Financial Conflict of Interest Policy of iRT

13.3.1 Definitions from 42 CFR 50.603

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

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.

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

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

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. For the purposes of this policy, the Institution is iRT.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

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 PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

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).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

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 subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a 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 PHS by the Institution under this subpart.

Significant financial interest 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 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 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) 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 Institution's FCOI policy will specify the details of this disclosure, which 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 if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-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 subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

13.2 FCOI overview

iRT encourages its employees to participate in sponsored research at iRT and to engage in other activities that further the aims of iRT to obtain, develop, and market products and services for children, adolescents, families, and communities. At the same time, iRT is committed to ensuring that investigators conduct research in an open and free atmosphere within the Company.

It is in the interest of iRT, individual employees, and Board members to strengthen trust and confidence in each other, to expedite resolution of problems, to mitigate the effect and to minimize organizational and individual stress that can be caused by an FCOI.

Employees are to avoid any FCOI, even the appearance of an FCOI. The appearance of an FCOI can cause embarrassment to the company and jeopardize its credibility. Any FCOI, potential FCOI, or the appearance of an FCOI is to be reported to your supervisor immediately.

Employees are to maintain independence and objectivity in research. Employees are called to maintain a sense of fairness, civility, ethics, and personal integrity whether or not law, regulation, or custom requires it.

The information above is only a sample of the regulatory requirements found in 42 CFR 50, Subpart F. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on OER's Conflict of Interest Web site at http://grants.nih.gov/grants/policy/coi/index.htm.

Additional resources are available at https://grants.nih.gov/grants/policy/coi/index.htm

13.3 Factors used in analyzing FCOI

Using reasonable-person standards, the President, Research-Related Financial Conflict of Interest Committee, IRB Chair, and/or IRB Committee will consider the following factors in its analysis of the reported SFI:

13.3.1 Amount of Risk

There are several types of risk associated with an FCOI. For example, there are also risks associated with FCOIs that can result in discomfort for subjects in research.

13.3.2 Effect of an FCOI on Subjective Decision-Making

The participation of the party with the FCOI could affect subjective decision-making, both consciously and subconsciously, and thus, influence the conflicted party's judgment or behavior. Subjective decisions that could be influenced by a conflict include the purchase of materials, selection of a vendor, personnel actions, design of a research project, choosing which subjects to enroll in a research project, clinical care provided to research subjects, use of subjects' confidential medical information, data collection and analysis, adverse event reporting, and the presentation of research findings.

13.3.3 Amount of Interaction Between the Conflicted Party and the Consultants, Vendors, Clients, or Research Subjects

Many of the concerns about the conflicted party's decisions will be lessened, if the conflicted party does not interact directly with the relevant party. For example, in studies using archival or web-based data, the conflicted investigator receives data and has no contact with the subjects. If the conflicted party can benefit from purchase of materials or selection of a vendor, then following iRT's procurement policy can mitigate against this happening.

13.3.4 Other Parties Involved in Overseeing the Conflict of Interest

Often, there are other parties besides the President, IRB Chair, or Research-Related Conflict of Interest (RRCOI) Committee involved in the oversight of conflicts of research.

For example, for FDA-regulated studies, the FDA will provide a scientific review of the research results.

NIH does detailed reviews of research proposals, in advance, and NIH inquires about conflicts of interest at certain procedural steps.

The iRT IRB has assigned subject advocates who sit in on the consent process, when appropriate.

Some research projects may be independently monitored by a scientist who is not an employee of iRT and has no conflict of interest that would compromise his or her role as an independent monitor.

The RRCOI Committee Members will consider the role and oversight of these and other such parties when assessing the presence of an FCOI.

13.4 General procedures

Upon hiring, iRT employees are expected to:

1. read this chapter containing iRT's Financial Conflict of Interest Policy
2. sign and submit the Financial Conflict of Interest Policy Acknowledgement Form

There are a range of potential COIs that can be reported after the initial report is filed. Thus, iRT's Policy on FCOI requires all employees to update their statement on outside commitments and SFIs, when one arises.

13.5 Research-related FCOI

NIH requires recipients and investigators (except Phase 1 SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

The requirements promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting SFI of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Thus, in compliance with federal regulations, iRT requires Principal Investigators and other key personnel on a sponsored project to disclose any SFIs (and those of his or her spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project.

