

## Administrative Guidelines

### 5. Conflicts of Interest and Commitment

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#### 5.1 Principles

The Scripps Research Institute (hereafter TSRI), in accordance with its mission to foster basic knowledge in the biosciences, to pursue scientific advances through interdisciplinary programs and collaborations, and to educate and train researchers, is supportive of the growing needs of its faculty to seek and participate in collaborative research with industry, to consult widely, and to engage in other activities which may benefit not only the participants but TSRI itself and the public at large.

TSRI is committed to ensuring that such activities are conducted properly and consistently with the principles of openness, trust, and free inquiry that are fundamental to the autonomy and well-being of a non-profit research institute and to the responsible management of the Institute's business.

TSRI has adopted this policy on Conflicts of Interest and Commitment (hereinafter "Policy") to identify and address the real, potential or apparent Conflicts of Interest and Conflicts of Commitment. This policy provides ethical principles and guidance for TSRI faculty and others in assessing their relationships and conduct with outside entities, educates the TSRI community about situations that generate Conflicts of Interest and Commitment, provides for management of those Conflicts, promotes the best interests of students and others whose work depends on faculty direction, and provides guidelines for particular Conflicts of Interest and Conflicts of Commitment.

#### 5.2 Definitions

##### 5.2A Business

Any entity, either for-profit or not-for-profit, that is not TSRI or a

governmental entity.

#### 5.2B Clinical Research

Any research or procedure involving human subjects in vivo or the use of human samples for the development and evaluation of patient therapies such as diagnostic tests, drug therapies, or medical devices. It includes early clinical studies, evaluative research, epidemiological studies and clinical trials. It excludes research using commercially obtained de-identified human cell lines as well as commercially obtained de-identified human tissue. It also excludes research that uses human tissue obtained from institutional tissue banks where the individual identifiers are unknown to the researcher. In general, the term includes all research required to be reviewed by an Institutional Review Board.

#### 5.2C Conflict Review Officer (CRO)

The CRO shall be appointed by the President. The CRO is responsible for implementing this Policy. That responsibility includes reviewing all disclosures of Significant Financial Interests, Conflicts of Interest and Conflicts of Commitment, and requiring any and all actions necessary to ensure that any Conflict of Interest or Commitment found will be managed, reduced or eliminated in accordance with this Policy.

#### 5.2D Covered Individual

Any TSRI employee, including but not limited to TSRI Professional Staff as defined in the TSRI Administrative Guidelines, Investigators, students, technicians, research support staff, and TSRI shared and support services staff, and any visitors using TSRI facilities to conduct research.

#### 5.2E Executive Position

Any person in a position having authority to direct or control a material segment of the operation or management of a Business, including, for example, as a director, trustee, officer or partner.

#### 5.2F Family

Includes a spouse and dependent persons as defined by the Internal Revenue Code.

#### 5.2G Institutional Responsibilities

Professional responsibilities on behalf of TSRI, including, but not limited to purchasing, teaching, research, administration, professional practice, institutional committee membership, and service on panels such as institutional Review Boards or Data and Safety Monitoring Boards.

#### 5.2H Investigator

An Investigator means the principal investigator, co-principal investigator(s), co-investigator(s), project director(s) at all levels, all personnel named in the application as Senior/Key personnel, and any other person, regardless of title, who is responsible for the design, conduct, or reporting of research funded by the PHS and other Federal agencies, or proposed for such funding.

### 5.2I Outside Professional Activities

An activity outside of TSRI engaged in by a Covered Individual in a professional capacity. Outside Professional Activities include, for example, consulting services, teaching, service on public or private boards and advisory committees, and service to governmental, nonprofit and professional organizations. Outside Professional Activities may be compensated or uncompensated.

### 5.2J PHS Awarding Component

The organizational unit of the U.S. Public Health Service (PHS) that funds Sponsored Research activity.

### 5.2K Scientific Trainee

Any graduate student or professional scientific trainee, including but not limited to members of the Scientific Staff working under the direction of a member of the Faculty. Included in this category are Research Associates and Senior Research Associates.

