
Policy Name: Financial Conflict of Interest (FCOI) for Investigators

Effective Date: 24 Jan 2024

Approval signature



Title President

Purpose:

The purpose of this policy is to prevent potential bias resulting from any Financial Conflict of Interest (FCOI) by individuals who have influence in the allocations and use of public funding in the conduct of research. This policy applies to research and initiatives funded by US Public Health Service (PHS) grants wherein Turner Scientific is the recipient of such funds. This policy aligns to the requirements within regulation [42 CFR Part 50-Subpart F](#) (FCOI regulation) with the goal of promoting objectivity and transparency in research.

Responsible Parties:

Investigators are responsible for disclosing any financial conflicts of interest in the design, conduct, or reporting of research funded under the PHS grant/agreements.

The FCOI Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists, related to an Investigator's institutional responsibilities.

The Authorized Organization Representative (AOR), when submitting a grant application, will certify the applicant Institution's compliance with the requirements of the FCOI Regulations.

This policy will be reviewed every 2 years.

Policy Statement:

NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of [42 CFR Part 50, Subpart F, "Promoting Objectivity in Research"](#) for which PHS funding is sought, as implemented in the 2011 Final Rule for grants and cooperative agreements.

This Financial Conflict of Interest policy (FCOI Policy) has been established to align with standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under the Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

This FCOI policy defines the requirements and processes for investigators, or individuals participating in PHS funded research, to identify and properly disclose any FCOIs. In addition, it outlines activities related to management, enforcement, and remedies for noncompliance.

DEFINITIONS

Investigator(s) include the Principal Investigator (PI)/Project Director and any other individuals, regardless of title or position who is responsible for the design, conduct, or reporting of PHS/NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the Company, and as defined by the Company, 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 for PHS funded research.

Financial interest means anything which has monetary value, and if the value is readily ascertainable.

Financial Conflicts of Interest (FCOI) in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research related to the PHS funded activity.

FCOI Manager is the grant recipient's designated official for managing the FCOI process related to a specific PHS grant.

Significant Financial Interest (SFI) is 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:

- 1) Regarding any publicly traded entity (other than Turner Scientific), 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.

- 2) Regarding any non-publicly traded entity (other than Turner Scientific), 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
- 3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

In addition, Investigators 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 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 this FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

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, if 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.

Subrecipient is a subcontractor or consortium participant who may indirectly receive grant funding via the Company that holds the prime contract with the US Government.

FCOI TRAINING

In compliance with federal regulations, all Turner Scientific Investigators who are planning to participate in or are participating in Public Health Service (PHS) funded research are required to:

- Review this FCOI policy, which is compliant with federal regulation.
- Complete the NIH's online [FCOI Training module](#):
 - Prior to engaging in research related to any PHS/NIH-funded grant
 - At least every four (4) years
 - Immediately, if:
 - Turner Scientific revises its FCOI policy that affects requirements of investigators.
 - An Investigator is new to the Company.
 - An Investigator is not in compliance with the policy or management plan.
- Understand the disclosure responsibilities of all foreign and domestic [significant financial interests \(SFI\)](#).

Upon completion of the training, a certificate of completion must be sent to the FCOI Manager. Investigators should also retain a copy for their records.

DISCLOSURE, REVIEW AND MONITORING REQUIREMENTS

Disclosure

The Principal Investigator of a research project will identify all Investigators required to disclose foreign and domestic SFIs (and those of the Investigator's spouse, partner, and dependent children) related to PHS funded activity, which meet the [definition of SFI](#). The Principal Investigator and FCOI Manager will be responsible for ensuring disclosures of any new (e.g., marriage, purchase, or inheritance) or increased financial interests are completed:

- Not later than at the time of application for PHS-funded research
- At least annually during the period of award, and
- Within 30 days of discovering or acquiring a new SFI

Review

Turner Scientific will designate an FCOI manager. Prior to expenditure of funds, the FCOI Manager will solicit and review Investigator disclosures to determine whether a potential FCOI exists related to an investigator's institutional responsibilities.

