

Contents

I. Introduction 2

 A. General Policy 2

 B. Scope 2

 C. Roles/Responsibilities 2

II. Definitions 3

III. Training Requirements 3

IV. Disclosure, Review and Monitoring 3

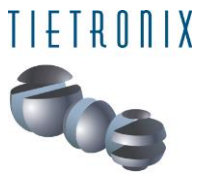
V. Reporting 4

VI. Records Management 5

VII. Enforcement, Remedies and Noncompliance 5

VIII. Subrecipients 6

IX. Public Accessibility 6



Financial Conflict of Interest Policy

TIE-PP-FCOI Rev 1
May 2021

This policy details the standards and instructions to comply with financial conflict of interest (FCOI) per 42 CFR PART 50 SUBPART F.

I. Introduction

A. General Policy

Tietronix Software is committed to integrity in our research and development efforts. This includes conducting research responsibly and following established research and funding guidelines. As an institution, we strive to promote the objectivity in research by establishing standards that preserve the integrity of research, protect the rights and safety of research subjects, and prevent bias in the design, conduct and reporting of research funded under PHS grants or cooperative agreements that may result from any financial conflict of interest by investigators or key personnel.

B. Scope

This statement of policy and procedures is intended to carry out Tietronix' responsibilities under 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought." This document applies to:

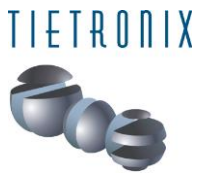
- Any Investigator conducting research that is PHS-funded. For purposes of financial disclosure only, this regulation also covers the spouse and dependent children of the investigator and key personnel.
- Any subgrantees, contractors, or collaborators contracted by Tietronix to carry out the PHS-funded research; Tietronix will take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to Tietronix that will enable Tietronix to comply with this subpart.

The president or the appointed designee (by the president) will have primary responsibility for implementation of the institution's policies and procedures regarding financial conflict of interest.

C. Roles/Responsibilities

a. Investigator and Key Personnel

- i. Any employee who serves as an investigator or key personnel and is planning to participate in PHS-funded research must disclose to the president or the appointed designee any significant financial interest (and those of the investigator's or key personnel's spouse and dependent children) no later than the time of application for PHS-funded research using the FCOI form.
- ii. Investigators or key personnel participating in PHS-funded research must disclose any significant financial interest (and those of the investigator's or key personnel's spouse and dependent children) no later than January 31, 2013, and every year thereafter, using the FCOI form.
- iii. Annual FCOI reports submitted to the president or the appointed designee (by the president) shall include any information that was not previously disclosed.



Financial Conflict of Interest Policy

TIE-PP-FCOI Rev 1
May 2021

- iv. Within 30 days of discovering or acquiring a significant financial interest, an investigator or key personnel shall submit an updated FCOI form.
- b. Institution (Tietronix Software)
 - i. Tietronix shall update and enforce this written policy in accordance with 42 CFR 50, Subpart F and will make the policy and applicable federal regulations available on the Tietronix website.
 - ii. Tietronix will inform each investigator and key personnel about this policy.
 - iii. Tietronix will inform any subrecipients involved in PHS-funded projects of this policy and requirements.

II. Definitions

Terms used have the same meaning as given them in the Public Health Service, Department of Health and Human Services, 42 CFR Part 50.

III. Training Requirements

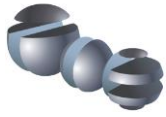
1. Each Investigator will be required to review this policy and understand the responsibility of disclosing any FCOIs using the Tietronix FCOI for Investigators form.
2. Each Investigator is required to complete the NIH FCOI training module (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html):
 - i. Prior to engaging in research related to any PHS-funded grant
 - ii. At least every four (4) years
 - iii. When any FCOI policy is revised
 - iv. If the investigator is new to the company
 - v. If the investigator is not in compliance with this policy or management plan

IV. Disclosure, Review and Monitoring

1. Disclosure:

Each Investigator is required to disclose their Significant Financial Interests (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 (42 CFR 50.603; 42 CFR 50.604(e)(1)-(3))

- i. No later than at the time of application for PHS-funded research
 - ii. Annually during the period of award
 - iii. Within 30 days of discovering or acquiring a new SFI
2. Review: Prior to expenditure of funds:
 - a. The president or the appointed designee will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to Investigator's responsibilities for a determination of an FCOI. The investigator may participate in making the determination of whether the SFI is an FCOI.
 - b. The guidelines for determining if SFI is an FCOI (42 CFR 50.604(f)):



Financial Conflict of Interest Policy

- i. Could this SFI be affected by the PHS-funded research.
 - ii. Is the SFI an entity whose financial interest could be affected by the research.
 - c. If the review shows an FCOI exists, then the president or the appointed designee will develop and implement a management plan to manage the financial conflict of interest (FCOI).
3. Monitoring:
 - a. For any Investigator who is new to participating in the research project or an existing Investigator discloses a new SFI, the president or the appointed designee shall within sixty (60) days review disclosures of SFIs, and determine if the SFI is related to PHS-funded research; if an FCOI exists, then implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI.
 - b. If an SFI is identified that was not disclosed by an Investigator timely or was not previously reviewed during the research project, the president or the appointed designee shall within sixty (60) days review the disclosures of SFIs, and determine whether the SFI is related to PHS-funded research and if an FCOI exists. If an FCOI exists, the president or the appointed designee will implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.
 - c. The president or the appointed designee will ensure all FCOIs are managed, take any actions as needed, and monitor compliance with management plans until the project is completed.