### 5.2L Significant Financial Interest

A Significant Financial Interest is one or more of the following interests of a Covered Individual or member of his or her Family that reasonably appears to be related to the Covered Individual's Institutional Responsibilities:

- a. Remuneration received from a Business in the twelve-month period immediately prior to the disclosure. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship);
- b. An equity interest held in a Business at the time of disclosure. For purposes of this definition, equity interest includes any stock, stock option, or other ownership interest; or
- c. Intellectual property rights (*e.g.*, patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

The term Significant Financial Interest does not include: (i) salary, royalties, or other remuneration paid by TSRI to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by TSRI, including intellectual property rights assigned to TSRI and agreements to share in royalties related to such rights; (ii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual does not directly control the investment decision made in these vehicles; (iii) 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 institution that is affiliated with an institution of higher education; and (iv) income from service on advisory panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.

For Investigators who are engaged in Sponsored Research funded by PHS, Significant Financial Interest includes, in addition to the interests described in Section [5.2L \(a\) - \(c\)](#) above, the interests described in [Section 1 of Appendix A](#) to this Policy.

### 5.2M Sponsored Research

Research, training and instructional projects involving funds, materials, services, or other compensation from a source outside of TSRI. The use of materials obtained under a Materials Transfer Agreement (MTA) may or may not constitute Sponsored Research depending on the type and magnitude of the obligations imposed on TSRI. Generally, agreements creating Sponsored Research will contain at least one of the following:

**5.2M(1)** The agreement binds TSRI to a line or field of scientific inquiry. Such specificity may be indicated by a plan, by the stipulation of requirements for orderly testing or validation of particular approaches, or by the designation of performance targets.

**5.2M(2)** A line item budget is involved. A line item budget details expenses by activity, function or project period. The designation of overhead (or indirect costs) qualifies a budget as "line item".

**5.2M(3)** Financial reports are required.

**5.2M(4)** The award is subject to external audit.

**5.2M(5)** The agreement provides for the disposition of either tangible or intangible properties which may result from the activity. Tangible properties include equipment, records, technical reports, theses or dissertations. Intangible properties include rights in data, copyrights, inventions, or know-how.

### 5.2N Technology

Diagnostic, therapeutic, medical or surgical procedure and any process, method, compound, drug or device.

## 5.3 Policy Statements

TSRI has adopted the following policy statements relating to Conflicts of Interest and Conflicts of Commitment.

### 5.3A Policy Applies to Covered Individuals

The TSRI Policy on Conflicts of Interest and Commitment applies to Covered Individuals. All Covered Individuals have an obligation to become familiar with, and abide by, the provisions of this Policy.

### 5.3B Duty to Promote the Best Interests and Integrity of TSRI

Covered Individuals all serve the research, educational and public purposes of TSRI. Accordingly, all Covered Individuals have a clear obligation to

conduct the affairs of TSRI and use TSRI resources in a manner consistent with those purposes, and to make all decisions on the basis of promoting the best interests and integrity of TSRI.

### 5.3C Preserve Objectivity

A Covered Individual shall conduct his or her activities in an objective, publicly disseminated manner, free from any undue influence or the perception of such influence arising from the Covered Individual's outside obligations.

### 5.3D Disclosure Obligation

Activities that create a real, potential or apparent Conflict of Interest or Commitment and other activities and interests that are required to be disclosed pursuant to this Policy shall be disclosed to the Conflict Review Officer (CRO) in accordance with pertinent provisions of this Policy and applicable law and regulation.

### 5.3E Situations Requiring Advanced Approval

A Covered Individual shall first obtain approval from the CRO before engaging in any activity or situation that may involve, or appear to involve, a real, potential or apparent Conflict of Interest or Commitment.

### 5.3F Nepotism

A Covered Individual shall not use undue influence or position or status at TSRI to employ a relative at TSRI, wherein relative is defined as husband, wife, father, mother, son, daughter, brother, sister, mother-in-law and father-in-law and any other dependent persons as defined by the Internal Revenue Code, and includes a domestic partner defined as a person who has committed to a long term personal relationship with another person of the same or opposite gender.

