

Procedures for Reporting and Management of Individual Financial Conflicts of Interest

I. Key policies

- a. University Individual Financial Conflict of Interest Policy (University Policy)
- b. Kansas Board of Regents policy on Commitment of Time, Conflict of Interest, Consulting and Other Employment (Regents Policy)

II. Introduction

All faculty and unclassified staff and any other members of the University community who are responsible for the design, conduct, or reporting of research or educational activities are required to disclose certain relevant financial interests for compliance with federal, Regents, and FHSU policies. These procedures provide operational guidance for implementing the University Individual Financial Conflict of Interest Policy, the Kansas Board of Regents (Regents) policy on Conflict of Interest, Conflict of Time Commitment, Consulting and Other Employment, and various federal regulations including the Public Health Service (PHS) regulations on Promoting Objectivity in Research, 42CFR50 subpart F and 45CFR94.

III. Definitions

Certification of significant financial interests (SFIs)

The Investigator's report to the University of Significant Financial Interests (SFI) is called a certification or a disclosure certification. There are three types of certifications:

Annual Certification – initiated by the University on employment and annually

Research Certification – initiated by a research administrator for investigators on PHS-compliant funding proposals

Update Certification – initiated by the individual to disclose a new financial interest or a change in a previously disclosed interest.

Financial Conflict of Interest Committee (FCOIC)

The FCOIC is a representative advisory committee of the University that advises the Institutional Official on conflict of interest matters. Disclosures of SFI are reviewed by the FCOIC which makes a recommendation to the Dean of the Graduate School and the Provost about the management of a conflict situation.

The FCOIC will consist, at a minimum, of five faculty and unclassified staff members and ex officio non-voting members from the Graduate School, IRB and IACUC. Voting members are appointed by the Dean of the Graduate School and serve rotating three-year terms. The Financial Conflict of Interest Committee is not a policy making body, but can make policy recommendations.

Covered Persons

All University faculty and other unclassified academic and professional staff are subject to University and Regents policies on financial conflicts of interest. Investigators are subject to federal regulations regarding financial conflict of interest and financial aspects of the University and Regents policies. An Investigator is defined as the project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted under the auspices of the University. Investigators may include, for example, University support staff, students, and, on PHS-compliant projects, collaborators or consultants not employed by the University.

Covered Person's Family

For all covered persons, an individual's financial interests include those of Family as defined below, with the exception of sponsored travel disclosures.

“Family” means any member of the individual's immediate family (spouse and dependent children), personal household, or associate entities (e.g., corporations, partnerships or trusts).

Financial Interest

A financial interest is anything of monetary value received or held by an individual or his or her family, whether or not the value is readily ascertainable, including, but not limited to:

- Remuneration (salary or other payments for services such as consulting fees, honoraria, or paid authorships for other than

- scholarly works);
- Equity or other legal interest (stock, stock options or other ownership interest in any corporation, partnership, limited liability company, proprietorship, trust, joint venture, or other business interest, including land used for income, owned within the preceding 12 months, or in the process of acquisition);
- Intellectual property rights and interests (e.g., patents, trademarks, service marks and copyrights),
- Sponsored or reimbursed travel undertaken by the individual and related to his/her institutional responsibilities, except for exclusions below.

Financial Interest does NOT include:

- salary, royalties, or other remuneration from the University, including funds and holdings acquired through the Regents retirement programs;
- travel reimbursed or sponsored by: U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI)

An SFI is a financial interest held by an individual (including Family) in any entity that reasonably appears to be related to the individual's University responsibilities, and meets one or more of the disclosure criteria on the applicable campus reporting form.

Financial Conflict of Interest (FCOI)

An FCOI is an SFI that the University reasonably determines could directly and significantly affect the design, conduct or reporting of University research or could directly and significantly influence the fulfillment of the individual's University responsibilities, or is in an entity whose financial interest could be affected by the research.

Institutional Official (IO)

The Institutional Official is the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests related to the individual's University responsibilities. The FHSU Institutional Official is designated as the Dean of the Graduate School. The Coordinator of the Office of Scholarship and Sponsored Projects oversees administrative processes related to conflict of interest disclosure, reporting and management and facilitates the work of the Financial Conflict of Interest Committee.

PHS-compliant

For the purposes of this document, "PHS compliant" describes funding agencies that have adopted or sponsor projects, proposed or funded, that are bound by the PHS regulations on Promoting Objectivity in Research, 42 CFR 50 subpart F and 45 CFR 94.