Federal regulations regarding FCOIs were issued by the Department of Health and Human Services (DHHS) that went into effect August 24, 2012. These regulations can be found here: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

13.5.1 Grant submission

When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of 42 CFR 50, Subpart F, including that:

1. There is in effect at the iRT an up-to-date, written and enforced administrative process to identify and manage FCOIs with respect to all research projects for which NIH funding is sought or received;
2. iRT shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of SFIs;
3. iRT shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH;
4. When requested, iRT will promptly make information available to the NIH/HHS relating to any Investigator disclosure of SFI and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;

13.5.2 iRT procedures for determination of a potential FCOI

Investigators conducting research involving human subjects are required to describe in iRT Institutional Review Board (IRB) Initial Proposal Cover Sheets any potential FCOI. Procedures related to FCOI and IRBs are described below.

PIs, Co-PIs, and in some instances, key personnel listed on a proposal for external funding must also complete a Part 1: Project-Specific Disclosure Form of a Significant Financial Interest (SFI) before submitting a proposal to or expending resources on a sponsored project funded by the Public Health Service, NSF, or other agencies adopting federal requirements.

There may be situations in which a previously-unreported FCOI is created or discovered. For example, a new investigator may join a project, or a current

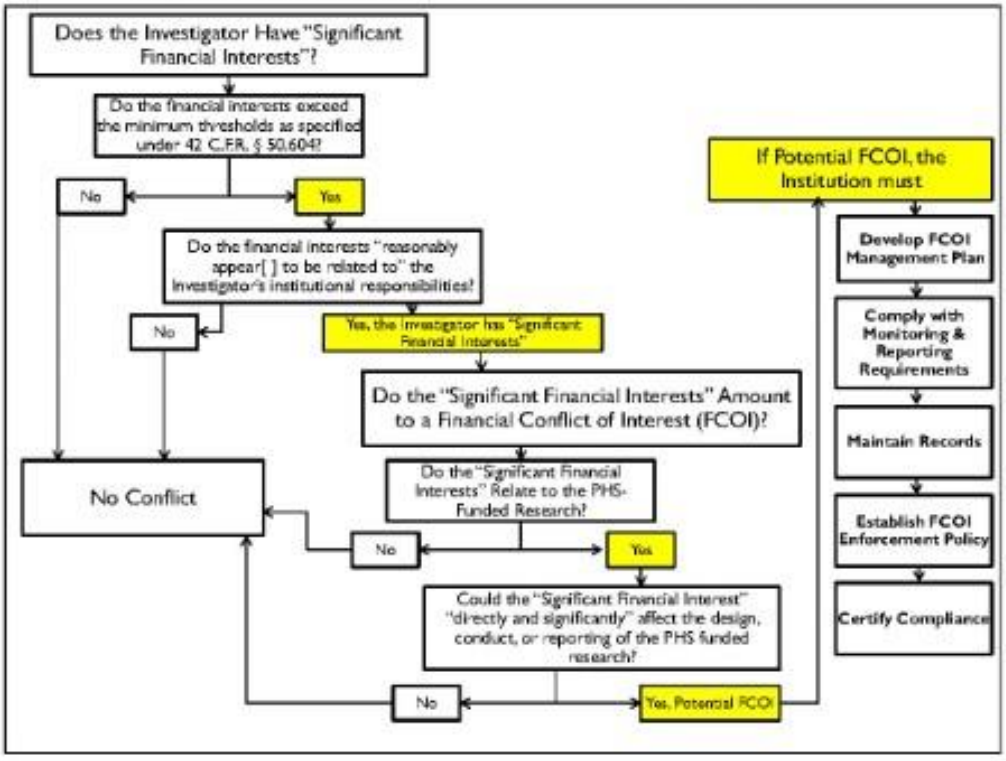
investigator may obtain, discover, or become aware of a potential SFI that could pose an FCOI.

The procedures for reporting and managing a potential FCOI are:

1. The Investigator will report the new SFI within 30 days of its discovery to the iRT Business Manager.
2. An iRT-appointed RRCOI Committee will review the submitted SFI Disclosure Form to determine if an FCOI exists.
3. If an FCOI exists, then the RRCOI committee will work with the Investigator, who has the FCOI, to create a Management Plan.
4. iRT will notify the NIH within 60 days of the reported SFI with the Management Plan for a specific NIH-funded project. (iRT will notify the NIH within 60 days of a new investigator joining the project, who has an FCOI.) Reports to the NIH will be submitted by the Business Manager through the eRA Commons website in the FCOI Module.

To guide the discussion, a flowchart of the process by which FCOIs are identified and managed pursuant to the PHS general objectivity requirements was adopted from the *Federal Financial Conflict of Interest rules and Biomedical Research: A Legal Overview Repor*t published online by the Congressional Research Service:

Figure 1. Summary of PHS General Objectivity Requirements



Source: Created by CRS.

