

# Tonix Government Awards Financial Conflict of Interest Policy

Current as of April 17, 2023

**SCOPE:** Company Wide. The Government Awards Financial Conflict of Interest Policy covers Tonix projects conducted with government funds and is applicable to all employees, sub recipients, consultants, or any other covered organizations or persons involved in governmental awards.

**PURPOSE:** Under this policy, Tonix strives to ensure that all work performed under Government Awards meets legal requirements, and that real or perceived conflicts of interest that could harm patients, the reputation of Tonix, the government agency providing the funding, and/or external partners are minimized or disclosed. As Tonix must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Government Awards. It is intended to comply with the requirements of federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 C.F.R. Part 50 Subpart F (titled Promoting Objectivity in Research), the NIH Grants Policy Statement ([grants.nih.gov/grants/policy](https://grants.nih.gov/grants/policy)) and 45 CFR Part 94 (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation FAR 52.203-16 (collectively referred to as the “Financial Conflict of Interest Rules”).

## DEFINITIONS:

**Conflict Management Plan:** the document specifying the actions to be taken to manage a Financial Conflict of Interest.

**External Partner:** a consultant, subcontractor, or sub-recipient performing work under a Government Award who is not employed by Tonix

**Government Award:** government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that Tonix receives directly from government agencies or indirectly from pass through entities. Government Awards do not include procurement contracts, payments for health care services provided under government health care programs (e.g., Medicare, Medicaid) or Medical Education and Research Costs (MERC)).

**Financial Conflict of Interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project.

**Immediate Family Member:** a spouse, domestic partner, child or step-child, parent or step-parent, or sibling or step-sibling.

## Investigator:

(1) For PHS-funded research: 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.

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

***Institutional Responsibilities:*** An Investigator's professional responsibilities on behalf of Tonix, which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

***Public Health Service (PHS):*** a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

***Research:*** 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.

***Remuneration:*** salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

***Significant Financial Interest:***

(1) A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(i) the value of any remuneration received from a public entity, (for example, Tonix) in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, which, when aggregated, exceeds \$5,000; or

(ii) the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, which, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., royalties and payments related to patents, copyrights and trademarks), upon receipt of income greater than \$5000 related to such rights and interests.

(2) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities if the cost or value received from a single entity exceeds \$5,000 for the preceding twelve (12) months. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located within the United States, a United States institution of higher education (as defined in 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.)

(3) A Significant Financial Interest does not include the following:

- Salary, royalties, or other remuneration paid by Tonix to the Investigator if the Investigator is currently employed or otherwise appointed by Tonix;
- Intellectual property rights assigned to Tonix and agreements to share in royalties related to such rights;
- 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 the authorship of academic or scholarly works
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located within the United States, a United States institution of higher education (as defined in 20 U.S.C. 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education; and
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

**POLICY:**

It is the policy of Tonix to comply with the Financial Conflict of Interest Rules. All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to Tonix by completing or updating a Significant Financial Interest (SFI) Disclosure Form. Investigators must complete or update this form before an application for a Government Award is submitted. Investigators also must update the form annually during the period of the award and use it to disclose to Tonix any new SFIs within thirty days of discovering or acquiring the SFI. If Tonix determines that an SFI constitutes a Financial Conflict of Interest ("FCOI"), Tonix will establish and monitor a Conflict Management Plan ("CMP") to manage or eliminate the conflict of interest. Tonix's Chief Financial Officer will be the conflict of interest official ("COIO") responsible for managing the conflict of interest process for Government Awards. No Government Award funds may be expended unless the COIO has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

***Duty to Cooperate***

If the COIO official requests additional information from an Investigator to assess whether a SFI constitutes an FCOI, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a CMP is implemented in connection with a SFI, the Investigator must comply with the CMP. Compliance with the requirements of this policy is a condition of employment with Tonix for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

***Education***

Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for Tonix; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator; (iv) and at least every four years.

### ***Public Posting of Policy***

Prior to the expenditure of any funds under a PHS-funded research project, Tonix will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria: (i) The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the Investigator and any other person identified as senior key personnel by Tonix in the grant application, progress report or any other report submitted to the PHS by Tonix; (ii) Tonix has determined that the SFI is related to the PHS-funded research; and (iii) Tonix has determined that the SFI is a Financial Conflict of Interest. The information that Tonix will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following: (i) the Investigator's name; (ii) the Investigator's title and role with respect to the research project; (iii) the name of the entity in which the SFI is held; (iv) The nature of the SFI; and (v) the approximate dollar value of the SFI in the following ranges: \$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. If Tonix uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if it is determined by the COIO that the SFI is related to the PHS-funded research and is a Financial Conflict of Interest.

