

# Financial Conflict of Interest Policy & Procedure

## Purpose:

ToxTrack aims to promote a culture of scientific objectivity and processes that and safeguard ethical practices such the formulation, execution, and reporting of Public Health Service (including NIH) funded research is free from bias, particularly resulting from Financial Conflict of Interest (FCOI).

## Policy:

This FCOI policy is applicable to every ToxTrack employee and/or contractor who is planning to or is participating in research activity that is wholly or partially supported by PHS funds. Under this policy, each such employee must:

- 1) disclose his or her significant financial interests (SFI) in non-ToxTrack entities that may appear to be related to the employee's professional responsibilities on behalf of ToxTrack
- 2) comply with a FCOI management plan, if a FCOI is identified, and
- 3) undergo FCOI training within 6 months of hire and then at least once every four years

The disclosure of SFI is essential for ToxTrack to determine if a FCOI exists, and in cases of confirmed FCOI, how it will be managed and reported in full compliance with government regulation. Non-disclosure or misrepresentation of SFI, as well as non-compliance with the FCOI management plan, may result in disciplinary action for the offending employee including, without limitation, suspension or termination of employment.

## Definitions:

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

*Significant Financial Interest (SFI)* exists if the value of remuneration for work, services, or other goods that, in good faith, appear related to the employee's ToxTrack responsibilities exceeds \$5000 USD in total value to any combination of the employee, employee's spouse, or employee's dependent children.

## Included Costs

- Salary or other payments for services (e.g. consulting fees) received in the prior twelve months preceding disclosure
- Equity interests (e.g. stocks, stock options, or other ownership interests). **NOTE:** equity interest, of any value, in a non-publicly traded entity constitutes an SFI
- Income from intellectual property rights owned by the employee

## Excluded Costs

- Salary, royalties, stock options, or other remunerations from ToxTrack

- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels, or derived from excluded sources including, and limited to, federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

#### Travel Costs

SFI disclosure includes travel that would appear to be related to the employee's ToxTrack responsibilities and was reimbursed or sponsored by an external non-ToxTrack entity. Such travel must be disclosed, no matter the amount, except when the expenses are covered by excluded sources including, and limited to, federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Aggregate – The threshold of \$5000 USD from any source is applied to the aggregation of Included Costs and Travel Costs

*Employee's ToxTrack Responsibilities* means conducting research, submitting patent applications, publication, technical committee membership, and teaching as an adjunct faculty at an Institute of Higher Education.

#### **Disclosure Procedure:**

Employees who are planning to or are participating in research activity that is either partially or wholly supported by PHS must disclose their SFI in a timely fashion, defined below, either to the Chief Executive Officer (CEO) or the designated ToxTrack FCOI official. The designated FCOI official will determine if the SFI constitutes and FCOI, based on guidance set by the ToxTrack CEO. If the SFI is determined to be an FCOI, the ToxTrack CEO will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation, and furthermore, to promptly notify the PHS funding component via a FCOI report.

As part of the FCOI management plan, the ToxTrack CEO will decide one or more actions depending on the situation, including requiring certain disclosures in public presentations, employee role reassignment, reduction or elimination of the SFI (e.g. sale of equity interest) or severance of relationships that create FCOI. Employees with an identified and confirmed FCOI must comply with the FCOI management plan.

#### **Administration**

The designated ToxTrack FCOI official is responsible for administration of this policy.

## **Protocol for Handling Financial Conflict of Interest**

This protocol, along with the Financial Conflict of Interest Policy & Procedure, constitute the ToxTrack FCOI policy. Capital terms in this protocol shall have the same meaning as set forth in the policy. The protocol outlines the procedure that will be followed as per regulation (Title 42 CFR 50.601-50.607)

This document specifies the FCOI protocol for PHS funded research, that is the step-by-step implementation of the ToxTrack FCOI policy.

### **Who is required to disclose financial interests**

Employees planning to or participating in research activity that is either partially or wholly supported by PHS funds are required to disclose financial interests (*“PHS-Funded Investigators”*)

### **SFI Disclosure**

PHS-Funded Investigators are required to disclose SFIs to either the ToxTrack CEO or the designated ToxTrack FCOI official, as follows:

- 1) Employees planning to participate in PHS-funded research are required to disclose all SFI’s prior to a submission of an application for PHS-funded research.
- 2) Once the research project has been funded, all PHS-Funded Investigators shall submit SFI disclosures within thirty (30) days of acquiring any new or increased SFI.
  - when a new investigator joins an ongoing PHS-funded project, the investigator shall submit SFI disclosures within thirty (30) days of joining the project
- 3) All PHS-Funded Investigators shall submit an updated SFI disclosure annually
- 4) SFI disclosures (except travel) must include the following information
  - Identify the sponsor/organizer; and
  - Nature of SFI (e.g., salary, license income, stock)
- 5) Externally funded travel also constitutes SFI, and therefore the disclosure requirements in this Section 2. That is, PHS-Funded Investigators shall submit SFI Disclosures for externally funded travel: prior to submission of an application for PHS funded research; and for PHS-funded projects within thirty (30) days of externally funded travel and in an annual update. The following travel related information must be disclosed:
  - Purpose,
  - Identity of the Sponsor/Organizer,
  - Destination, and
  - Duration