13.5.3 Management Plan for FCOI

An SFI is not intrinsically wrong. Rather, the purpose in analyzing a potential FCOI is in trying to determine when the SFI offers incentive to the investigators or other parties to breach a duty to research subjects or to society, and how to address the FCOI. As individuals vary in their personal integrity, iRT uses two reasonable-person standards for analysis:

> First, the reviewers consider whether the FCOI could challenge the integrity of a reasonable individual.
>
> Second, the reviewers consider whether the FCOI would appear to a reasonable member of the general public to be a conflict that could challenge the integrity of the conflicted party.

The RRCOI Committee shall determine the terms, conditions, and restrictions, if any, that are required as part of a Management Plan. The Committee will most likely need to discuss these terms with the PI on the project in question to ensure that the Plan is consistent with the goals and methods of the research project.

The Business Manager will share the Part 2: Decision by the Research-Related Financial Conflict of Interest Committee and Management Plan for a Specific Project in writing to the investigator and will be signed by the conflicted investigator.

The Management Plan will address, at a minimum:

- The role and principal duties of the conflicted Investigator in the research project
- How the Management Plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the Management Plan
- Monitoring compliance with the Management Plan

The Management Plan may require that one or more of the following actions are taken in order to manage, reduce, or eliminate a potential FCOI that was not managed or prior disclosed by iRT:

- Disclosure of the FCOI, in each public presentation of the results of the Research and to request an addendum to previously published presentations, if not disclosed previously.
- Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals, or committees.
- Disqualification from participation in all or a portion of the PHS-funded Research.
- Requiring that SFI Interests be divested, restructured, or placed in blind trust.
- Modification or severance of relationships that create a potential FCOI.
- Changing terms of agreement relating to the PHS-funded Research.
- Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted.
- Requiring additional disclosures or actions.
- Requiring non-participation in any business transactions between iRT and parties to agreements involving sponsored PHS-funded Research.

13.5.4 Reporting FCOIs to federal Awarding Component

When the RRFCOI Committee determines that an FCOI exists, iRT must report to the NIH Awarding IC through the submission of initial and annual FCOI reports.

The initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model
- Name of Investigator (if different from the PD/PI) with the FCOI
- Name of the entity with which the Investigator has an FCOI
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel)
- A description how the SFI relates to the NIH-funded research
- The basis for the Institution's determination that the SFI conflicts with the research
- Key elements of the Management Plan include:
    1. Role and principal duties of the conflicted Investigator in the research project
    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
    6. Other information, as needed.

The initial and annual FCOI Report must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until iRT reports that the FCOI no longer exists.

The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the Management Plan, if applicable.

iRT will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible website or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

Changes to the FCOI policy and new investigators will be reported to the NIH within 60 days.

13.5.5 Public Disclosure of FCOIs

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site **or** written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and
(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site **or** written response to any requestor within five 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 significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant 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.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

13.5.6 Management of potential FCOIs with subrecipients

iRT will incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of iRT or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must report identified Financial Conflicts of Interest to iRT in sufficient time to allow iRT to report the FCOI to the NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)

13.6 Training requirements of iRT employees

Investigators (as defined in this policy) are responsible to:

1. Read the National Institute of Health ("NIH") Regulations and Code of Federal Regulations ("CFR") on FCOI.
   a. NIH Financial Conflict of Interest Overview: http://grants.nih.gov/grants/policy/coi/
   b. Federal Register Notice for 45 CFR Part 50 Subpart F and 45 CFR 94: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf
   c. FCOI Frequently Asked Questions: http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
2. Complete the NIH tutorial on FCOI prior to completing this form: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm
3. Forward the tutorial's Certificate of Completion to Tami Schwend

iRT will require each Investigator (including subrecipient Investigators, if applicable), as defined in this Policy, to complete training prior to engaging in research supported by PHS and then, periodically, at least every four years, and immediately under the designated circumstances:

- FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to the research project
- iRT finds an Investigator noncompliant with the Institution's FCOI policy, or his or her Management Plan.

iRT will also provide internal training to employees on iRT's FCOI Policy, particularly, if any changes are made to the policy.

13.7 Records retention

Records of and related to SFI disclosures shall be retained by iRT for no less than three (3) years after the termination or completion of the PHS-funded research to which they relate or from the date the final expenditure report is submitted to the PHS Awarding Component, whichever is later.

13.8 Reporting of FCOI and Management Plan in Specific Protocols Proposals to the IRB

13.8.1 Role of the IRB

The IRB is the primary authority at iRT responsible for ensuring that human research subjects are protected in accordance with federal regulations, company policies, and ethical principles. One of the primary responsibilities of the IRB is to ensure that human research subjects receive all information needed to provide informed consent.

The IRB's consideration of investigators' financial interests is intended to ensure"

1) that the informed consent process provides the subjects with the facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study, and

2) that no conflict exists that would otherwise compromise the protection of human subjects.