V. Reporting

The following outlines the reporting requirements to NIH:

1. Initial, annual and revised FCOI report will be submitted:
 - a. Prior to expenditure of funds
 - b. Within 60 days of a new Investigator joining the project
 - c. Within 60 days of new or newly identified FCOIs for the Investigators
 - d. Annually, at the time of annual progress report, or extension (if applicable), the status of FCOI and any changes to the management plan until the project is completed.
 - e. If any new information is discovered following a review of any previously submitted report
2. Tietronix will report to NIH promptly if any bias is found with the design, conduct or reporting of PHS-funded research. This will include a Mitigation Report explaining what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation. This will include all the reporting elements as required by the 42 CFR 50.605(a)(3)(iii).
3. Tietronix will report to NIH if an Investigator fails to comply with this policy or an FCOI management plan appears to have biased the design, conduct or reporting of the PHS-funded



research. Tietronix will report to NIH the corrective actions for noncompliance with the policy or management plan.

VI. Records Management

Tietronix will maintain all FCOI-related records (even if no disclosure or FCOI was determined) relating to all the Investigator(s) disclosures of financial interests for at least 3 years from the date of the final expenditures report is submitted, or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.

VII. Enforcement, Remedies and Noncompliance

Failure to comply with this policy may lead to disciplinary or corrective action including but not limited to, removal from the PHS-funded research project, suspending or terminating the project, imposition of award conditions such as denying use of funds for parts of or all activities, suspension of funding, withholding further awards from project or program, and any other remedies that may be legally available.

Tietronix will complete a retrospective review within 120 days of a determination of noncompliance when:

- A SFI is not disclosed timely.
- A SFI is not previously reviewed.
- An FCOI is not identified or managed in a time manner.

Including:

- Failure by the investigator to disclose a SFI that Tietronix determines constitutes a financial conflict of interest.
- Failure by Tietronix to review or manage the financial conflict of interest.
- Failure by the investigator to comply with the financial conflict of interest management plan.

This retrospective review will be documents to include at a minimum:

- Project Number
- Project Title
- PD/PI or contact PD/PI if a multiple PD/PI model is used
- Name of the investigator with the FCOI
- Name of the entity with which the investigator has an FCOI
- Reasons for the retrospective review
- Detailed methodology used for the retrospective review
- Findings of the review
- Conclusions drawn from the review



Tietronix will ensure that in any case in which the Department of Health and Human Services determines that a PHS-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 not managed or reported as required by the regulation, Tietronix shall require the Investigator involved to:

- Disclose the FCOI whenever there is a public presentation of the results of the research
- Request an addendum to previously published presentations

VIII. Subrecipients

Subrecipients participating in PHS-funded projects will be informed of this policy and required to follow the FCOI policy of Tietronix or the FCOI policy of the subrecipient. The subrecipients will be informed of the requirements (42 CFR 50.604(c)).

Tietronix will include in the subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its investigators in a time frame that allows Tietronix to report identified FCOIs to the NIH as required by the regulation.

If applicable, Tietronix will include in the subrecipient agreement a requirement to solicit and review subrecipient investigator disclosures that enable Tietronix to identify, manage and report identified FCOIs to the NIH.

IX. Public Accessibility

1. Tietronix will post this policy on its website (www.tietronix.com).
2. Prior to the expenditure of any funds under a PHS-funded research project, the president or the appointed designee must respond in writing within five days to a requestor for information concerning any significant financial interest disclosures that meet the following criteria:
 - a. Any significant financial interest disclosed and is still held by the investigator or key personnel.
 - b. The significant financial interest was determined to be related to the PHS-funded research project.
 - c. The significant financial interest was determined to be an FCOI.
 - d. The information released to the requestor must include the following:
 - i. Investigator or key personnel name and title
 - ii. The role of the investigator or key personnel in the research project
 - iii. The name of the entity in which the significant financial interest is held
 - iv. The nature of the significant financial interest and the approximate dollar range of the significant financial interest or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures.
 - v. The written response will note that the information provided is current as of the date of the correspondence, that FCOI information is updated biannually or within



Financial Conflict of Interest Policy

60 days of identification of a new FCOI. Requestor would have to make subsequent request to receive information.

3. Tietronix may choose to post FCOI disclosures on its website and if posted will update information every six months.
 - a. Additional financial interest not previously disclosed or disclosure of financial interest of an investigator or key personnel new to a PHS-funded research project where there is updated information relating to the PHS-funded research and is considered a FCOI, will be posted to the web within 60 days.
 - b. If information is posted on the website, the web page will note that the information provided is current as of the date listed and is subject to updates within 60 days of receiving updated information or on a biannual basis.
4. Information posted shall remain available for public information requests for at least three years from the date that the information was most recently updated.