



POLICY AND PROCEDURES FOR THE DISCLOSURE AND REPORTING OF FINANCIAL CONFLICT OF INTEREST

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I. Overview

This Financial Conflict of Interest (FCOI) Policy is intended to protect the objectivity and integrity of the work of Fast-Track Drugs & Biologics, LLC (Fast-Track) and its individual staff members. The Policy is designed to ensure that staff members identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as Investigators, researchers or administrators. An effective conflict of interest policy helps both to safeguard the work and reputations of Fast-Track's staff members and to ensure Fast-Track's compliance with Federal and other regulatory requirements relating to conflicts of interest.

A Financial Conflict of Interest may result when an employee or consultant acquires a *Significant Financial Interest*¹ in an entity external to Fast-Track, and that entity is related to Research funded by a Public Health Service (PHS) with whom Fast-Track is contracted to perform work. To determine whether or not such a *Significant Financial Interest* has the potential to be a FCOI, it is necessary for Fast-Track employees and consultants to disclose all Financial Interests in such entities as they relate to their Fast-Track responsibilities, and for Fast-Track's Executive to review the disclosures. To that end, this FCOI Policy requires **ALL** investigators of sponsored Research to report Financial Interests related to their responsibilities **BEFORE** Fast-Track's filing of applications or proposals for funding.

The Policy requires all Investigators and most employees participating in a PHS-funded Research Project to file disclosure forms annually and to update their disclosures when circumstances change. In addition, all Investigators must update their forms within 30 days of discovering or acquiring a new *Significant Financial Interest* related to their responsibilities.

It is important to distinguish between **Financial Interests** and *Significant Financial Interest* as applied throughout this Policy. A Financial Interest may or may not be Significant, depending on whether or not it meets the criteria set forth in Section IV-11 herein. Regulations call for the disclosure, reporting and mitigation only of *Significant Financial Interests* that have the potential to affect the design, conduct or reporting (publication) of PHS-funded Research – i.e., to create a potential FCOI. Financial Interests that do not meet the criteria set forth in Section IV-11 herein are not considered FCOI potential.

¹ Throughout this Policy, the term "Significant Financial Interest" is italicized to better distinguish it from "Financial Interest."

II. Policy

Fast-Track takes seriously any actual or potential FCOI that could affect the integrity of any Research funded under a Public Health Service (“PHS”) contract. As a result, and in compliance with Federal laws and regulations, an Investigator conducting Research on behalf of Fast-Track shall not participate in any PHS-funded Research if he or she has a *Significant Financial Interest* (SFI) that could influence the design, conduct or reporting of such Research activity, and that cannot be effectively mitigated during the award’s performance period. Fast-Track will take immediate action under this Policy to manage, reduce or eliminate any such FCOI that is brought to its attention.

Fast-Track employees and scientists may collaborate with universities, research groups, private businesses, or government institutions to develop scientific and medical breakthroughs or to provide expertise. To assure professional and commercial integrity in such matters, Fast-Track reviews the financial aspects between its employees and consultants and these collaborations and, when appropriate, puts measures in place to eliminate, minimize, and manage any FCOI that may arise.

As set forth herein, all PHS-funded Research undertaken at Fast-Track shall be conducted in full compliance with this Policy and under all applicable Federal and State laws to promote transparency as to any FCOI in Research, including, without limitation, Title 45 CFR Part 94, pertaining to Research contracts (collectively, “FCOI Regulations”). Investigators failing to comply with these FCOI Regulations shall be subject to sanctions, up to and including termination of employment or removal from the Research project.

Fast-Track will comply with regulatory requirements relating to our institutional responsibilities, including certification of compliance, maintenance of records, responses to requests for information, and reporting requirements. Questions regarding this Policy and the Health and Human Services regulations should be directed to Mr. William Rickman, Chief Executive Officer. The requirements contained in this Policy are summarized in the [FAQs](#) at the end of this document.

III. Background

The United States Department of Health and Human Services (DHHS) has issued revised regulations pertaining to FCOI. The regulations require that all individuals who participate in the design, conduct, or reporting of Research funded by the PHS complete training on financial conflicts, and disclose personal Financial Interests that could give rise to an actual conflict of interest or the appearance of such a conflict. A copy of the full text of the regulations and the final rule implementing the regulations published in the Federal Register can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

All Fast-Track research professionals, including full- and part-time employees and consultants, will be required to complete [training](#) identified in this Policy, submit an electronic [Financial Conflict of Interest Disclosure Form](#), and disclose relevant Financial Interests *if they worked on a PHS-funded project in the preceding year, if they expect to work on a PHS-funded project in the upcoming year, or at any time they are named in a proposal for a PHS-funded project*. Key members of management and certain administrative and support department staff also will be required to complete the training and the screening/disclosure form, and provide relevant disclosures.

The PHS financial conflict of interest disclosure requirement is entirely consistent with Fast-Track's corporate values, including objectivity in our work and our commitment to avoid actual or apparent conflicts of interest. The requirements of this Policy should be read in conjunction with Fast-Track's Conflict of Interest Policy, which provides general instruction on preventing, recognizing, and mitigating conflicts of interest.

IV. Definitions

1. **Disclosure** means an Investigator's disclosure of *Significant Financial Interests* to Fast-Track.
2. **Financial Conflict of Interest (FCOI)** means a *Significant Financial Interest* that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
3. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.
4. **Healthcare-Related Entities** include any organization or entity (including both publicly traded and private companies) that provides healthcare-related products or services, including but not limited to:
 - Healthcare providers, including hospitals and clinics;
 - Healthcare insurance companies;
 - Healthcare research or service organizations;
 - Health information technology companies;
 - Medical device and equipment manufacturers and distributors;
 - Medical technology companies;
 - Pharmaceutical companies;
 - Other organizations that could be affected by healthcare-related research, including alcohol, tobacco, or food products companies;
 - Any other entity, publicly-traded or private, that could be materially affected by the conduct or results of PHS-funded research.

5. ***Institutional Responsibilities*** means an Investigator's professional responsibilities relating to seeking (by submission of proposals for the award of contracts or grants) or conducting PHS-funded research, including but not limited to: research; research consultation; teaching; professional practice; peer review; editing, publication, and dissemination of Research; service on panels such as Institutional Review Boards (IRBs), Data and Safety Monitoring Boards (DSMBs), or Human Subjects Protection Committees; and relevant work performed in administrative or support functions.
6. ***Investigator*** means 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. For purposes of this policy, this includes the following at Fast-Track:
- All research professionals (including all research titles);
 - Research Assistants;
 - Project Associates;
 - Survey Research Group;
 - Peer reviewers;
 - Medical Monitors;
 - Medical Writers;
 - Research Programmers;
 - Communications Analysts;
 - Human Subjects Protection Committee members; and
 - Key members of the administrative staff, including senior administrative staff; staff responsible for the editing, publication, or dissemination of Fast-Track research; and management and professional staff.
7. ***Key Personnel*** means the Project Director or Principal Investigator, and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242-70, and identified as key personnel in the proposal and contract.
8. ***Managing an FCOI*** means taking action to address an FCOI, which can include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. This action must be detailed in a [Management Plan](#).
9. ***PHS*** means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health. The PHS includes the agencies listed below:

- 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)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness & Response (ASPR)
- Office of Global Affairs (OGA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

In addition to the PHS agencies listed above, Fast-Track Investigators responsible for the design, conduct, or reporting of Research funded by the Centers for Medicare and Medicaid Services (CMS) also must comply with this policy.