University Responsibilities

An individual's responsibilities on behalf of the University, which may include (but are not limited to), activities such as teaching, research, research consultation, administration, professional practice, institutional committee memberships, and service on panels such as Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC).

IV. Reporting Requirements

A. Who is required to file?

1. Covered Persons as defined above: Faculty, other unclassified staff, and other investigators
2. Non-FHSU Investigators on proposed or funded PHS-compliant sponsored projects

For subrecipient Investigators from a PHS-compliant organization, the Investigator's home organization will be asked to certify that a PHS-compliant policy is in place and to report any Financial Conflicts of Interest with the current project to FHSU.

For consultants or collaborators not employed by a PHS-compliant organization, individuals must complete FHSU FCOI training. In case there is not sufficient time to accomplish this before the proposal is submitted, the OSSP will provide access to online training, however, prior to engaging in the project, the individual must complete the FHSU training and have the initial certification reviewed and any identified conflicts managed.

B. Individual responsibilities

1. Policy awareness

Upon initial appointment the University will inform faculty and unclassified staff of the obligation to disclose certain SFI and time commitments per the University and Regents policies and federal regulations, which are posted on the FHSU website. It is the individual's responsibility to read and understand the policies. Links to these policies and related federal regulations are available

through the Office of Scholarship and Sponsored Projects (OSSP) website. Any questions regarding the policies or procedures should be directed to the OSSP.

2. Filing timely, complete and accurate reports

Reporting requirements vary depending on whether an individual is employed as a faculty or unclassified staff member or is filing for the purpose of participating on a sponsored research project. Consequences for not filing timely, complete or accurate disclosures are discussed in section IX. Enforcement.

3. Compliance with approved conflict management plans

Conflict management plans will specify conditions to ensure appropriate transparency and adequate separation between university responsibilities and the outside interest. In some cases, the plan will identify a monitor and set due dates for reports to the Institutional Official. When an individual accepts a management plan he or she agrees to abide by its terms. Failure to adhere to an accepted management plan may trigger disciplinary action as described in section IX. Enforcement.

4. FCOI training for investigators on PHS-compliant sponsored projects

Each Investigator on a project funded by a PHS-compliant sponsor must complete FCOI training on the University policy and key elements of the federal regulation prior to engaging in research on the project and subsequently at least every four years. For new or renewing awards, all Investigators must be up to date with FCOI training before award funds will be made available. Likewise, any Investigator new to an on-going project must complete the training before engaging in the project. The FHSU training is sponsored by the OSSP.

Training is also required within a reasonable period of time as determined by the Institutional Official in the event that the University policy or procedures are revised in any manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

C. What to disclose

Regardless of the disclosure requirements, the individual, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to be a conflict of interest. It may be helpful to have the following types of documents on hand for reference when completing the forms: Stock option agreements, stock portfolio summary, consulting agreements, travel reimbursement receipts by external entities, federal income tax form 1040 and/or 1099 forms.

1. Significant financial interests (SFI)

Disclosure of SFI applies to all faculty and unclassified staff and any individual who is an investigator on a PHS-compliant sponsored project. An individual's financial interests include those of the individual and his or her Family (see Definitions).

a. Disclosure criteria

Individuals are required to disclose financial interests held by the individual or immediate family in any entity that reasonably appears to be related to the individual's University responsibilities, and meets one or more of the following criteria:

- i. A financial interest worth \$5,000 or more in any entity, where the value is the aggregate of any remuneration received from the entity in the twelve months preceding the disclosure plus any equity interest in the entity as of the date of disclosure or, if the equity interest was liquidated or ownership transferred in the previous 12 months, value of the equity as of the date of liquidation or transfer.
- ii. Any equity interest in a non-publicly traded entity as of the date of disclosure or, if the equity interest was liquidated or ownership transferred in the previous 12 months, value of the equity as of the date of liquidation or transfer, regardless of whether the value can be determined through reference to public prices or other reasonable measures of fair market value.
- iii. Intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests.
- iv. Sponsored or reimbursed travel in the past 12 months from any external entity that is reasonably related to your University responsibilities. Sponsored travel is disclosed for the individual only; it does not apply to family members. In addition, it is not necessary to report travel that is reimbursed or sponsored by:
 - a) A federal, state, or local government agency;
 - b) An Institution of higher education as defined at 20 U.S.C. 1001(a);
 - c) An academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

It is not necessary to disclose salary, royalties, or other remuneration from the University, including funds and holdings acquired through the Regents retirement programs.