### ***Reporting of Financial Conflicts of Interest for PHS-Funded Projects***

Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the COIO will report all Financial Conflicts of Interest that have not been eliminated to the relevant agency and will ensure that an appropriate CMP has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the COIO will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The COIO also will provide an annual FCOI report that addresses the status of any previously reported FCOI's and CMP's related to an ongoing PHS-funded project.

### **Procedure for Tonix employees and by External Partners that do not have their own FCOI policy.**

1. Before the expenditure of funds under a Government Award, Investigators must read this policy and complete training on Tonix's Government Awards FCOI Policy. Training can be completed using the NIH FCOI tutorial found at <https://youtu.be/moaXNaZdvrw> or CITI COI training found at: <https://about.citiprogram.org/en/homepage/> (subscription required).

2. Training must be documented by submitting the Tonix Government Award FCOI Training Certification Form to the COIO. The required training is valid for four years.
3. Before an application for a Government Award is submitted by Tonix and before any funds are expended, each Investigator must complete and return to the COIO the Tonix Significant Financial Interest (SFI) Disclosure Form.
4. Investigators must update the SFI Disclosure Form annually and within 30 days of the Investigator or an Immediate Family Member of an Investigator acquiring SFI, for example, Tonix stock or stock options.
5. Each Investigator must update their SFI Disclosure Form when he/she is a recipient of Tonix sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.
6. If the COIO determines a FCOI exists, he/she will create a CMP.
7. The COIO will ensure that CMPs are properly implemented and will monitor compliance with CMPs. The COIO will review the status of established CMPs at intervals determined by and indicated in the CMP, and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.
8. Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.
9. For PHS-funded projects, the COIO will disclose the FCOI and CMP to the PHS awarding agency before the expenditure of any federal funds.
10. For PHS-funded projects, Tonix will make FCOI information available to those who submit a request by sending an email to [COIO@tonixpharma.com](mailto:COIO@tonixpharma.com). Responses will be sent by the COIO within ten business days.
11. Tonix will keep records related to FCOI and the related CMP for the longer of at least three years after:
  - a. the date of creation;
  - b. the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
  - c. the date of final resolution of any investigation, audit, or similar action involving the records; or
  - d. the date required to be in compliance with Tonix's Record Retention policies.
12. The COIO will ensure that the contract between the External Partner and Tonix contains language requiring compliance with this policy.

### **Procedure for External Partners with their own PHS Rule policy**

1. Prior to any application submitted by Tonix for a Government Award, the COIO must receive confirmation the External Partner has an FCOI policy that meets the PHS FCOI Rules.
2. The External Partner will have two options to verify they have a FCOI:
  1. Register with the FDP Clearinghouse, <https://fdpclearinghouse.org/>. The COIO will verify registration with the FDP Clearinghouse before submission.
  2. Certify to the COIO that their policy meets the requirements of the PHS FCOI.
3. The contract between the External Partner and Tonix will contain language requiring compliance with the organization's FCOI Policy.

### **Failure to Comply with Tonix's Government Awards Financial Conflict of Interest Policy**

Whenever an FCOI is not identified or managed in a timely manner, including, for example, because the underlying SFI is not disclosed timely by an Investigator or, because an FCOI was not timely reviewed or reported by a sub-recipient or by Tonix); or because an Investigator failed to comply with a management plan, then Tonix will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

Tonix shall document the retrospective review and its review shall include the following key elements:

- A. Project number;
- B. Project title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has an FCOI
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- H. Findings of the review; and
- I. Conclusions of the review.

The COIO will determine if the research was biased.

If bias is found, Tonix will develop and implement a plan to mitigate the bias. Tonix will notify PHS promptly and will submit a mitigation report to PHS within 120 days of the determination of noncompliance. No expenditures of funds on PHS awards will be permitted unless the Investigator has complied with the requirements of this Appendix and has agreed, in writing, to comply with any Tonix FCOI management plan. In any case in which the Department of Health and Human Services determines that a PHS-funded 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 the PHS regulations, Tonix will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the research and to request an addendum to previously published presentations. Any failure by an individual to adhere to this policy may be cause for disciplinary action, including, in severe cases, termination.

COIO Contact information: [COIO@tonixpharma.com](mailto:COIO@tonixpharma.com)