

TDA Research, Inc.

FINANCIAL CONFLICT OF INTEREST POLICY

Purpose:

The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought at <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#subpart-F>.

Scope:

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research funded by Public Health Service (PHS) or National Institute of Health (NIH).

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in written research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) or National Institute of Health (NIH) funds be subcontracted by TDA to a subrecipient institution without a conflict of interest in research policy, a agreement must state that this policy shall apply to the subrecipient.

Definitions:

Investigator The PI and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

Conflict of Interest Committee (COIC) management employees of TDA who will review all reported and perceived financial of interest requests and all Role and Responsibility Surveys completed as necessary.

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Financial Conflict of Interest A financial conflict of interest exists when the institution's designated official(s) reasonably determines that an [investigator's significant financial interest \(SFI\)](#) could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The institution is required to review each Investigator SFI disclosure to determine if a SFI:

1. is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research)

and

2. could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Significant Financial Interest (SFI) 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 located in the United States, 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 must specify the details of this reimbursed travel, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Reporting of reimbursed travel is only required when the total of the reimbursed travel, aggregated to include the Investigator, investigator's spouse and dependent children, exceeds \$5000 over the previous 12 month period.
3. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000)

The term *significant financial interest* does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by TDA to the Investigator if the Investigator is currently employed or otherwise appointed by TDA, including intellectual property rights assigned to the TDA and agreements to share in royalties related to such rights
- Any ownership interest in TDA 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 located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), a United States academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education located in the United States;
- income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education as defined at 20 U.S.C. 1001(a), a United States academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education

Policy

Each year any investigator who conducts research on any TDA project must disclose all significant financial interests (SFIs) or within 30 days after he/she becomes aware of new SFI or after a financial conflict of interest has been eliminated.

Investigators are required to complete the annual Role and Responsibility Survey form even if they have no financial interest to report. If not already on file, the Role and Responsibility Survey by the Investigator is also required at the time a research proposal is submitted to TDA's Chief Technology Officer in order to ensure compliance with Federal disclosure and management requirements.

Procedure

Investigator Responsibilities

Investigators are responsible for:

- Disclosing all significant financial interests
- Providing updates to disclosed information as needed
- Completing all required training and education

- Completing the annual disclosure form even if they have no financial interests to report.

Financial Conflicts of Interest (FCOI)

A financial conflict of interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct or reporting of PHS funded research at TDA.

This policy addresses individual financial conflicts of interest; however, TDA may also have conflicts of interest in research whenever the financial interests of TDA, or of an TDA official acting within his or her authority on behalf of TDA, might affect—or reasonably appear to affect—TDA processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

Review of FCOIs

TDA's COIC review committee conducts an initial review of all disclosures. If necessary, the FCOI review committee obtains additional information from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The committee then formally identifies cases that require further review by management.

The Committee will review each Research Role and Responsibility Survey for disclosure to determine if a SFI is:

- related to the Investigator's NIH-funded research. An SFI is related to NIH-funded research when the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research, and
- a FCOI. An SFI is considered a FCOI when the SFI could directly and significantly (i.e., have a material effect) affect the design, conduct, or reporting of the NIH-funded research.

Management and Reporting of FCOIs

When the COIC determines that an FCOI exists, TDA will report to the NIH awarding Institute or Center through the submission of an initial (Original) and annual FCOI report using the [eRA Commons FCOI Module](#).

For cases that require action, a plan of action will be developed by members of TDA's COIC on a case by case basis. Such a plan will include some or all of the following as deemed appropriate:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research to research personnel working on the study, to the Institution Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.), if appropriate;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create the actual or potential conflict of interest;
- If it proves impossible to reach an acceptable plan of action, funds will be returned to the sponsor.

A draft of the plan of action will be provided to the Investigator for review and comment before it is finalized. The Investigator and their immediate supervisor must sign the approved plan to acknowledge their agreement to comply.

If the TDA COIC identifies an SFI that was not disclosed or reviewed in a timely manner, it will initiate the review process and an interim plan of action will be implemented when necessary.

- TDA will maintain records of and, when requested, will promptly make information available to the NIH relating to any Investigator disclosure of financial interests 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.