D. When to disclose

1. First Certification

On employment: All faculty and unclassified staff must file an initial disclosure and certification of SFI and external professional time commitments on employment. The initial disclosure form is the same as the Annual Certification.

Prior to proposal submission: In the case of Investigators who are not faculty or unclassified staff, the initial report must be filed prior to submission of a research proposal. The initial certification may be either a Research or an Annual Certification.

2. Annual Certification

All Covered Persons must review and provide updates, if any, to previously disclosed interests within 30 days of receiving notice to file an annual certification, or prior to proposal submission if this occurs in the meantime.

Notifications to file the Annual Certification are sent by e-mail early each fall semester.

3. Update Certification— on acquisition of a new SFI

All Covered Persons are responsible for filing an Update Certification within 30 days of acquisition of a new SFI (e.g., through marriage, inheritance, purchase, or employment) that is related to University responsibilities. Update Certifications are initiated by the individual using forms posted on the OSSP FCOI website.

Reimbursed or sponsored travel is reported via the Update Certification, no later than 30 days after the travel.

4. Research Certification—prior to submission of a PHS-compliant funding proposal

To document compliance with PHS regulations, all Investigators on a PHS-compliant project will actively certify that their disclosures to the University are complete, accurate and up to date. A Research Certification notification will be e-mailed to all Investigators on the PHS-compliant project. Each Investigator must submit his/her certification prior to proposal submission. It is also possible to disclose additional interests or to provide updates to existing disclosures through this process. For certain non-FHSU investigators, an equivalent form will be provided by the OSSP.

Any new investigator who is added to a PHS-compliant project after proposal submission or during the course of the project, must similarly disclose their SFI prior to participation in the project.

5. Prior to submission of funding proposals not subject to PHS compliance

Prior to submission of any sponsored project proposal, the Principal Investigator and all other Investigators on the project must have disclosed an up-to-date listing of their Significant Financial Interests (SFI) on a current annual or initial certification form.

For faculty and unclassified staff, research administrators will verify that a current certification is on file for each Investigator. During the period of award, each investigator is responsible for initiating an Update Certification to disclose a new SFI within 30 days of its discovery or acquisition.

Other Investigators: non-FHSU researchers on the project who are not faculty or unclassified staff and who are determined by the PI to contribute to the project at the level of an investigator may be asked to file a certification of SFI prior to proposal submission.

V. Disclosure Review

The University is responsible for reviewing all disclosures of SFI and for determining whether the relationship constitutes a conflict with University responsibilities.

A. No review required

When a certification contains no disclosures of SFI or time commitment, no supervisor or administrative review is required. The individual's obligation to report is satisfied until the next annual, or PHS research related certification is due or until the individual's circumstances change such that an ad hoc update certification is required. Compliance status of faculty and unclassified staff annual certifications will be reported by the OSSP to respective supervisors, chairs, deans, directors and the provost.

B. Supervisor review

For annual and update certifications with SFI reported, the immediate supervisor provides the initial review. The supervisor is given the opportunity to comment on any disclosures of SFI before signing the form and advancing it to the Administrative Review.

In cases of dual appointments, where there is reporting responsibility to more than one unit, individuals should add review by their second supervisors. If the certification requires supervisor review, it will be routed to the supervisors sequentially.

For Investigators who are not FHSU faculty or unclassified staff, such as students, adjunct faculty or non-FHSU collaborators, the "supervisor" is the PI of the sponsored project.

Research certifications for PHS-compliant projects that require review will be routed directly to Administrative Review without review by the Supervisor to ensure timely processing.

C. Administrative review

1. Research Integrity initial review

The OSSP will make an initial review and assessment of disclosures. The OSSP may request clarification or additional information of the discloser to facilitate the initial assessment. In limited circumstances, when it is clear that a disclosed relationship does not require management, the disclosure review, determination and response will be handled administratively in consultation with the FCOIC chair, and reported to the FCOIC and Institutional Official.

2. Financial Conflict of Interest Committee review

Disclosure certifications that cannot be dispensed administratively will be reviewed by the FCOIC to determine whether a conflict exists and if so, the appropriate conditions to manage it. See sections VI and V for more information about conflict determinations and management plans.

3. Research Certifications

Research certifications (for PHS-compliant projects) that contain disclosures of SFI are reviewed by the OSSP and, if necessary, the FCOIC. An Investigator's SFI disclosures will be compared to the PHS-compliant project to determine if a SFI is related to the project and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that project. FCOIs must be identified, managed and reported to the funding agency prior to expenditures of award funds.

