



5603 Arapahoe Avenue, Suite 1
Boulder, CO 80303
303-952-2905 • www.LightDeckDx.com

Financial Conflict of Interest (FCOI) Policy

Table of Contents

Financial Conflict of Interest (FCOI) Policy	1
Purpose.....	2
Definitions.....	2
Policy.....	4
Disclosure of Financial Interest.....	5
Subrecipients	6
Investigators.....	6
Disclosure Review.....	7
Designated Official Responsibilities	8
Management of FCOI	9
Management Plan	9
Retrospective Reviews.....	10
Reporting Financial Conflicts of Interest.....	10
Submission of Initial FCOI Reports	10
Submission of New FCOI Reports Post Award.....	10
Submission of Annual FCOI Reports	11
Content of Reports.....	11
Public Information.....	12
Training	12
Remedies.....	12
Records.....	12
Regulatory Authority	13
References	13

Purpose

LightDeck Diagnostics requires that the design, conduct, and reporting of research performed within the organization and equally through cooperative agreements with other organizations or individuals as contractors or subcontractors will be free from bias resulting from Investigator financial conflicts of interest.

Federal regulations, including PHS 42 CFR Part 50 Subpart F (Promoting Objectivity in Research) and 45 CFR Part 94 (Responsible Prospective Contractors), require institutions have enforceable policies and procedures in place to ensure that all Investigators disclose all significant financial interests that may present actual, or potential conflicts of interest in relationship to Federally funded sponsored projects.

A financial conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to LightDeck Diagnostics such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain. Potential and actual financial conflicts of interest depend on the situation and both must be managed accordingly.

Definitions

Awarding Component means the organizational unit of the federal government that funds the research subject to this regulation.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to the Institution.

Disclosure Review Committee means the designated individuals responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's institutional responsibilities.

FCOI report means the Institution's report of a financial conflict of interest to an Awarding Component.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.

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

Institution means MBio Diagnostics, Inc. dba LightDeck Diagnostics.

Institutional Responsibilities mean an Investigator's professional responsibilities on behalf of the Institution, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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 agency, or proposed for such funding, which may include, for example,

collaborators or consultants. The term investigator includes the investigator's spouse and dependent children.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a federally funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under the regulation.

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).

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or 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). As used in this regulation, the term includes any such activity for which research funding is available from an Awarding Component through a contract, grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the Awarding Component by the Institution under the regulation.

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:
 - (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve (12) 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;
 - (ii) 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 (12) 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
 - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- 2) For PHS-funding, Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the Institutional official(s) will determine whether further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.
- 3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 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 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.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Policy

It is the Institution's responsibility to determine whether a significant financial interest (SFI) relates to federally funded research and whether it is a financial conflict of interest (FCOI).

Therefore, the Institution has established standards that provide a reasonable expectation that the design, conduct, and reporting of federally funded research will be free from bias resulting from Investigator FCOI.

If the Institution carries out federally funded research through subcontractors, or collaborators, the company will take reasonable steps to ensure that Investigators working for such entities comply with the requirements of 45 C.F.R. 50 Subpart F "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (FCOI Regulation) and 45 C.F.R Part 94, Responsible Prospective Contractors, or applicable Awarding Component regulation, either by requiring those Investigators to comply with the Institution's Policy or by

requiring the entities to provide assurances to the Institution that will enable the company to comply with the requirements of the FCOI regulation.

All Investigators will be informed of this FCOI policy, their reporting responsibilities, and the applicable regulations governing this Policy.

It is the Institution's policy to require each Investigator to disclose SFIs, and those of the Investigator's spouse and dependent children, related to the Investigator's Institutional Responsibilities that meet or exceed the regulatory definition of SFI:

1. No later than at the time of application for federally funded research
2. At least annually during the period of the award
3. Within thirty (30) days of discovering or acquiring a new SFI

This Policy establishes the disclosure, review, and monitoring requirements for FCOI regulation compliance.

The Institution will post the most recent version of this FCOI policy on its public website.

Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict.

Pursuant to 42 CFR 50.602, this policy does not apply to SBIR Program Phase I applications.

[Disclosure of Financial Interest](#)

All Investigators are required to disclose SFIs to the Institution as described below. The Disclosure Review Committee is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

A. Initial Disclosure

Prior to applications for federally funded projects, the Investigator must disclose to the Disclosure Review Committee the Investigator's SFIs no later than the date of submission of the Institution's proposal. The Institution will not submit a research proposal unless the Investigator(s) have submitted such disclosures.

B. Annual Disclosures

All Investigators must disclose their SFIs that are related to the Investigator's Institutional Responsibilities to the Institution on an annual basis. All forms should be submitted to the Disclosure Review Committee at time of progress reports.

C. New Investigators

All new Investigators must disclose their SFIs to the Institution, through the Disclosure Review Committee, prior to participating in federally funded research.

D. Updated Disclosure

In addition, all Investigators must submit to the Disclosure Review Committee an ad hoc disclosure of any SFI they acquire or discover during the year within thirty (30) days of discovering or acquiring the SFI.