An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest:

- could be affected by the PHS-funded research; or
- is in an entity whose financial interest could be affected by the research.

If it is determined that there is a potential conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce, or eliminate specific SFIs to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct or reporting of research, and the FCOI manager will develop an FCOI management plan. The plan may outline terms, conditions, and restrictions, if any, to ensure compliance with this policy.

Investigators must formally agree to the proposed management strategies. All management plans are required to be signed by the Investigator. Compliance of the management plan will be monitored by the FCOI Manager.

REPORTING REQUIREMENTS

The FCOI Manager is responsible for the reporting disposition of matters (initial, annual (i.e., ongoing) and revised FCOI reports) involving disclosures of SFI in accordance with applicable federal requirements via the eRA Commons FCOI Module. The following reporting times are required:

- Prior to the expenditure of funds
- Within sixty (60) days of disclosure for an Investigator who is newly participating in the project
- Within sixty (60) days for newly identified FCOIs, for existing Investigators
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension).
- After any retrospective reviews, to update a previously submitted report, if new information is discovered following completion of the review, including Mitigation reports.

NIH is to be notified promptly if:

- an Investigator fails to comply with this FCOI policy.

- noncompliance with an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

MAINTENANCE OF RECORDS

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential FCOI, shall be retained by the FCOI Manager for

- three (3) years from the date the final expenditure report or
- where applicable, from other dates specified in [45 CFR 75.361](#) for different situations.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of financial interests or failure to comply with a requirement of the management plan, disciplinary proceedings may be taken against the violating individual.

Whenever an SFI is identified, that was not disclosed timely to the FCOI Manager, a **retrospective review** will be completed within 120 days of discovery of noncompliance to determine whether any PHS-funded research, or portion thereof, conducted during the period of the noncompliance, was biased in the design, conduct, or reporting of such research. Updated FCOIs will be submitted to the FCOI Manager. Required retrospective review elements are outlined in [42 CFR 50.605\(a\)\(3\)\(iii\)](#). A mitigation report will be required to be submitted to NIH.

Additionally, in any case in which the FCOI Manager determines that a PHS-funded **project of clinical research** whose purpose is to evaluate the safety or effectiveness of a vaccine, drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported, as required, Turner Scientific will require the Investigator involved to disclose the financial conflict of interest

- in each public presentation of the results of the PHS funded research and to request an addendum to previously published presentations under PHS Funded research.

SUBRECIPIENT REQUIREMENTS

When carrying out the PHS-funded research through a subrecipient (e.g., subcontractors), Turner Scientific shall establish a written agreement (e.g., subaward contract) which confirms that the investigators of the subrecipient institution will comply with this policy or provide certification that their organization is compliant with the Federal policy, 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research ([42 CFR part 50 subpart F](#)).

If an SFI is identified by the sub-award recipient, they are required to notify the PI and FCOI Manager of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported

conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.

PUBLIC ACCESSIBILITY REQUIREMENTS

Turner Scientific will publish its FCOI policy on its public website, www.turnerscientific.com. Turner Scientific will also make available information concerning identified FCOIs held by senior/key personnel, publicly assessable prior to the expenditure of funds. This information will:

- Include the minimal elements as provided in the regulation.
- Be posted on a Public Website or made available within five (5) business days of a written request.
- Be updated, at least annually.
- Be updated, within sixty (60) days of a newly identified FCOI.
- Remain available for three (3) years from the date the information was most recently updated.

References:

eCFR: [42 CFR Part 50 Subpart F-Promoting Objectivity in Research](#)
[NIH Grants & Funding Frequently Asked Questions \(FAQs\)](#)
[NIH Grants Policy Statement](#)
[NIH Grants & Funding FCOI Training](#)
 Turner Scientific SOP 285, *Financial Conflicts of Interest Procedures*

Version History:

| Version # | Description | Effective date |
|-----------|-------------|----------------|
| v1 | New policy | 24 Jan 2024 |
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