
 - a. This policy changes in a manner that affects Investigator requirements
 - b. An Investigator is new to a subrecipient and will be working on PHS funded research
 - c. An Investigator is found to be noncompliant with this policy or their approved action plan
3. ***Review of FCOIs.*** ABFM's FCOI administrator conducts an initial review of all disclosures. If necessary, the FCOI administrator obtains additional information from the Investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The administrator then formally identifies cases that require further review by management.

ABFM's Research Integrity Committee will review the collected information to determine whether a financial conflict of interest exists by considering the following:

- a. Impact on integrity of research data;
- b. Risks to rights and safety of animal and/or human research subjects;
- c. Risks to the rights of students and trainees participating in research; and
- d. Appearance of conflict of interest.

If a financial conflict of interest is identified, ABFM's Research Integrity Committee will determine whether the research can be undertaken.

4. ***Management of FCOIs.*** For cases that require action, a plan of action will be developed by members of ABFM's Research Integrity Committee on a case-by-case basis. Such a plan will include some or all of the following as deemed appropriate:
 - a. Public disclosure of FCOI (e.g., when presenting or publishing the research);
 - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - c. Appointment of an independent monitor of capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); o
- g. Severance of relationships that create financial conflicts.

A draft of the plan of action will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.

If the Institution identifies an SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim plan of action will be implemented within 60 days when necessary. The ABFM shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

5. Reporting. ABFM will provide to the PHS Awarding Component a FCOI report as outlined:

- a. Prior to the ABFM's expenditure of any funds under the PHS-funded research project, the ABFM will provide a FCOI report to the PHS Awarding Component regarding any SFI found to be a FCOI. The ABFM shall provide an FCOI report within sixty (60) days of identification of an Investigator who is new to the project.
- b. The ABFM shall also provide a FCOI report to the PHS Awarding Component within sixty (60) calendar days for any SFI that ABFM identifies as conflicting after the ABFM's initial FCOI Report, ensuring that the ABFM has implemented a management plan in accordance with the regulations. Where an FCOI report involves a SFI that was not disclosed by an Investigator, or was not reviewed or managed by the ABFM, the ABFM is required to complete a retrospective review to determine whether any PHS-funded research was biased. If bias is found, the ABFM is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- c. Any FCOI report required under paragraphs 5(a) or 5(b) shall include sufficient information to enable PHS Awarding Component to understand the extent of the FCOI and the appropriateness of the ABFM's management plan. This report will include, but are not limited to, the following:
 - i. Project number;
 - ii. PD/PI
 - iii. Name of the Investigator with the FCOI;
 - iv. Name of the entity with which the Investigator has a FCOI;
 - v. Nature of the financial interest;
 - vi. Value of the financial interest or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - vii. A description of how the financial interest relates to the PHS-funded research and the basis for the ABFM's determination that the financial interest conflicts with such research; and
 - viii. A description of the key elements of the ABFM's management plan, including:
 - 1. Role and principal duties of the conflicted Investigator in the research project;
 - 2. Conditions of the management plan;
 - 3. How the management plan is designed to safeguard objectivity in the research project;
 - 4. Confirmation of the Investigator's agreement to the management plan;
 - 5. How the management plan will be monitored to ensure Investigator compliance; and
 - 6. Other information as needed.

- d. Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
 - i. Status of the FCOI;
 - ii. Changes to the management plan; and
 - iii. Specification as to whether the financial conflict is still being managed or why the FCOI no longer exists.

6. *Noncompliance.*

- a. In the event an SFI is not disclosed or reviewed in a timely manner, ABFM will review the Investigator's financial interest, determine if it is related to PHS-funded research, and determine whether an FCOI exists, and if so:
 - i. Implement an action plan for ongoing research, at a minimum implement an interim action plan
 - ii. Complete a retrospective review of Investigator's activities and the PHS funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
 - iii. If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report.
- b. If the failure of an Investigator to comply with the ABFM's FCOI policy or management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the ABFM shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The ABFM will enforce any applicable corrective actions the PHS requires while the Investigator is employed.
- c. If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 conflicting interest that was not managed or reported to ABFM, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

- 7. *Subrecipients.*** For PHS-funded research that involves subrecipients at other Institutions, ABFM requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators.

If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution.

Subrecipient Institutions who rely on their own FCOI policy must report identified FCOI to the ABFM in sufficient time to allow the ABFM to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the ABFM FCOI Research policy. A subrecipient's failure to promptly comply with the ABFM policy will be considered grounds for immediate termination by ABFM of any applicable subcontract or subaward. The written agreement terms required by ABFM will contain a provision that subrecipients will report to ABFM, as the pass-through entity, any identified FCOI in sufficient time for ABFM to report and manage the FCOI and meet the reporting obligations.

8. ***Maintenance of Records.*** The ABFM shall maintain records relating to all Investigator disclosures of financial interests, the ABFM's review of such disclosures, and all actions under this policy or retrospective review for at least three (3) years from the date the final expenditures report is submitted to the PHS or any other dates specified in 45 CFR 75.361, where applicable.
9. ***Public Accessibility.*** This policy will be posted on the ABFM's public website www.theabfm.org. Prior to the expenditure of any funds under a PHS-funded research project, information concerning identified FCOIs held by senior/key personnel will be provided via email within five (5) business days of a request. The written response will include:
 - a. Investigator's name;
 - b. Investigator's title and role in the research project;
 - c. Name of the entity in which the SFI is held;
 - d. Nature of the SFI; and
 - e. Approximate dollar value of the significant financial interest or a statement that the value cannot be readily determined.

This information will remain available for three (3) years from the date the information was last updated.

Please complete the following disclosure material and return to the Research Integrity Committee at your convenience.