10. Research means a systematic investigation, study, or experiment designed to develop or contribute to the generalizable knowledge relating broadly to public health, including behavioral and social-sciences Research. The term encompasses basic and applied Research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which Research funding is available from the PHS.

11. Significant Financial Interest (SFI) means:

- a. “Significant” means that the Financial Interest would have a material effect on the Research.
- b. A *Significant Financial Interest* means a Financial Interest in any Healthcare-Related Entity consisting of one or more of the following interests of the Investigator, and of the Investigator's spouse or domestic partner, dependent child, or other member of the Investigator's household, if: (i) the Financial Interest reasonably appears to be related to the Investigator's Institutional Responsibilities at Fast-Track, and (ii) the aggregate value of all interests held in a particular publicly-traded or non-publicly-traded Healthcare-Related Entity exceeds \$5,000:
 - 1) Remuneration (including consulting fees, honoraria, and any other fee for services);
 - 2) Defined benefit pension payments or other post-employment payments;
 - 3) Service in a management position such as a board member, director, officer, partner, or trustee of a Healthcare-Related Entity;
 - 4) Any fiduciary role for an entity;

- 5) Ownership of an equity interest (including stock, stock options, bonds, or any other ownership interest), as determined through reference to public prices or other reasonable measures of fair market value;
- 6) Holdings in a healthcare sector-oriented mutual fund;
- 7) Intellectual property rights (e.g., patents or copyrights) from which income is received, including from any clinical trial;
- 8) Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities:
 - i. Sponsored travel means travel expenses paid on behalf of an Investigator (or relevant family member) rather than paid by reimbursement;
 - ii. Travel reimbursed or sponsored by the following is excluded: federal, state, or local government agencies; institutions of higher education; academic teaching hospitals; medical centers; and research institutes affiliated with institutions of higher education;
 - iii. Investigators will be required to provide the following information with respect to any reimbursed or sponsored travel: name of entity that sponsored or reimbursed any expenses associated with the trip; purpose of the trip; destination; date and duration of the trip; and amount of reimbursement received.

c. SFIs do not include:

- 1) Salary, wages, and remuneration paid by Fast-Track;
- 2) Travel expenses paid or reimbursed by Fast-Track;
- 3) Income from mutual funds and retirement accounts (other than healthcare sector-oriented funds, see IV-11.b(6), above), as long as the Investigator does not directly control the investment decisions made by the funds;
- 4) Income from seminars, lectures, or teaching engagements sponsored by a 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;
- 5) Service on advisory committees or review panels for a 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.

12. Sponsored Program means a Research or other activity supported or paid for in whole or in part, directly or indirectly, from external sources. "Sponsored program support" means the funds or other things of value given to enable a sponsored program to be performed. An external source can include a government department or agency (foreign, Federal, State, or local); a not-for-profit foundation, corporation or organization; a for-profit corporation or business entity; and any natural person

who supports research or other activities through the donation or commitment of funds other than Fast-Track funds.

13. *Subrecipient* means an individual or entity receiving Federal funds that have come from or through Fast-Track to conduct a substantive portion of the PHS-funded Research, and is accountable to Fast-Track for programmatic outcomes and compliance matters. Subrecipients include subcontractors, vendors and consultants.

14. *Technology* means any instrument, machine, device, process, software, compound, drug, or diagnostic, medical or surgical procedure.

V. Financial Conflict of Interest Guidelines

Typically, a financial conflict of interest may arise when a person (or his or her family member) has the opportunity to influence Fast-Track business, administrative, or other decisions in ways that could lead to personal gain or advantage of any kind. A conflict of interest may also exist when a person (or his or her family member) has a *Significant Financial Interest* in a business from which he or she receives sponsored program support, or whose value may be affected by Research in which the person participates.

While it is difficult to specify precisely what constitutes an objectionable conflict in all situations, the guidelines set forth below establish general standards by which individuals must evaluate their behavior. The guidelines are divided into three categories: (1) conduct presumptively prohibited; (2) conduct permitted only after review and approval; and (3) conduct merely requiring disclosure. The guidelines are not exhaustive of all potential conflict of interest situations. Where facts known to a person reasonably suggest an actual or apparent conflict of interest, that person is required to disclose the circumstances and avoid the conflict of interest in good faith consistent with the spirit and objectives of this Policy.

A. Conduct Presumptively Prohibited

Presumptively prohibited conduct presents a prima facie conflict of interest and may not ordinarily be engaged in by any person covered under this Policy. The presumption may be rebutted and the conduct permitted if the person establishes by clear and persuasive evidence that such permission is justified by compelling circumstances. The following factors, among others, may be considered in evaluating whether the person has made a sufficient showing of compelling circumstances: the nature of the Research activities or the Fast-Track business involved; the magnitude of the interest and the degree to which it is related to the Research activities or the Fast-Track business involved; in clinical Research, the degree of risk to the human subjects involved that is inherent in the Research; and the extent to which the interest is amenable to effective oversight and management.

1. Significant Financial Interest in a Business

If a Fast-Track employee or a member of his or her family possesses a *Significant Financial Interest* (other than a consulting agreement) in a business, then that person may not receive sponsored program support from the business, or assign subordinate staff to projects supported wholly or partially by sponsored program funding from the business. In other words, Fast-Track employees cannot assign other employees to projects of interest to or supported by a business (through sponsored research or a contribution) in which they or an immediate family member has a financial or business interest (other than royalty income). In the same manner, Fast-Track employees cannot receive sponsored research support or contributions (in dollars or in kind) from a business in which they, an immediate family member, or an associated entity has a financial or business interest.

2. Participation in Fast-Track Decisions

A Fast-Track employee may not participate in any Fast-Track decision that relates to or has any effect on a business:

- In which the employee or a member of the employee's family has a *Significant Financial Interest* or;
- With which the employee or a member of the employee's family has or is negotiating to have any paid consulting or employment relationship.

Under such circumstances, a Fast-Track employee shall promptly and fully disclose the conflict and recuse himself or herself from any participation in such a decision.

3. Gratuities, Gifts and Favors

A Fast-Track employee may not solicit or accept gratuities, gifts, favors or anything of monetary value, in excess of \$100 per year per source, from an individual or a business that:

- Provides sponsored program support to that employee; or
- Has or seeks to have a business association with Fast-Track over which the employee has authority or influence.

Moreover, a Fast-Track employee participating in the selection, award or administration of agreements using Federal funds may not solicit or accept gratuities, gifts, favors or anything of monetary value from grantees/contractors or potential grantees/contractors, regardless of value.

B. Conduct Permitted Only After Review and Approval

This section of the guidelines describes conduct a Fast-Track employee may engage in only after review and approval in accordance with Section VII of this Policy. The factors specified in Section V.A above may also be considered in addressing requests under this section.

1. *Significant Financial Interest in a Business*

If a Fast-Track employee or a member of his or her family possesses a *Significant Financial Interest* (other than a consulting relationship) in a business, then unless he or she first discloses the *Significant Financial Interest* and receives approval in accordance with Section VII of this Policy, that person may not engage in Research on projects that, whether or not sponsored by the business, involve technology owned by or contractually obligated (for example, through a license) to the business.