E. Travel

For PHS awards, Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities (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 disclosure is not required if the travel 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 institute of higher education. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Disclosure Review Committee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI with the Investigator's research.

Subrecipients

The Institution will establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the Institution or the FCOI policy of the subrecipient. This will be done either via obtaining a certification from the subrecipient that its FCOI policy complies with the regulation or include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures in a time frame that allows the Institution to identify, manage and report identified FCOIs as required by the regulation.

Investigators

The Institution's FCOI Policy requires that by the time an application is submitted to an Awarding Component, each Investigator who is to participate in the federally funded research has submitted to the Disclosure Review Committee a listing of his/her known SFIs (and those of his/her spouse and dependent children):

- A. That would reasonably appear to be affected by the research for which federal funding is sought; and
- B. In entities whose financial interests would reasonably appear to be affected by the research.

All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable SFIs are obtained.

Whenever the Institution implements a management plan, it shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project.

The Institution shall inform each Investigator of its policy on FCOI, the Investigator's responsibilities regarding disclosure of SFIs, and of the regulations.

The Institution will require that each Investigator, who is planning to participate in the research, disclose to the Disclosure Review Committee the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for the federally funded research project.

The Institution will require each Investigator who is participating in the federally funded research to submit an updated disclosure of SFIs at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution, or in a subsequent disclosure of SFIs (e.g., any financial conflict of interest identified on a federally

funded project that was transferred from another Institution) and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

The Institution will require each Investigator who is participating in the research to submit an updated disclosure of SFIs within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

In any case which the Awarding Component determines that a federally funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by regulation, the Institution shall require the Investigator involved to: 1) disclose the FCOI in each public presentation of the results of research, and 2) request an addendum to previously published presentations.

Disclosure Review

Prior to the Institution's expenditure of any funds under a federally funded research project, and annually thereafter, the Disclosure Review Committee shall:

1. Review all Investigator disclosures of SFIs:
 - Equity Interest – Non-publicly traded entity (e.g., stock, stock option, or other ownership interest)
 - Equity Interest – Publicly traded entity (e.g., stock, stock option, or other ownership interest)
 - Intellectual property rights (e.g., royalties, patents, copyrights) not from the awardee institution
 - Investment vehicles, such as mutual funds and retirement accounts, controlled by the investigator
 - Other (Provide an explanation that describes the SFI)
 - Payment for services (e.g., consulting fees, honoraria, paid authorship)
 - Reimbursed or sponsored travel
 - Salary not from the Institution
2. Determine whether any SFIs relate to the Research;
3. Determine whether an FCOI exists that could directly and significantly affect the design, conduct, or reporting of the Research; and,
4. If so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- (i) Public disclosure of FCOI (e.g., when presenting or publishing the Research);
- (ii) For research projects involving human subjects research, disclosure of FCOI directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias, resulting from the FCOI;
- (iv) Modification of the research plan;

- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Designated Official Responsibilities

The Institution has designated the Disclosure Review Committee to solicit and review disclosures of SFIs from each Investigator (and those of the Investigator's spouse and dependent children) who is planning to participate in, or is participating in, the federally funded Research.

Prior to the Institution's expenditure of funds, and annually thereafter, the Disclosure Review Committee shall:

- A. Review all Investigator disclosures of SFIs;
- B. Determine if any SFIs relate to funded research; and
- C. Determine whether an FCOI exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI.

These requirements shall be conducted:

- A. When required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI; or
- B. Within thirty (30) days whenever the Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.

Depending on the nature of the SFI, the Institution may determine that additional interim measures are necessary regarding the Investigator's participation in the funded research project between the date of disclosure and the completion of the Institution's review.

An Investigator's SFI is related to funded research when the Disclosure Review Committee reasonably determines that the SFI could be affected by the funded research; or is in an entity whose financial interest could be affected by the research.

An FCOI exists when the Disclosure Review Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the federally funded research.

The Institution may involve the Investigator in the designated official(s)'s determination of whether a SFI is related to the federally funded research.

The Disclosure Review Committee shall have the authority to establish adequate enforcement mechanisms and provide for sanctions where appropriate.

The Disclosure Review Committee must inform each Investigator of the:

- A. Federal Regulation;
- B. Institution's policy on FCOI; and
- C. Investigator's responsibilities regarding disclosure of SFIs

Management of FCOI

The Institution shall certify in each application for funding to which FCOI regulations apply, that it:

- A. Has in effect an up to date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the Awarding Component;
- B. Shall promote and enforce Investigator compliance requirements including those pertaining to disclosure of SFIs;
- C. Shall manage FCOI and provide initial and ongoing FCOI reports to the Awarding Component consistent with regulations; and
- D. Agrees to make information available, promptly upon request, to the Awarding Component relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether the disclosure resulted in the Institution's determination of an FCOI.

The Institution may use the following examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- a) Public disclosure of FCOIs (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of FCOI directly to participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- 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); or
- g) Severance of relationships that create financial conflicts.

