

## TFF Pharmaceuticals, Inc. Financial Conflict of Interest Policy

### 1.0 PURPOSE

This policy defines the term *Financial Conflict of Interest* and establishes procedures for identifying, evaluating, reporting, and managing financial relationships that could affect the objectivity or integrity of research conducted by or business conducted at TFF Pharmaceuticals, Inc. (“TFF Pharmaceuticals, Inc.” or “Company” or “The Institution”). The intention of this policy is to identify and eliminate or manage any possible threat to the integrity of the research conducted by TFF Pharmaceuticals, Inc. It is also designed to educate TFF Pharmaceuticals, Inc. employees about disclosure requirements, and it provides information about how conflicts of interest are assessed. This policy implements the requirements of 42 C.F.R. Part 50, Subpart F, *Promoting Objectivity in Research* and 45 C.F.R. Part 94, *Responsible Prospective Contractors*,<sup>1</sup> applying to PHS-sponsored grants and government contracts.

### 2.0 SCOPE

This policy governing financial conflict of interest applies to all Investigators of TFF Pharmaceuticals, Inc. The Company Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Company Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Company policy. Investigators at TFF Pharmaceuticals, Inc. are typically named as Principal Investigator, Project Manager, Sr. Scientist, or Sr. Engineer on PHS-sponsored grants and government contracts.

### 3.0 REFERENCED DOCUMENTS

N/A

### 4.0 DEFINITIONS

***Company Official*** means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s Company responsibilities. For the purposes of this policy, the Company Official is designated as Kirk Coleman.

***Company Responsibilities*** means the Investigator’s responsibilities associated with his or her Company appointment or position, such as research, teaching, administration, and internal and external professional committee service.

***Family*** means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

***Financial Interest*** means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited

---

<sup>1</sup> The regulations do not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards.

to: salary or other payments for services (*e.g.*, consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (*e.g.*, stocks, stock options, or other ownership interests); and intellectual property rights and interests (*e.g.*, patents, trademarks, service marks, copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

**Financial Interest** does NOT include:

- a) salary, royalties, or other remuneration from TFF Pharmaceuticals, Inc. (including intellectual property rights assigned to the Company, agreements to share in royalties related to such rights, and any ownership interest in the Company);
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, **Financial Interest** also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Company responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

**Financial Conflict of Interest (“FCOI”)** means a Significant Financial Interest (or, where the Company Official requires disclosure of other Financial Interests, a Financial Interest) that the Company reasonably determines could directly and significantly affect the design, conduct, or reporting of Company research.

**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. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include project managers or senior scientists or senior engineers, if they are named as Senior/Key Personnel in a proposal.

**Public Health Service (“PHS”)** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

**Research** means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health. 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).

**Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

**Significant Financial Interest (SFI)** means a Financial Interest that reasonably appears to be related to the Investigator's Company Responsibilities, and is:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- d) income related to intellectual property rights and interests not reimbursed through the Company.

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution 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, 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; or income from service on advisory committees or review panels for a Federal, state, or local government agency, 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.

## **5.0 RESPONSIBILITIES**

TFF Pharmaceuticals, Inc. requires that Investigators conduct their affairs so as to avoid or minimize conflicts of interest, and they must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Company to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator will discuss the situation with the Company Official. A conflict of interest depends on the situation, not on the character or actions of the individual.

Prohibited situations include any financial interest that directly and significantly affects the design, conduct, or reporting of Company research.

The Company will not permit the incurring of any expenses on federal grants unless, or until, all identified conflicts of interest have been eliminated or properly addressed through a Company-approved Management Plan.

## **6.0 PROCEDURE**

### **a. DISCLOSURE OF FINANCIAL INTERESTS**

All Investigators are required to disclose their outside financial interests to the Company on an annual and on an ad hoc basis, as described below. The Company Official or designee is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

#### **i. Annual Disclosures**

On an annual basis, all Investigators must disclose their Significant Financial Interests to the Company Official or designee. All forms should be submitted to the Company Official or designee by March 1 for the previous calendar year.

#### **ii. Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Company, through the Company Official or designee, within 30 days of his/her initial appointment or employment.