13.8.2 Role of Investigators and Key Personnel

For all protocols submitted to the IRB, including new protocols and those submitted for renewal, each participating investigator and key study person must read this chapter.

In addition to the Part 1: Project-Specific Disclosure Form of a Significant Financial Interest (SFI), investigators conducting research involving human subjects are required to disclose to the iRT Institutional Review Board information about protocol-specific financial conflicts of interest, when appropriate, on the Initial Proposal Cover Sheet, by responding to item #13 (Potential Conflict of Interest). The item reads as follows:

> In reference to the research proposed in this form, will any of the study investigators or staff, or their immediate family members such as a spouse, significant other, dependent children, or parents, HAVE A CONFLICT OF INTEREST? Conflicts of interest could include an intellectual property interest, patent rights, copyright, ownership interest (equity, stock options), and/or personal compensation in the form of salary, consulting fees, honoria, royalties, and gifts THAT COULD POSSIBLY BE VIEWED AS COMPROMISING THE INTEGRITY OF THE RESEARCH.
>
> If the answer is "yes," please include an explanation below, noting the individual(s), the nature of the possible conflict(s), and if relevant, how the conflict(s) has/have been minimized.
>
> ☐ No, not for anyone listed above as project personnel
>
> ☐ Yes (include explanation as above)

Before the IRB meeting at which a protocol is scheduled for consideration, the IRB Chair will review the response to item #13 on the Initial Proposal Cover Sheet to

determine if there are related actual or potential conflicts. The Chair will evaluate such conflicts and, if relevant, provide a summary to the Committee. The Chair and/or Committee will determine:

(1) whether the conflict is permissible in the context of the protocol, and, if so,

(2) whether the conflict warrants disclosure to potential subjects as part of the informed consent process.

The IRB Chair will share relevant information with the President, who may make additional findings and recommendations regarding actual and potential FOICs.

Below is an example of a response to item #13 (Potential Conflict of Interest):

> The investigator may receive bonuses or royalties based upon future sales of the program being evaluated in this study. This financial conflict of interest is currently minimal, and this financial conflict of interest is minimized through training and following standardized data collection procedures that do not involve the investigator's involvement in the consenting, data collection, and data analysis activities. The specific procedures will be based upon the contents of this IRB proposal to reduce any risks of coercion of research participants. The data collected in the proposed study will be entered into the computer by a trained research assistant. The databases will be de-identified (i.e., anonymized) and analyzed by a statistician assigned to work on the project who does not have an FCOI. The raw and analysis databases, as well as the results of analyses will be archived on the password-protected server. The raw databases, analysis databases, and final statistical analyses can be made available to the funder for independent review.

13.8.3 Possible IRB Actions

Actions to consider in the research protocol, if an investigator is found to have an FCOI:

- Including information in the informed consent document, such as:
  - the source of funding and funding arrangements for the conduct and review of research, or
  - information about a financial arrangement of an institution or an investigator and how it is being managed.
- Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as:
  - having another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.
  - Using independent monitoring of the research.

13.8.4 Additional information

For additional resources, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/index.html

13.9 Failure to disclose SFI in a timely way

Whenever the Institution identifies an SFI that was not disclosed in a timely way by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within 60 days: review the SFI; determine whether it is related to PHS-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)(A) In addition, whenever an FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a 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 PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

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

(1) Project number;
(2) Project title;
(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
(4) Name of the Investigator with the FCOI;
(5) Name of the entity with which the Investigator has a financial conflict of interest;
(6) Reason(s) for the retrospective review;
(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
(8) Findings of the review; and
(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a Mitigation Report to the PHS Awarding Component. The Mitigation Report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this chapter. Depending on the nature of the FCOI, an Institution may determine that

additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

13.10 Issues of noncompliance

Whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose an SFI
- Failure by the Institution to review or manage an FCOI
- Failure to comply with the Management Plan

If an investigator is found to be noncompliant with iRT's FCOI policy, a review of noncompliance will be performed and submitted to the NIH within 120 days of initial discovery, as detailed in 13.5.1.

iRT will complete a retrospective review of the Investigator's activities and the project to determine if there was any bias in the design, conduct or reporting of such research. This process will be accomplished within 120 days of the determination of noncompliance. If bias is found in the retrospective review, a revised FCOI and Management Plan will be submitted to NIH within 60 days through the eRA Commons FCOI module by the Business Manager, as detailed in 13.6.

iRT will mitigate the new FCOI using the methods detailed above in 13.5. If deemed necessary by the retrospective review, iRT will also implement employee sanctions and/or additional administrative actions to ensure that there are no further issues of noncompliance. A description of these mitigation measures will be included in the retrospective review submitted to the NIH.