VI. Identifying and Managing Financial Conflicts of Interest (FCOI)

A FCOI will exist when the Institutional Official or designee determines that a SFI could directly and significantly affect the design, conduct, or reporting of research or influence the fulfillment of other university responsibilities. If a FCOI exists, the Institutional Official, through OSSP, the FCOIC, and department will take action to eliminate, reduce, or manage the conflict, as appropriate.

A. Guidelines for determining conflict of interest

The Financial Conflict of Interest Committee (FCOIC) or designated official will determine whether an investigator's SFI is related to his or her University responsibilities and, if so, will determine whether the SFI is a FCOI. An investigator's SFI is related to the research when the FCOIC or designated official reasonably determines that the SFI could directly and significantly be affected by the research conducted on the sponsored project; or is in an entity whose financial interest could be affected by the research.

In making determinations of FCOI, the FCOIC or designated official will be guided by the principles discussed in the University Policy and these Procedures, and may be informed by the deliberations of the relevant Institutional Review Board (IRB) or other administrative bodies, as appropriate. Factors considered by the FCOIC or designated official include the role of the investigator and the opportunity (if any), to bias the research results or fulfillment of other University responsibilities such as advising students or dispensation of resources, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. The FCOIC or designated official may involve the investigator in the determination of whether a SFI is related to the research.

B. Factors considered in determining whether an SFI is an FCOI

Factors taken into consideration in the determination of an FCOI include, but are not limited to:

a) Nature of the research

- i. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes;
- ii. Whether other scientists are independently pursuing similar questions;
- iii. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely;
- iv. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias;
- v. Whether the goal of the research is to evaluate an invention licensed to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention);
- vi. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI;
- vii. Whether the aim of the project is a comparative evaluation of a technology in which an investigator has a SFI.

b) Where the research involves human subjects,

- i. the level of risk to the subjects;
- ii. whether there are double blind conditions or the involvement of a data and safety monitoring board,

c) Where the SFI is in a privately held company,

- i. whether research SFI could result in the researcher having influence over company decisions,
- ii. whether the research could have a significant impact on the company business or financial outlook.

d) The depth of the relationship

- i. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity);
- ii. The number and nature of relationships the individual has with an entity. (Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts.)

e) Whether the project involves a subaward to or other business relationship with an entity in which the investigator has a SFI.

f) Whether the situation involves the direction or employment of students who will perform work that will benefit an entity in which the individual has an SFI.

g) Whether the situation involves University resources that could be of value to the entity in which the investigator has a SFI.

C. FCOI management

If the Institutional Official or designee determines that a FCOI can be managed, a written and approved management plan must be in place before any related research, or other activity monitored by the plan, goes forward. The conditions set forth in the management plan depend on the nature and complexity of the relationships between the individual and the entity and the individual's University responsibilities.

1. Key considerations in management plans

If a conflict of interest exists, the FCOIC or designated official will determine by what means the conflict should be avoided or managed in order to mitigate undue bias. Examples of means to manage FCOI include the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee. The FCOIC or designated official will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

2. Management plan strategies

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

a) Disclosure

- i. Public disclosure of FCOI (e.g., when presenting or publishing the research);
- ii. Written disclosure of the conflict to all individuals working on the research project.

b) For research projects involving human subjects,

- i. disclosure of FCOI directly to human participants;
- ii. use of a data and safety monitoring board;
- iii. use of double-blind conditions;
- iv. provisions to conduct the work simultaneously at multiple sites.

c) Modification of the research plan

- i. Change of personnel or personnel responsibilities;
- ii. Disqualification of personnel from participation in all or a portion of the research;
- iii. Outsourcing a portion of the research.

d) Modification of the individual's relationship to the entity

- i. Reduction or elimination of the financial interest (e.g. sale of an equity Interest);
- ii. Severance of relationships that create financial conflicts.

e) For situations involving direction of students

- i. Disclosure of relationship to students;
- ii. Following University policy on Employment of Students in Faculty-owned Business.

f) For situations involving use of University resources

- i. Refraining from engaging in business transactions that involve the entity and the university;
- ii. Oversight of financial aspects of a sponsored project.

g) Monitoring compliance

- i. 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;
- ii. Periodic reports on the research progress and compliance with the plan to the FCOIC or designated official.

3. Management plan development

The OSSP will facilitate the development of a management plan, in consultation with the Individual, supervisor, and FCOIC. The management plan is recommended for approval by the FCOIC to the Institutional Official. The plan must be accepted by the Individual and Plan Monitor, if any, before final approval by the Institutional Official.