Prior to submitting applications for sponsored projects and again before entering into sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Company Official an ad hoc updated disclosure of his/her Significant Financial Interests with the outside entity. The initial disclosure includes reimbursed or sponsored travel that is received in the preceding 12 months. The Company will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Company Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

#### **iii. Travel**

Investigators must also disclose reimbursed or sponsored travel related to their company responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Company Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

#### **iv. PHS Reporting**

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to the regulations, if bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component 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. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

**b. SUBAWARDS / SUBCONTRACTS (for PHS-Funded Sponsors)**

**i. At time of Proposal:**

- The TFF Pharmaceuticals, Inc. *Financial Interests Report* form (or subrecipient's PHS-compliant FCOI reporting form) must be completed and any Conflicts of Interest declared.
- Subrecipient organization will certify that it currently has a PHS FCOI-compliant policy in place (Form Appendix B, *Subrecipient FCOI Compliance Confirmation*, or subrecipient's own PHS-compliant FCOI certification form).
- If subrecipient organization does NOT have a PHS-compliant policy, it will certify that it intends to have a PHS-compliant FCOI policy in place by the time of award, OR certify that it intends to abide by TFF Pharmaceuticals, Inc.'s policy.
- Subrecipient organization will certify that each Investigator will complete the required training prior to engaging in any PHS-funded grant/contract.

## **ii. At Just In Time (JIT)**

In order to expedite the process at time of award, TFF Pharmaceuticals, Inc. will send subrecipient the TFF Pharmaceuticals, Inc. *Financial Interests Report* form at JIT to complete and return (if applicable). Alternatively, subrecipient may send its own company or institutional PHS FCOI-compliant reporting form for each Investigator.

Subrecipient will be asked to re-certify that it has a PHS-compliant policy in place (using TFF Pharmaceuticals, Inc. Form Appendix B or subrecipient's own certification form). Subrecipient will declare if there have been any changes in its conflict of interest status and whether those conflicts are required to be managed.

If Subrecipient has any conflicts requiring management, TFF Pharmaceuticals, Inc. will report to the PHS agency.

## **iii. At Time of Award**

If the Award did not require a Just In Time (JIT) process, then the following will happen at the time of award:

- The *Financial Interests Report* form will be completed for subrecipient's Investigators.
- Subrecipient will re-certify that it has a PHS FCOI-compliant policy in place.
- Subrecipient will declare if there were any changes in its conflict of interest status, and if those conflicts are required to be managed.
- Subrecipient will report any conflicts requiring management, and it will submit information to TFF Pharmaceuticals, Inc., who will report to the PHS agency.

Note: Until a FCOI compliance certification form is completed and all conflicts of interest are managed and reported, the award agreement for TFF Pharmaceuticals, Inc. and all of its subawards cannot be executed.

## **iv. Ongoing Compliance**

- Subrecipient organization will disclose to TFF Pharmaceuticals, Inc. any conflicts of interest that arise and are required to be managed during the life of the award.
- Subrecipient will certify annually if there have been any changes to its conflict of interest status.
- Subrecipient investigators will be required to disclose any reimbursed or sponsored travel related to their Company responsibilities.
- Subrecipient Investigators are required to renew their training every four years.

## **c. REVIEW AND DECISION OF THE COMPANY OFFICIAL**

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

Should any reported conflict or non-compliance require reporting to PHS, the Company Official or designee will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee so that they may fulfill their reporting obligations to the PHS.

#### **d. INVESTIGATOR NON-COMPLIANCE**

##### **i. Disciplinary Action**

In the event of an Investigator's failure to comply with this Policy, the Company Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Company Official is implemented.

A Company Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Company Official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision.

## **ii. Retrospective Review**

Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii) (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution'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.

(B) The Institution 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.

In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this regulation, the Institution shall require the Investigator involved to 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.

### **e. TRAINING**

Each Investigator must complete training on this Policy upon implementation of the policy, upon hire by TFF Pharmaceuticals, Inc. (if hired post-implementation), prior to engaging in research funded by PHS, and at least every four years after the Investigator's initial training.



Investigators must also complete training within a reasonable period of time as determined by the Company Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that an Investigator has not complied with this policy or with a management plan related to their activities.

**f. RECORD RETENTION**

The Company Official or designee will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

**g. CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Company may make such information available to an agency funding research of the Company, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Company, if requested or required. If the Company is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

**h. PUBLIC ACCESSIBILITY**

(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the 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 of the significant financial interest (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 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel

for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to regulations shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

## **7.0 EXTERNAL STANDARDS**

N/A

## **8.0 ASSOCIATED TEMPLATES, GUIDELINES AND FORMS**

Any forms or other documents associated with the procedure or work instruction must be listed in this section.

<u>Document ID</u>	<u>Document Name</u>
Appendix A	Financial Interests Report
Appendix B	Subrecipient FCOI Compliance Confirmation