2. *Consulting Relationships*

A Fast-Track employee may neither enter into nor continue a consulting relationship with a business from which he or she receives sponsored program support, or that has or seeks to have a business association with Fast-Track over which the employee has authority or influence, unless the employee first discloses the facts and receives approval in accordance with Section VII of this Policy.

3. *Use of the Fast-Track Name*

A Fast-Track employee who has a *Significant Financial Interest* in a business, or is affiliated with or performs services for a business, may not authorize that business to use Fast-Track's name, symbols, or logo to imply endorsement of the business by Fast-Track, or to give undue prominence to the fact that the employee is associated with Fast-Track, unless the employee first discloses the facts and receives approval in accordance with Section VII of this Policy.

4. *Government-Funded Activities*

If a Fast-Track employee or a member of his or her family has a *Significant Financial Interest* in a business, that person may not, without prior disclosure and approval in accordance with Section VII of this Policy, be responsible for the design, conduct or reporting of or otherwise participate in government-funded research or clinical care activities that could directly and significantly be affected by such business interest.

C. Conduct Requiring Disclosure

This section of the guidelines describes conduct which, while not presumptively prohibited or subject to prior approval of an institutional official, must be disclosed in accordance with Section VI of this Policy. Conduct requiring disclosure is subject to review in accordance with Section VII of this policy and, depending on the circumstances, may be conditioned or prohibited. Such conduct may also be subject to other Fast-Track policies. The factors specified in Section V-A above may also be considered in addressing matters disclosed under this section.

1. Service in an Executive Position with a Non-Fast-Track Entity

If a Fast-Track employee assumes or holds a compensated or uncompensated executive position in, or serves with or without compensation on any advisory board of a business (not including a government agency, nonprofit organization, or an accredited educational institution) with which Fast-Track has a substantial business relationship known to the employee, the employee must promptly and fully disclose the facts in accordance with Section VI of this Policy, and recuse himself or herself from participation in any Fast-Track decision that relates to or has an effect on the subject business.

2. Publications or Presentations

If a Fast-Track employee or a member of his or her family possesses a *Significant Financial Interest* in a business, that person may not publish or give a public oral presentation on the results of Research sponsored by such a business, or of Research on technology owned by or contractually obligated to such a business, without first disclaiming in the publication or presentation any endorsement by Fast-Track. The person must also disclose the *Significant Financial Interest* to the potential publisher or sponsor of the public presentation, regardless of whether the publisher requires such a disclosure.

3. Consulting Relationships

If a Fast-Track employee enters into a consulting relationship with a business, and the consulting agreement is in the field of the employee's professional responsibility at Fast-Track, he or she must fully and promptly disclose the facts in accordance with Section VI of the Policy, regardless of whether or not the employee receives sponsored program support from the business, or has any other *Significant Financial Interest* in the business, and must recuse himself or herself from participation in any Fast-Track decision that relates to or has an effect on the subject business.

VI. Financial Reporting Requirements

Financial reporting is a two-part process that is shared between Fast-Track employees and consultants, and Fast-Track's executive. It consists of 1) disclosure of Financial Interests and *Significant Financial Interests* by all Fast-Track employees and consultants, and 2) reporting in a FCOI Report any *Significant Financial Interests* to the PHS-awarding component by Fast-Track's executive.

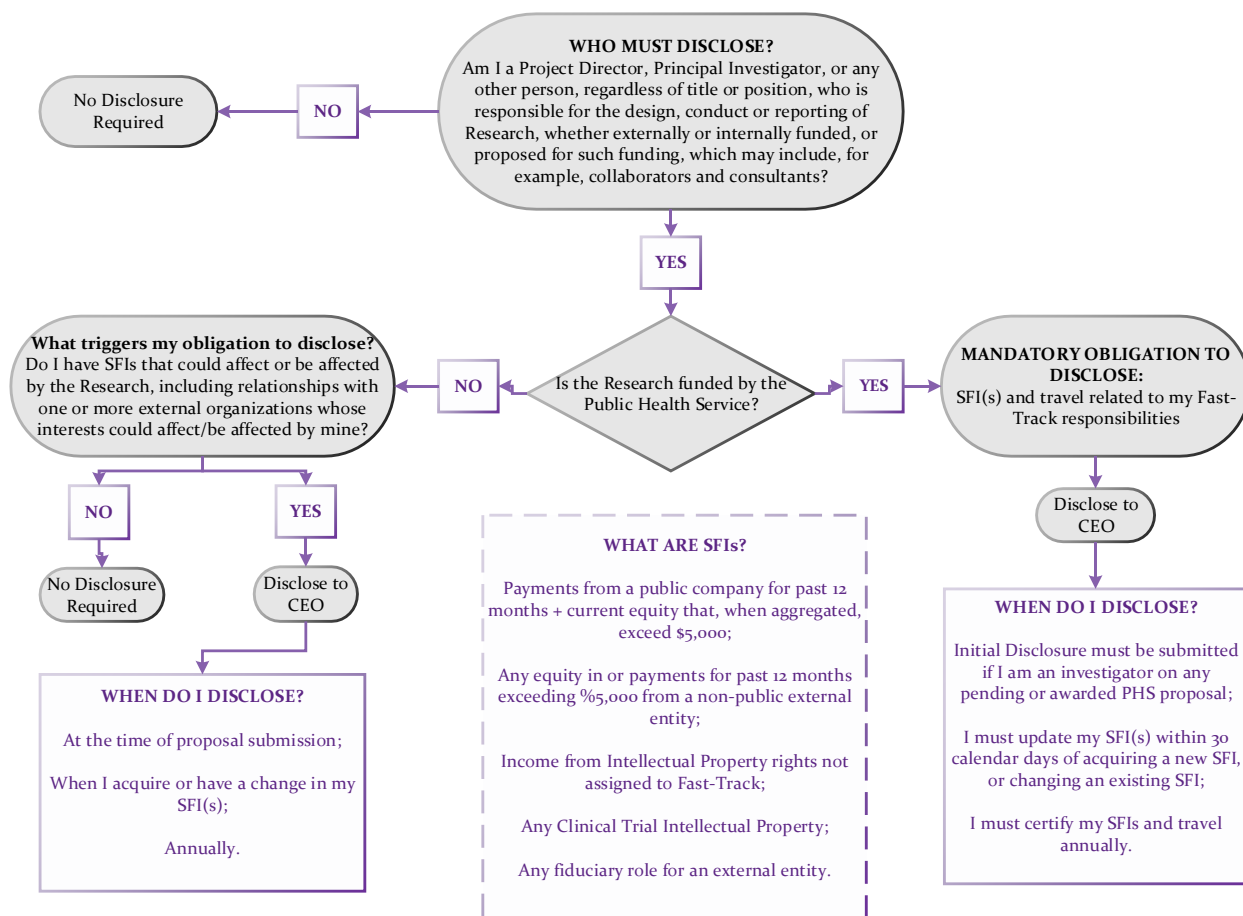
All full- and part-time Fast-Track Investigators (employees) as defined in Section IV-6 herein, and all consultants proposed for or working under a PHS-funded Research award must complete a screening form (the Fast-Track FCOI Disclosure Form) disclosing all Financial Interests (Significant or otherwise) relating to Research funded by a PHS, and must also complete the related training described in this Policy. All Investigators must fully and accurately complete the form within the time allotted depending on the circumstances giving rise to the need for disclosure. A flowchart illustrating disclosure requirements is provided at the end of this Policy.