To address complex situations, a management plan monitor or committee may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan. Periodic reports to the Institutional Official, through the FCOIC, will be specified in the management plan.

4. Implementation and record-keeping

The FCOIC or designated official will keep a record of the decisions regarding the disposition of certifications that contain SFI and of the relevant information for at least three years. For Investigators on PHS-compliant projects, records will be kept three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the subaward and relevant PHS Regulations. If the FCOIC or designated official prescribes monitoring of the activity, it will describe what monitoring shall be

performed and what records are to be kept. No expenditure on a project supported by a PHS compliant sponsor will be permitted until the investigator has complied with the applicable disclosure requirements and has agreed, in writing, to comply with an accepted and approved plan to manage the Financial Conflict of Interest (FCOI). The FCOIC or designated official will notify the agency of the existence and the nature of a FCOI and other details as required by federal regulations, including periodic updates of the status of the FCOI during the award.

VII. Conflict of Interest Reporting System

A. Online reporting system

All reporting and review of disclosed financial interests use specific certification forms. The reporting system guides individuals through the applicable disclosure criteria and collects information about each entity with which an individual has financial interests that meet the disclosure criteria. The various aspects of the relationship with the disclosed entity (for example, one may receive salary from and hold an equity interest in a single entity) will be recorded at the time of disclosure and may be updated whenever necessary. An individual's list of disclosed entities will be saved as a continuing part of his or her reporting record to facilitate annual, research and update certifications.

B. Workflow and documentation

The certifications will be sent to the OSSP for routing and review. The OSSP will coordinate record review, determinations and correspondence, develop and approve management plans, and log periodic reports from the management plan monitor.

VIII. Institutional Reporting of FCOI information

A. Public accessibility of FCOI on PHS-compliant projects

Prior to the expenditure of any funds under a PHS prime- or sub-award, the University will ensure public accessibility, by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- i. The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by the University in the subaward application to the PHS Grantee, progress report or any other report submitted to the PHS Grantee;
- ii. The University has determined that the SFI is related to the research funded through a PHS award or subaward; and
- iii. The University has determined that the SFI is a Financial Conflict of Interest.

The information that the University will make available via written response to any requestor within five days of request will include the following:

- i. The Investigator's name, title and role with respect to the research project;
 - ii. The name of the entity in which the Significant Financial Interest is held; and the nature of the SFI; and
 - iii. The approximate dollar value of the SFI in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a 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
- Information made publicly accessible in accordance with the PHS regulation requirements, as described above, will be updated at least annually, and within sixty days of identifying a new or previously undisclosed FCOI of senior/key personnel on the project. This publicly accessible information will remain available for responses to written requests for at least three years from the date that the information was most recently updated.

B. Institutional reporting to funding agencies

1. Prior to expenditures

Prior to the expenditure of any funds under a PHS-compliant award or sub-award, the University will provide to the PHS-compliant sponsor a FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the subaward is ongoing (including any extensions) the University will provide to the PHS-compliant sponsor an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

2. During a sponsored project

For any SFI that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS funded research project (e.g., upon the participation of an Investigator who is new to the research project), the University will provide to the PHS-compliant sponsor, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the University has implemented a management plan and the Investigator has agreed to the relevant management plan.

IX. Enforcement

A. Consequences of non-compliance with Policy and Procedures

Violations of the Policy and/or Procedures will be managed in accordance with applicable University policies and procedures.

1. Examples of violations

Examples of violations include but are not limited to the failure to file timely reports; filing incomplete, erroneous, or inaccurate reports; or failure to comply with the prescribed Conflict of Interest Procedures for managing or resolving conflicts of interest. Violations relating to a federally funded project shall be managed in accordance with the Conflict of Interest Procedures and the requirements of the applicable awarding authority (i.e., 42 CFR 50 subpart F and 45 CFR 94.)

2. Failure to comply

In the event of an Investigator's failure to comply with the University Policy and Procedures, the Institutional Official may suspend all relevant activities until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented. At a minimum, violations may result in proposals being held from submission or award funds retained until compliance requirements are met. Non-compliance may also be noted in the personnel file. Omitting or misrepresenting information in reports or non-compliance with a management plan may result in more stringent disciplinary action as outlined in University Policy.

B. Procedure for discovery of an undisclosed SFI on a PHS-compliant project

1. Retrospective review

If the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a SFI that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

2. Agency report and mitigation plan

The OSSP will update any previously submitted report to the PHS-compliant sponsor relating to the research, 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 PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.