- TDA will maintain records of financial disclosures and any resulting action must be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

Appeals

Investigators may appeal TDA'S COIC decisions in writing within 15 days of receipt of the finalized action plan or other decision of the committee. The written appeal should include details regarding circumstances which support the request for a proposed revision to a TDA'S decision. An Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management and Monitoring Plan, and previous meeting minutes, to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Appeals Committee is final and binding.

Confidentiality

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel.

Reporting

Elements of an FCOI Report

The FCOI regulation requires institutions to submit the following information when reporting an FCOI:

- The name of the investigator with the FCOI
- The name of the entity with which the investigator has an FCOI
- The nature of the Significant Financial Interest (SFI)
- The value of the financial interest
- Description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research
- Description of the key elements of the institution's management plan, including other required information

Submitting an FCOI Report

Report FCOIs for grants and cooperative agreements through the eRA Commons FCOI Module. For contracts, contact the NIH Contracting Officer identified on the contract.

Reporting

As required, TDA will provide to the NIH a FCOI report via the eRA Commons FCOI Module as outlined in the regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, TDA COIC will provide a FCOI report regarding any SFI found to be a FCOI. TDA will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research

- Key elements of the FCOI action plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the action plan
- Justification that an FCOI no longer exists

Subrecipients

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, TDA requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the TDA in sufficient time to allow the TDA to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the TDA FCOI in Research policy. A subrecipient's failure to promptly comply with the TDA policy will be considered grounds for immediate termination by TDA of any applicable subcontract or subaward. The written agreement terms required by TDA will contain a provision that subrecipients will report to TDA as the pass-through entity, any identified FCOI in sufficient time to allow TDA to report and manage the FCOI and meet the reporting obligations described above.

Enforcement

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or TDA.

Policy Revision

TDA may modify this policy to conform to organizational changes and circumstances including revisions to federal or state law or regulations. The TDA'S will have 30 business days to review and comment on any proposed revisions. TDA's Board of Directors is responsible for granting final approval for these policy revisions. It will review all proposed revisions, in collaboration with management, and will consider the committee's feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.

Additional Requirements

The following **additional** requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

Public Accessibility

This policy will be posted, on TDA's public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via **an email** response within five business days from when the Research Official receives the request. This information may be requested by **emailing krhodus@TDA.com**

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the Significant Financial Interest (salary, royalty, reimbursed or sponsored travel, etc.)
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will remain available for three years from the date the information was most recently updated.

Training Requirements

PHS-funded Investigators must complete FCOI training of the institution's policy, the regulation, and of the Investigator's responsibility to disclose SFIs prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to a subrecipient and will be working on PHS- funded research
- An Investigator is found to be noncompliant with this policy or their approved action plan

Complete the FCOI Training module located at <http://grants.nih.gov/grants/policy/coi/fcoi-training.htm> to fulfil the requirements to be trained on the FCOI regulation and provide a copy of the certificate of completion to krhodus@tda.com

Investigator/Institutional Non-Compliance

If an SFI is not disclosed or reviewed in a timely manner, TDA will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether an FCOI exists, and if so:

- Implement an action plan for ongoing research, at a minimum implement an interim action plan
- Complete a retrospective review of Investigator's activities and the PHS- funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research

Retrospective Review

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to timely disclose a SFI that is later determined by TDA to constitute a FCOI; failure by TDA to timely review or manage such an FCOI; or failure by the Investigator to comply with a FCOI management plan, TDA shall, within 120 days of TDA'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.

Under PHS policy, TDA 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.

Based on the results of the retrospective review, if appropriate, TDA shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, TDA 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 TDA'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, TDA will submit FCOI reports annually, as specified elsewhere in this policy.

If the retrospective review finds that the Investigator knew, or should have known about the FCOI related to his/her PHS funded research at TDA, but failed to disclose in compliance with this policy,. If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 a conflicting interest that was not managed or reported to TDA , the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

NIH Reporting Requirements

If TDA is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.

Responsibilities and Authorities:

Investigators participating in, or planning to participate in the design, conduct, or reporting of research including Public Health Service (PHS) or National Institute of Health (NIH) funded research at TDA have the authority and responsibility for the activities in this policy.