The disclosure is forwarded to the Chief Executive Officer for review and subsequent action if needed. It is only *Significant Financial Interests* that give rise to a potential FCOI.

Failure to accurately and timely complete the training and the form, and to provide updates as required by this Policy could result in disciplinary action, up to and including termination.

A. Mandatory Financial Disclosures

As previously stated in this Policy, financial disclosures are intended to identify both Financial Interests and *Significant Financial Interests* in conjunction with an Investigator's responsibilities under a PHS-funded award. Financial disclosures are required of any Investigator or Key Personnel proposed for performance of a PHS-funded award, or for any Investigator or Key Personnel participating on the PHS-funded project any time during its period of performance. Such disclosures are required initially and annually thereafter, as described below.



1. Initial Financial Disclosures

Under this Policy, all Fast-Track employees and consultants proposed for PHS-funded work, or assigned to work on a PHS-funded award during its performance (whether or not proposed) shall complete Fast-Track's [FCOI Disclosure Form](#), regardless of whether their Financial Interest is Significant or not. The disclosure will be reviewed by Fast-Track's Chief Executive Officer to determine if a potential exists for a Financial Conflict of Interest relative to the Investigator's responsibilities on the proposed or ongoing Research project.

2. Annual Financial Disclosures

All employees are expected to recognize their continuing obligation to timely disclose relevant Financial Interests to ensure Fast-Track's compliance with the reporting and certification requirements of the PHS regulations. All Investigators participating in PHS-funded Research must update their disclosure form at least annually *and within 30 days of receiving, acquiring, or discovering² either a new Financial Interest or additional*

² i.e., through purchase, marriage or inheritance.

interests from an entity previously disclosed by the Investigator throughout the award's period of performance.

Annual disclosures shall include submission of any new *Significant Financial Interests*. Such disclosure shall include any information that was not disclosed initially to Fast-Track, or in a subsequent disclosure of *Significant Financial Interests* (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously-disclosed *Significant Financial Interest* (e.g., the updated value of a previously-disclosed equity interest). These updated disclosures shall be submitted to Fast-Track's Chief Executive Officer via email as instructed on the form.

If there are no updates to report on the previously-filed disclosure form, Fast-Track employees and consultant are required to re-certify their original Financial Interest disclosures and submit them to the Chief Executive Officer.

3. Disclosing Investigator's Significant Financial Interests

It is each Investigator's responsibility to disclose all of his or her (including immediate family and dependents) *Significant Financial Interests* as defined in Section IV-11 herein. All such *Significant Financial Interests* shall be submitted on Fast-Track's [FCOI Disclosure Form](#). Investigators named in a proposal for a PHS-funded project must complete the training, and the screening and disclosure form ***before the proposal is submitted***. Investigators who participate in the design, conduct, or reporting of PHS-funded work awarded also must complete the training and the screening/disclosure form ***before beginning any work on the project***, whether or not they were named in the proposal. Investigators are required to disclose their *Significant Financial Interests* (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities:

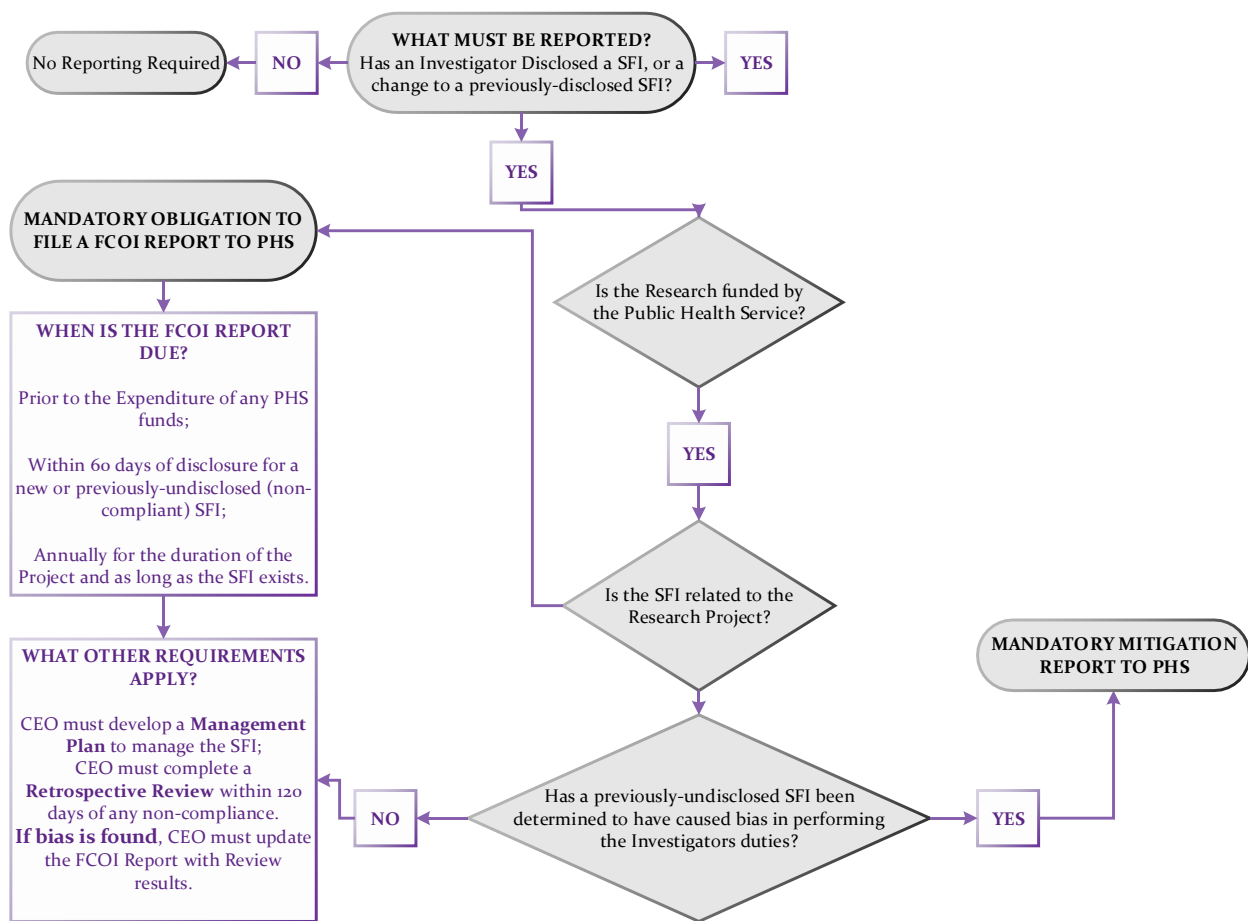
- 1) No later than at the time of application for NIH-funded research;
- 2) Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new *Significant Financial Interest* (see Section VI-A.4 below); and
- 3) At least annually, in accordance with the specific time period prescribed by this Policy (See Section VI-B.3 below), during the period of award.