Management Plan

FCOI management plans, including those of subrecipients as applicable, shall be monitored with their associated projects and include the following items:

- A. The role and principal duties of the conflicted Investigator in the research project;
- B. Conditions of the management plan;
- C. How the management plan is designed to safeguard objectivity in the research project;
- D. Confirmation of the Investigator's agreement to the management plan;
- E. How the management plan will be monitored to ensure Investigator compliance; and
- F. Other information as needed.

The Institution's management plans may include reduction or elimination of the SFI.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 C.F.R. Part 94, under Management of Conflicting Interests.

The Disclosure Review Committee will periodically review the ongoing activity, monitor the conduct of the activity, to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

Retrospective Reviews

Whenever the Institution identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the Disclosure Review Committee shall, within sixty (60) days, or as required by regulation: review the SFI; determine whether it is related to the funded research; determine whether an FCOI exists; and, if so:

- (i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward;
- (ii) In addition, whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute an FCOI; failure by the Institution to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any federally funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all the following key elements:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the Investigator with the FCOI;
- v. Name of the entity with which the Investigator has an FCOI;
- vi. Reason(s) for the retrospective review;
- vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- viii. Findings of the review; and
- ix. Conclusions of the review.

Reporting Financial Conflicts of Interest

Submission of Initial FCOI Reports

When the proposal is funded, prior to the Institution's expenditure of any funds under the research project, the Institution shall provide to the Awarding Component, consistent with regulations, an FCOI report regarding any Investigator's SFI found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies an FCOI and eliminates it prior to the expenditure of the research project funds, it shall not submit an FCOI report to the Awarding Component.

Submission of New FCOI Reports Post Award

For any SFI that the Institution identifies as conflicting after the Institution's initial FCOI report during an ongoing research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the Awarding Component, consistent with regulations, within sixty (60) days or as required, an FCOI report regarding the FCOI and ensure that the Institution has implemented a management plan in accordance with this Policy.

Where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), it also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research.

Additionally, if bias is found, the Institution is required to notify the Awarding Component promptly and submit a mitigation report to the Awarding Component. This will be the responsibility of the Disclosure Review Committee.

Submission of Annual FCOI Reports

For any FCOI previously reported by the Institution regarding an ongoing research project, it shall provide to the Awarding Component, consistent with regulations, an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Institution shall provide annual FCOI reports to the Awarding Component, consistent with regulations, for the duration of the project period (including extensions with or without funds) in the time and manner specified by the Awarding Component.

In addition to the types of FCOI as defined in this Policy, the Institution may require the reporting of other FCOI in its Policy, as it deems appropriate.

Content of Reports

Any FCOI report required shall include sufficient information to enable the Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- i. Project/Contract number;
- 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. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest (dollar ranges are permissible: \$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;
- vii. A description of how the financial interest relates to the research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- viii. A description of the key elements of the Institution's management plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the management plan;
 - c. How the management plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the management plan;
 - e. How the management plan will be monitored to ensure Investigator compliance; and

- f. Other information as needed.

Public Information

Prior to the Institution's expenditure of any funds under a PHS-funded research project, it shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five (5) business days of a request, of information concerning any SFI disclosed to the Institution that meets the following three criteria:

- A. The SFI was disclosed and is still held by key personnel as defined in this part;
- B. The Institution determines that the SFI is related to the research; and
- C. The Institution determines that the SFI is an FCOI.

The information that the Institution makes available via written response to any requestor within five (5) business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges are permissible: \$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 concerning the SFIs of an individual shall remain available, for responses to written requests for at least three (3) years from the date that the information was most recently updated.

Training

Each Investigator, including subrecipient Investigator(s), must complete FCOI training prior to engaging in federally funded research and at least every four (4) years, and immediately under the designated circumstances:

- A. The Institution's FCOI policy changes in a manner that affects Investigator requirements.
- B. An Investigator is new to the Institution.
- C. The Institution finds that an Investigator is not in compliance with this Policy or management plan.

The Institution will utilize resources available on NIH's Office of Extramural Research Financial Conflict of Interest website found at <http://grants.nih.gov/grants/policy/coi/> to satisfy some of the training requirements. A PDF of the FCOI certificate will be required after completion of each training. The Institution will also provide additional training regarding Investigator's responsibilities for disclosure of SFI's and of the Institution's specific FCOI Policy.

Remedies

If the failure of an Investigator to comply with the Institution's FCOI Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the federally funded research, the Institution shall promptly notify the Awarding Component of the corrective action taken or to be taken.

Records

The Institution shall maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three (3) years after final payment or, where applicable, for other dates specified in 45 CFR 75.361, where applicable.

Regulatory Authority

This Policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this Policy and the requirements, the requirements shall take precedence.

References

- [42 CFR Part 50 Subpart F](#) (Promoting Objectivity in Research)
- [45 CFR Part 94](#) (Responsible Prospective Contractors)
- [NIH Financial Conflicts of Interests Page](#)
- [NIH FCOI Frequently Asked Questions](#)