### **Reviews of Disclosure**

All SFI disclosures, including those submitted by a new investigator who joins an ongoing-PHS funded project, will be reviewed by the designated ToxTrack FCOI official. The review will determine whether an SFI is related to the PHS-funded research, and therefore an FCOI. The

designated ToxTrack FCOI official may involve the relevant investigator in the review, and request additional information from the investigator.

When an SFI that was not disclosed by a PHS-Funded Investigator in a timely manner is identified, the designated ToxTrack FCOI official will determine if FCOI exists, develop and implement a management plan within sixty (60) days after the identification of the SFI. In addition, the designated ToxTrack FCOI official will conduct a retrospective review of the SFIs for the PHS-Funded Investigator within one hundred twenty (120) days and document it.

### **Management of FCOI**

For each disclosure that leads to determination of FCOI, the ToxTrack CEO will discuss and approve the implementation of a management plan developed by the designated ToxTrack FCOI official. PHS-Funded Investigators with an identified FCOI must comply with the management plan will include the following elements at a minimum:

- 1) The role and principal duties of the conflicted PHS-Funded Investigator in the research project;
- 2) Conditions of the management plans
- 3) How the management plan is designed to safeguard objectivity in the research project
- 4) Confirmation of the PHS-Funded Investigator's agreement to the management plan; and
- 5) How the management plan will be monitored to ensure PHS-Funded Investigator compliance. Examples of conditions or restrictions that may be imposed to managed a PHS-Funded Investigator's FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g. when presenting or publishing PHS-funded research; to staff members involved with PHS-funded research, to Institutional Review Boards);
- For research projects involving human subjects research, disclosure of FCOI directly to patients;
- Appointment of an independent monitor capable of taking measures to protect the formulation, execution, and reporting of the research against bias resulting from FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g. sales of an equity interest); or
- Severance of relationships that create financial conflicts.

### **Reporting FCOI to PHS Awarding Component (e.g. the NIH)**

Based on the FCOI management plan, the designated ToxTrack FCOI official will submit an initial FCOI report to the PHS-funding component (e.g. the NIH). The report will be submitted, for example using the ERA Commons for NIH, and consist of all elements required by the

regulation.

The FCOI report will be submitted prior to the expenditure of funders under the Notice of Award. FCOIs identified during the period of award will be submitted to the NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

### **Training for FCOI**

PHS-Funded Investigators must undergo training with respect to this Policy, Protocol, and PHS FCOI rules and regulations as follows:

- 1) When a new employee joins ToxTrack;
- 2) Prior to participating in PHS-funded research, and at least once every four years;
- 3) When the ToxTrack FCOI policy changes in a manner that effects PHS-Funded Investigator disclosure or compliance requirements; and,
- 4) If ToxTrack CEO determines that PHS-Funded Investigator is not compliant with the FCOI Policy or an FCOI Management plan.

NIH web-based training ( <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> ) will be used. Employees must save and print the FCOI Certificate as proof of completion.

### **Sanctions for Violation of Policy**

Disclosure of SFI is essential for ToxTrack to implement its FCOI policy. If a PHS-Funded Investigator fails to comply with this policy (with regard for instance to the SFI disclosure requirement or implementation of the FCOI management plan), and appears to have biased the PHS-funded research, the ToxTrack CEO will implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the employee may be subject to employment discipline including, without limitation, suspension and termination of employment.

In any case, the PHS-funding agency will be promptly notified

### **Retention of Records**

Records of financial disclosures and any resulting action will be maintained for three (3) years from the date of submission of the final expenditures report.

### **Subrecipient Compliance**

When working with a subrecipient, a written agreement will be put in place to clarify: (a) which organization's (prime awardee or subrecipient) FCOI policy will be followed, and, (b) in either case, clarify the timeline for disclosure and reporting. Note that the prime awardee is responsible for monitoring the subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOI.

### **Public Accessibility**

As required by PHS regulation, the ToxTrack FCOI policy is being made accessible on the ToxTrack website.

if a PHS-funded Investigator holds financial interests that are determined to be FCOI, as required by PHS regulation, these will be posted on the website as follows

- 1) Include the minimum elements required by the regulation
- 2) update within sixty (60) days of a newly identified FCOI
- 3) Update annually; and
- 4) Remain available for three years.