4. Disclosing an After-Acquired Financial Interest

All persons identified in Section IV-6 of this Policy are required to submit revised Financial Disclosure Forms at any point at which their most recent disclosure becomes incomplete or inaccurate (e.g., if a *Significant Financial Interest* arises or changes, a

research activity commences, a funding application is submitted, or the person's Fast-Track authority or influence changes). Such after-acquired Financial Interest(s) shall be reported to Fast-Track's Chief Executive Officer within 30 days of discovering or acquiring the interest. Fast-Track's Chief Executive Officer shall review the disclosure, determine if it is pertinent to the Research project, and if so, implement a [Management Plan](#) specifying how the interest will be managed, and submit an FCOI Report to the PHS-awarding component identifying any new or increased *Significant Financial Interest* and its management within sixty (60) days of acquiring the information.

B. FCOI Reporting



1. Initial Reporting: Prior to Expenditure of Funds

Prior to its expenditure of any funds under a PHS-funded research project, Fast-Track is required to provide to the PHS an FCOI Report regarding any Investigator *Significant Financial Interest* determined to be a Financial Conflict of Interest. Fast-Track must also provide an FCOI Report whenever an Investigator does not timely disclose a *Significant*

Financial Interest or whenever Fast-Track, for whatever reason, does not review a disclosed *Significant Financial Interest* but subsequently determines that a Financial Conflict of Interest exists. Fast-Track will not expend any funds under a PHS-funded Research project in the event an Investigator reports a *Significant Financial Interest*, without first providing a FCOI Report to the PHS Awarding Component outlining Fast-Track's implementation of a [Management Plan](#) for an Investigator with a *Significant Financial Interest*. However, if Fast-Track eliminates the conflict of interest prior to the expenditure of PHS-awarded funds, a FCOI Report will not need to be submitted to the PHS.

2. Initial Reporting: During an Ongoing PHS Research Project

Fast-Track is required to submit an FCOI Report within sixty (60) days after its determination that a FCOI exists for an Investigator who is newly participating in the Research project, or for an Investigator working on the project who discloses a new *Significant Financial Interest* to Fast-Track during the period of performance.

Whenever an Investigator does not disclose timely a previously-existing *Significant Financial Interest*, or Fast-Track fails to review a previously-existing *Significant Financial Interest* during an ongoing PHS-funded project, Fast-Track's Chief Executive Officer shall, within sixty (60) days:

- 1) Review the *Significant Financial Interest*;
- 2) Determine whether it is related to the PHS-funded research;
- 3) Determine whether a Financial Conflict of Interest exists. If so, Fast-Track will implement, on at least an interim basis, a [Management Plan](#) that shall specify the actions that have been, or will be, taken to manage such Financial Conflict of Interest going forward, and submit an FCOI Report to the PHS-awarding component.

In addition to the FCOI Report, Fast-Track must, within 120 days of its determination of noncompliance, complete a [Retrospective Review](#) of the Investigator's Research 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.

Based on the results of the Retrospective Review, if appropriate, Fast-Track will update the previously-submitted FCOI Report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If bias is found, Fast-Track shall notify the PHS and submit a [Mitigation Report](#) that includes the key elements documented in the Retrospective Review, a description of the impact of the bias on the Research project, and Fast-Track's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter Fast-Track will submit FCOI Reports annually for the Investigator involved.

3. Annual Reporting

Fast-Track is required to submit to the PHS an annual FCOI Report that addresses the status of the Financial Conflict of Interest and any changes to the [Management Plan](#) for the duration of the PHS-funded Research project. Annual FCOI Reports are required to be submitted for the duration of the project period (including extensions with or without funds). The annual FCOI Report is due at the same time as when Fast-Track is required to submit the Annual Progress Report.

For any previously-reported Financial Conflict of Interest, Fast-Track shall provide an annual FCOI Report that addresses the status of the *Significant Financial Interest* and any changes to the [Management Plan](#). Annual FCOI Reports shall specify whether the Financial Conflict of Interest is still being managed, or explain why the Financial Conflict of Interest no longer exists.

VII. Review and Evaluation of Financial Interests Disclosed by Investigators

A disclosure of a Financial Interest does not, by itself, create an impermissible conflict of interest. Each Financial Interest disclosure will be reviewed by the Chief Executive Officer and President of Fast-Track. A financial conflict of interest exists when it can reasonably be determined that such an interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research. Fast-Track will take appropriate steps to Manage FCOIs to ensure that Fast-Track's Research is free of bias, or of the appearance of bias. As described in the PHS regulations, some examples of how financial conflicts of interest may be addressed and managed include:

- Public disclosure of an Investigator's *Significant Financial Interests*; disclosures will only occur after notice to and consultation with the Investigator;
- Disclosure of FCOI directly to participants in Research projects involving human subjects;
- Monitoring of Research projects by reviewers who do not have FCOI and who are capable of implementing measures to protect the design, conduct, or reporting of the Research against bias arising from identified FCOI;
- Modification of the research plan, including, for example, change of personnel or personnel responsibilities with respect to particular tasks;
- Disqualification of personnel from participation in all or a portion of a Research project funded by PHS;
- Reduction or elimination of a *Significant Financial Interest* (e.g., sale of stock);
- Severance of relationships (e.g., consulting activities) that create actual or potential conflicts.

A. Designated Official's Review of Disclosure Forms

The Chief Executive Officer is responsible for determining when an actual or potential conflict of interest exists in a given situation — that is, when a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of PHS-funded research — and for taking action as necessary to manage such conflicts of interest, including development and implementation of a [Management Plan](#). This responsibility will be exercised in cooperation with the relevant corporate manager and with full participation by the employee or consultant. Several criteria may be considered in determining whether a particular Financial Interest creates a conflict of interest with respect to a particular PHS-funded project.

If any *Significant Financial Interest* is disclosed on the [Fast-Track FCOI Disclosure Form](#), Fast-Track's Chief Executive Officer will contact the Investigator for any additional information and documentation necessary to complete the review. Reviews will be completed by the Chief Executive Officer within forty-five (45) days of receipt of the Investigator's disclosure form and any necessary supporting documentation. The review must be completed before any expenses are incurred under a PHS-funded award and before any Research can begin. An Investigator shall not conduct Research for any PHS-funded project if he or she receives notification from Fast-Track's Chief Executive Officer that such participation has not been approved.

An Investigator's *Significant Financial Interest* is related to PHS-funded Research when Fast-Track's Chief Executive Officer reasonably determines that it could be affected by the PHS-funded Research, or is an entity whose Financial Interest could be affected by the Research.

B. Standards for Approval for Financial Disclosures

Any Investigator or Key Personnel with a *Significant Financial Interest* on proposed or awarded PHS-funded Research will only be approved for performance on such Research if the Chief Executive Officer determines that no FCOI exists, or that an adequate [Management Plan](#) can be implemented to manage or eliminate a Financial Conflict of Interest.

C. Retrospective Review

When Fast-Track identifies a *Significant Financial Interest* that was not timely disclosed by an Investigator, or otherwise was not previously reviewed during a PHS-funded Research project, the Chief Executive Officer will review the Financial Interest and determine whether it is related to the PHS-funded Research, and whether it is a *Significant Financial Interest* within sixty (60) days. In addition, the Chief Executive Officer will

conduct and document a Retrospective Review in the case of non-compliance with this policy. This review will be conducted within one hundred and twenty (120) days of the Chief Executive Officer's determination of such non-compliance.

Fast-Track's documentation of a Retrospective Review shall include, but not be limited to the following key elements:

- Project Number;
- Project Title;
- Project Director or Investigator name and contact information;
- Name of the entity with which the Project Director or Investigator has the FCOI;
- Reason(s) for the Retrospective Review;
- Detailed methodology used for the Retrospective Review (e.g., process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the Retrospective Review, if appropriate, Fast-Track shall update the previously-submitted FCOI Report, specifying the actions that will be taken to manage the financial conflict of interest going forward. However, if no bias is found following completion of the Retrospective Review, Fast-Track will not be required to submit a revised FCOI Report to notify the PHS either that the review was completed or that bias was not found.

1. Management Plan

The Chief Executive Officer will implement a [Management Plan](#) (see Section VIII-A below) specifying actions that have been or will be taken to manage the *Significant Financial Interest*.

2. Mitigation Report

If bias is identified as a result of the Retrospective Review, Fast-Track will promptly notify the PHS-Awarding Component and submit a [Mitigation Report](#) (See Section VIII-B below).

VIII. Remedies

A. Management Plan

The Chief Executive Officer shall determine the terms, conditions and restrictions, if any, that are required as part of a Management Plan to address a FCOI. The Chief Executive Officer will convey the Management Plan in writing to the person(s) deemed appropriate. The Management Plan will address, at a minimum:

- The role and principal duties of the conflicted Investigator in the Research project;
- Conditions of the Management Plan;
- How the Management Plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the Management Plan;
- Implementing and monitoring compliance with the Management Plan.

The Management Plan may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential FCOI that was not managed or prior disclosed by Fast-Track:

- Disclosure of the Financial Conflict of Interest, in each public presentation of the results of the Research and to request an addendum to previously published presentations;
- Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
- Disqualification from participation in all or a portion of the PHS-funded Research;
- Requiring that *Significant Financial Interest(s)* be divested, restructured, or placed in blind trust;
- Modification or severance of relationships that create a potential FCOI;
- Changing terms of agreement relating to the PHS-funded Research;
- Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
- Requiring additional disclosures or actions; or
- Requiring non-participation in any business transactions between Fast-Track and parties to agreements involving sponsored PHS-funded Research.

B. Mitigation Report

The Mitigation Report must include, at a minimum, the key elements documented in the Retrospective Review above, a description of the impact of the bias on the Research project, and Fast-Track'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, Fast-Track will submit FCOI Reports annually, as specified elsewhere in this Policy. Depending on the nature of the financial conflict of interest, Fast-Track may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined, and the completion of Fast-Track's Retrospective Review.

IX. Sanctions and Remedies for Violation of Fast-Track's FCOI Policy

Whenever an Investigator has violated this policy, including failure to make a required disclosure of *Significant Financial Interests* or failure to comply with the requirements of any Management Plan, the Chief Executive Officer shall be responsible for enforcing this Policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to: 1) suspending expenditures on the applicable Research account; 2) suspending performance by the conflicted Investigator; and 3) instituting disciplinary measures to include suspension or termination of such Investigator.

X. Subrecipient Requirements

Each Subrecipient (generally, this is a Subcontractor) Investigator is subject to financial conflict of interest rules, and must provide assurances to Fast-Track that Subrecipient has policies and procedures no less stringent than this FCOI Policy. Fast-Track takes reasonable steps to confirm that all Investigators who are Sub-awardees participating in PHS-funded Research are in compliance with the FCOI regulations. Such reasonable steps include:

- Incorporating into a written agreement that dictates that Subrecipient will adhere to Fast-Track's FCOI Policy if it is determined that the FCOI Policy applies to Subrecipient's Investigators;
- If the Subrecipient Investigator is to comply with Subrecipient's own FCOI Policy, the Subrecipient shall certify that such policy complies with Fast-Track's FCOI Policy, or if certification cannot be obtained, the written agreement must state the subrecipient Investigators are subject to disclosing to Fast-Track *Significant*

Financial Interests that are directly related to the Subrecipient's work on behalf of Fast-Track;

- Subrecipient's Investigators must comply with the Subrecipient's FCOI Policy and the agreement shall specify time period(s) for the Subrecipient to report all identified financial conflicts of interest to Fast-Track so that Fast-Track can provide timely FCOI Reports, as necessary, to the PHS. Alternatively, Subrecipient's Investigators must comply with Fast-Track's FCOI Policy and the agreement shall specify time period(s) for the Subrecipient to submit all Investigator disclosures of *Significant Financial Interests* to Fast-Track so that Fast-Track can comply timely with its review, management, and reporting obligations; and
- Provision by Fast-Track of FCOI Reports to the PHS-Awarding component regarding all financial conflicts of interest of all Subrecipient Investigators prior to the expenditure of funds, and within sixty (60) days of any subsequently identified FCOI.

XI. Reporting to PHS Awarding Component

Fast-Track's Chief Executive Officer shall be responsible for reporting to the applicable PHS-Awarding Component all *Significant Financial Interests* in accordance with Federal requirements. Fast-Track will promptly notify the applicable PHS-Awarding Component in accordance with Federal regulations if bias is found with the design, conduct, or reporting of any Research.

A. Regular FCOI Reporting Requirements

Fast-Track's Chief Executive Officer is responsible for reporting Financial Interest information to the NIH Era Commons FCOI Module as summarized in the table below.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Contract Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of Financial Interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when Fast-Track is required to submit annual progress report, multi-year progress report, or at time of extension.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

B. FCOI Noncompliance Reporting

Fast-Track's Chief Executive Officer is responsible for reporting on FCOI noncompliance as summarized in the table below.

Summary of FCOI Noncompliance and FCOI Reporting	
FCOI Report (within 60 days of identification)	Whenever Fast-Track identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.
Retrospective Review (to determine bias)	If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. 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.
Update/Revise FCOI Report (following retrospective review)	If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report.
Mitigation Report (promptly after retrospective review)	If bias is found, <ul style="list-style-type: none"> • Notify NIH promptly • Submit Mitigation Report through FCOI Module
Annual FCOI Report	Submit annual FCOI report thereafter through FCOI Module

XII. Public Reporting

A. Public Accessibility to Fast-Track's FCOI Policy

Prior to any expenditures of funds under a PHS-funded Research project, Fast-Track shall ensure public accessibility, via its publicly-accessible website, of information concerning any *Significant Financial Interest* disclosed to Fast-Track that meets the following criteria:

- The *Significant Financial Interest* was disclosed and is still held by an Investigator or Key Personnel as defined in Section IV-6 herein;
- Fast-Track determines that the *Significant Financial Interest* is related to the PHS-funded Research; and
- Fast-Track determines that the *Significant Financial Interest* is a financial conflict of interest.

The information that Fast-Track makes available to any requestor shall include, at a minimum, the following:

- Investigator's name;
- Investigator's title and role with respect to the Research project;
- The name of the entity in which the *Significant Financial Interest* is held;
- The nature of the *Significant Financial Interest*; and
- The approximate dollar value (dollar ranges are permissible: \$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 in increments of \$50,000), or a statement that the interest value cannot be determined through reference to public prices or other reasonable measures of fair market value.

The information Fast-Track posts shall be updated at least annually. In addition, Fast-Track shall update the website within 60 days of its receipt or identification of information concerning any additional *Significant Financial Interest* of the Investigator or Key Personnel for the PHS-funded Research project that was not previously disclosed, or upon disclosure of a *Significant Financial Interest* that is new to the PH-funded Research project, if Fast-Track determines that the *Significant Financial Interest* is related to the PHS-funded Research and is a financial conflict of interest.

Information concerning the *Significant Financial Interest(s)* of an individual shall remain available, for posting to Fast-Track's publicly-available website, for at least three (3) years from the date that the information was most recently updated.

B. Special Considerations for Clinical Trials

In situations where the DHHS 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 or Key Personnel with a financial conflict of interest that was not managed or reported as required by this Policy, Fast-Track will require that the Investigator disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously-published presentations.

XIII. Record Retention of Financial Conflict of Interest Disclosure Forms

Records of and related to *Significant Financial Interest* disclosures shall be retained by Fast-Track for no less than three (3) years after the termination or completion of the PHS-funded Research to which they relate or from the date the final expenditure report is submitted to the PHS Awarding Component, whichever is later.

XIV. Training on Fast-Track's FCOI Policy

Each Investigator who is a Fast-Track employee or consultant will be trained prior to engaging in any PHS-funded Research and then periodically, ***but no less than once every four years***. Each such Investigator is required to certify that they have completed the NIH's Financial Conflict of Interest training program (available at <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) to ensure the Investigator understands and is compliant with this policy. Each such Investigator will certify they have:

- 1) Reviewed the NIH Regulations on Financial Conflict of Interest (COI) (accessible at https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf), including details of all disclosure requirements and FAQs (accessible at https://grants.nih.gov/grants/policy/coi/coi_faqs.htm);
- 2) Reviewed this Fast-Track policy on FCOI; and
- 3) Completed the web-based NIH FCOI training and exhibit such training with their submission of the FCOI Online Tutorial Certificate of Completion. This information is also contained on [Fast-Track's FCOI Disclosure Form](#). Additional training may be necessary if Fast-Track's Financial Conflict of Interest policy changes in a manner that affects Investigator requirements, or if an Investigator is found to be non-compliant with Fast-Track's FCOI policy or Management Plan.



FINANCIAL CONFLICT OF INTEREST ("FCOI") DISCLOSURE FORM

For Public Health Service Funded Research

Investigators are responsible to:

1. Read Fast-Track's Financial Conflict of Interest Policy.
2. Complete the NIH tutorial on FCOI prior to completing this form:
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.
3. Forward the tutorial's Certificate of Completion to Heidi Leinneweber at
hleinneweber@fasttrackresearch.com.

INVESTIGATOR INFORMATION

Name and Title:

Company (if other than Fast-Track):

Project Title:

Sponsor:

DISCLOSURE OF SIGNIFICANT INTEREST

As the Investigator of a PHS-funded research contract, you are required to disclose any *Significant Financial Interest* ("SFI") that could directly and significantly affect the design, conduct, or reporting of PHS-funded research pursuant to 45 CFR 94.3. One or more of the following interests would warrant disclosure of a SFI:

- Remuneration received from a publicly-traded entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary; equity interest includes stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- Remuneration received from a non-publicly-traded entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity in such entity;
- Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interest;
- Any reimbursed or sponsored travel expenses;
- Any fiduciary role for an entity.

PLEASE CHECK ONE OF THE FOLLOWING:

_____ I have NO *Significant Financial Interests* to disclose which relate to my institutional responsibilities (if you are NOT disclosing any *Significant Financial Interest*, please read and sign the “Investigator Certification” on page 3).

OR

_____ I am disclosing *Significant Financial Interest(s)* as defined under Federal Regulation 45 CFR 94.3 (and those of my spouse and dependent children), which relate to my institutional responsibilities (if YES, you are disclosing *Significant Financial Interest(s)*, please answer the subsequent questions followed by reading and signing the Investigator Certification on page 3).

PLEASE CHECK WHICH TYPE OF SFI YOU ARE DISCLOSING:

_____ Initial disclosure prior to making a research submission

_____ After-acquired *Significant Financial Interest(s)*

_____ Annual disclosure of *Significant Financial Interest(s)*

Name and address of Entity (corporation, partnership, private practice, non-publicly-traded entity(ies), etc.)

Principal type of business: _____

Value of the SFI (in US Dollars): _____

How does the SFI relate to PHS-funded research?

Did you receive any remuneration from any publicly-graded entity in the twelve (12) months preceding the disclosure* **AND** the value of any equity in the entity as of the date of disclosure, **when aggregated**, exceeds \$5,000? **Yes**____ **No** ____

- Did you receive any remuneration from any non-publicly-traded entity in the twelve (12) months preceding the disclosure*, **when aggregated**, exceeds \$5,000? Or did you (or your spouse or your dependent children) hold any equity in any non-publicly-traded entity? **Yes** ____ **No** ____

***Exclusions --** excluded from income disclosure: NOT required to disclose 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. NOT required to disclose income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- Do you have any income from an interest in any intellectual property right affected by the project?
Yes ____ No ____
- In the last twelve (12) months, did you receive reimbursed or sponsored travel from the entity **?
Yes ____ No ____
 - If YES, please provide the following trip details for each such trip (may use a separate page):
 1. Purpose of trip: _____
 2. Sponsor/Organizer: _____
 3. Destination: _____
 4. Duration: _____

****Exclusions** -- excluded from travel disclosure: NOT required to disclose travel that is reimbursed or sponsored by a Federal, State, or local government agency, an institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Fast-Track will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

INVESTIGATOR CERTIFICATION

I agree to complete the FCOI training at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> prior to engaging in research related to any PHS/NIH-funded grant or contract and anytime thereafter, and, immediately upon other events, as defined per Fast-Track policy. Upon completion of each training session, I will send an email with Certificate of Completion to: Heidi Leinneweber at hleinneweber@fasttrackresearch.com.

If the proposed project is funded by PHS/NIH, I agree, for the duration of the project, to update this disclosure either on an annual basis, or within 30 days if new reportable SFI(s) are obtained (such as through purchase, marriage or inheritance, for example).

I agree to provide additional details needed by Fast-Track to meet NIH's institutional filing, annual reporting and other requirements, and to cooperate in the development of a Management Plan to address any actual or potential conflict of interest identified via this Disclosure.

If I participate in a project involving subrecipient organizations, I agree to assist Fast-Track in obtaining required disclosures in a timely manner from all subrecipient Investigators, and to assist Fast-Track, if requested, to manage any FCOIs of a subrecipient Investigator to assure compliance with these regulations.

I agree to comply with any retrospective reviews, conditions or restrictions imposed by Fast-Track to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signed:	Date:
Printed Name:	Title:

FREQUENTLY ASKED QUESTIONS

What is the Purpose of this Policy?

This Financial Conflicts of Interest Policy is intended to protect the objectivity and integrity of the work of Fast-Track and its individual staff members. The Policy is designed to ensure that staff members identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as researchers and administrators. An effective conflicts-of-interest policy helps both to safeguard the work and reputations of Fast-Track staff members, and to ensure Fast-Track's compliance with Federal and other regulatory requirements relating to conflicts of interest.

To Whom Does It Apply?

It applies to all Fast-Track employees and consultants. In addition to the generally-applicable requirements, the policy imposes special requirements on “Investigators” and “Project Directors” who are involved in externally sponsored research activities. Subrecipients (Subcontractors) are also required to comply with FCOI regulations, whether through their own FOCI policy or by agreeing to comply with this Fast-Track FCOI Policy.

What Conduct Is of Concern Under This Policy?

In general, the Policy focuses on personal or familial Financial Interests that could bias or appear to bias the employee's work at Fast-Track. The Policy requires staff members to consider whether they have personal or familial Financial Interests that intersect significantly with their Fast-Track responsibilities, and provides a process for disclosing such interests and for dealing with resultant actual or potential conflicts. The Guidelines in Section V of the Policy describe three categories of conduct that are either forbidden (presumptively or in the absence of advance disclosure and approval), or not normally forbidden but nonetheless requiring disclosure.

The first category (Section V-A) includes conduct that is "presumptively prohibited" because it presents a clear conflict of interest. Such conduct includes, for example, a researcher's receiving sponsored program support from an entity in which he or she has a *Significant Financial Interest*, an administrator's participating in a Fast-Track decision that relates to an entity in which that administrator has a *Significant Financial Interest*, or any employee's accepting a gift worth more than \$100 from an entity that has a business relationship with Fast-Track over which the employee has influence or authority.

The second category (Section V-B) includes conduct that has the potential to affect, or appear to affect, one's objectivity and thus is permitted only if it has been disclosed,

reviewed and approved in advance. This category has particular application to researchers who hold *Significant Financial Interests* in, consulting relationships with, or executive positions in business entities that provide sponsored program support or otherwise seek to associate with Fast-Track. This category also covers the use of Fast-Track's name or facilities by business entities in which individual employees hold *Significant Financial Interests*, and participation in certain government-funded activities.

The third category (Section V-C) includes conduct that is not presumptively prohibited but requires disclosure, and, in certain situations, may be conditioned or prohibited to ensure objectivity and protect against bias or the appearance of bias. Disclosure of Financial Interests is required for the conduct, publication and presentation of research. Similarly, one who serves in an executive position for an outside entity that has a business relationship with Fast-Track, or as a consultant to an outside entity that operates in the field of one's work at Fast-Track, must disclose these roles and avoid participation in Fast-Track decisions relating to that entity.

What is a Financial Interest?

A Financial Interest is anything of monetary value, related to an Investigator's responsibilities at Fast-Track, whether or not the value is readily ascertainable, in any of these categories:

- Remuneration or compensation (e.g., salary, consulting fees, honoraria, etc.) from an external public or private company;
- Equity (e.g., stock, stock options or other ownership interest) in a public or private company;
- Intellectual property rights (e.g., patents, copyrights), and any royalties and licensing income from such rights;
- A position in an outside entity that gives rise to a fiduciary duty, such as director, officer, partner, trustee, employee or any position of management,
- For Investigators with PHS funding, also any reimbursed or sponsored travel.

A Financial Interest **DOES NOT** include:

- Salary, royalties or other remuneration from Fast-Track;
- Income or travel from seminars, lectures or other engagements sponsored or paid by a public 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;
- Income or travel from service on advisory committees or review panels sponsored or paid by a public 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;

- 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.

Who Is Required to Make Financial Disclosures Under This Policy?

All employees, with limited exceptions, are being asked to make financial disclosures. The Policy requires that initial, annual and updated disclosure forms be submitted in designated situations by certain staff. Given both the difficulty of determining up front which faculty and staff are in what situations and the relative simplicity of making financial disclosures, Fast-Track has determined that it is best to solicit disclosures from all employees with very limited exceptions. All employees should complete an initial form or update their existing form. The form should include the Financial Interest(s), if any, of the Investigator, and his or her spouse or domestic partner, and/or dependent child(ren).

To Whom Are Financial Disclosures Submitted?

The Policy provides for the submittal of financial disclosures to Fast-Track's Chief Executive Officer.

What Happens After I Submit the Financial Disclosure?

The disclosure is reviewed by the Chief Executive Officer, who will determine whether or not it identifies an actual or potential conflict of interest and, if so, what action is required to manage the situation appropriately. The Chief Executive Officer may request additional information from an employee in order to make these determinations. In the case of an identified conflict, the Chief Executive Officer may work with the staff member to put in place and to document an appropriate conflict management plan. An employee who disagrees with the decision of the Chief Executive Officer may seek review by the President.

Is the Information That I Disclose Confidential?

Yes. The Policy provides that financial disclosures will be considered confidential and that the information on the disclosure forms will be shared only with those who have a need to know under the Policy and/or applicable law. The disclosures are intended to elicit information that is necessary to determine whether a financial conflict of interest exists, and do not require the disclosure of financial or other information that is not relevant for that purpose. Additional information provided to the Chief Executive Officer (if required) will be considered confidential to the same extent as that provided in the disclosure.

Do I have Any Continuing Obligations?

Yes. All Fast-Track staff members and consultants are required, on an ongoing basis, to comply with the provisions of the Policy and the terms of any existing conflict management plan, to identify situations that could create the appearance of a conflict of interest, and to submit annual and updated disclosures as required. If your Financial Interests or responsibilities while working for Fast-Track change in any significant way, you must update your disclosure.

What If I Still Have Questions About the Policy?

When in doubt, disclose. You may also consult Chief Executive Officer, who plays a critical role in enforcing the Policy and providing guidance on its obligations and procedures.

Does the Policy Include Additional Disclosure and Reporting Requirements FOR PHS and Other Externally-Funded Researchers (“Investigators”)?

Yes. The Department of Health and Human Services has rules that impose additional requirements relating to financial disclosures and reporting for those who are involved with Public Health Service funded research. In general, prior to engaging in work on sponsored projects, Investigators are required to make disclosures of Financial Interests and relationships at a lower dollar threshold and covering a broader range of activities than non-investigators. In addition, investigators are required to submit “study specific” disclosure forms for each individual sponsored project. Fast-Track is required to identify, evaluate and manage or eliminate investigator financial conflicts of interest and, in some instances, to make information about them public and provide reports to government agencies.

How Do I Know If I Am An “Investigator?”

You are an “Investigator” if you are the Principal Investigator, co-Principal Investigator, co-Investigator, Project Director or any other person, regardless of your title or position, who is responsible for the design, conduct or reporting of research activities funded by a Federal government agency or other external sponsor, or proposed for such funding. This is a broad definition, and if you have any doubts about whether you could be classified as an “Investigator,” you should contact the Chief Executive Officer and ask for clarification.

How Do I Complete FCOI Training?

Investigators who receive Public Health Service (PHS) funding must undergo conflict of interest (FCOI) training before engaging in the funded research. To complete the training, visit <https://grants.nih.gov/grants/policy/coin/tutorial2011/fcoi.htm>, print the Training Certificate, and submit it to the Chief Financial Officer.