### 5.3G Accountability for Financial Interests of Family Members

A Covered Individual is accountable under this policy for any financial interest or Business relationship of his/her Family that would, if the financial interest or Business relationship were held directly by the Covered Individual, create a Conflict of Interest.

### 5.3H Uniform Consulting Provisions

A Covered Individual shall abide by TSRI's Uniform Consulting Agreement Provisions.

### 5.3I Obey the Law

A Covered Individual must comply with all applicable laws of the United States, its states and territories and other countries where TSRI conducts business.

## 5.4 Conflicts of Interest

### 5.4A Definition

A Conflict of Interest is a situation in which a Covered Individual, or a

member of the Covered Individual's Family, has a Significant Financial Interest or non-financial interest that may compromise, or provide the incentive to compromise, the Covered Individual's behavior in the conduct of his or her activities at TSRI, the Covered Individual's influence on decisions that TSRI may make, or the Covered Individual's influence over his or her associates outside TSRI. A Conflict of Interest may be real, potential or apparent.

In accordance with federal regulations applicable to federally Sponsored Research, TSRI makes determinations regarding Financial Conflicts of interest (FCOI) of Investigators in Sponsored Research. The standard for determining whether a Financial Conflict of Interest exists in Sponsored Research is set forth in [Section 5.41\(2\)a](#) of this policy.

#### 5.4B Objective Standard

A determination as to whether or not a situation gives rise to a Conflict of Interest is made from the perspective of a reasonable member of the general public, and is based on the facts and circumstances surrounding the situation. A Conflict of Interest depends on the situation but not on the character of the individual. The mere existence of a Conflict of Interest does not necessarily imply wrongdoing on anyone's part.

#### 5.4C Conflicts of Interest Policy Implementation Guidelines

The following is an illustrative, non-exhaustive list of outside relationships subject to this policy. These examples have been divided into three categories:

Category I: Situations that are generally not allowable because they represent Conflicts of Interest that are inconsistent with TSRI policies.

Category II: Situations that may be allowable, if the CRO can design and implement special safeguards appropriate for the circumstances.

Category III: Situations that are usually allowable, provided that standard policies and safeguards are followed, e.g., timely disclosure and use of TSRI's Uniform Consulting Provisions.

The establishment of specific categories under the guidelines for both Conflicts of Interest and Conflicts of Commitment is not intended to serve as a rigid or comprehensive code of conduct or to define inflexible rules. Covered Individuals, in participating in activities outside TSRI and in reference to the guidelines of this policy, shall demonstrate at all times their commitment to the highest intellectual and ethical standards.

#### **5.4C(1) Category I: Situations Generally Not Allowable**

##### **5.4C(1)a Executive Position**

A Covered Individual or Family member serving in an Executive Position for a Business or other entity that deals or seeks to deal with TSRI.

##### **5.4C(1)b Clinical Research**

A Covered Individual participating at TSRI, or as a TSRI researcher at TSRI or at another institution, in the design, conduct or reporting of Clinical

Research on a Technology owned by, licensed to or otherwise contractually obligated to a Business in which the Covered Individual has a Significant Financial Interest.

**5.4C(1)c Using TSRI Resources to Support Consulting Activities**

A Covered Individual using TSRI resources, including facilities, personnel, equipment, or proprietary information, except in a purely incidental way, as part of the Covered Individual's consulting or other Outside Professional Activities, or for any other purpose unrelated to the education, research, scholarship, and public service related to TSRI business.

**5.4C(1)d Doing Business With TSRI**

A Covered Individual or Family member directly or indirectly leasing, renting, trading or selling real or personal property to TSRI.

**5.4C(1)e Influencing Negotiations**

A Covered Individual influencing or participating in the negotiation of a contract between TSRI and a Business in which the Covered Individual has or seeks to have a Significant Financial Interest.

**5.4C(1)f Limitations on Publication and Objectivity**

A Covered Individual entering into an agreement with a Business that prohibits or unduly limits publication, or evaluation of research by reviewing entities, or that links payment to favorable research results.

**5.4C(1)g Political Lobbying and Contributions**

A Covered Individual using TSRI resources, including facilities, personnel, equipment, or confidential information, for lobbying purposes or political contributions.

**5.4C(1)h Political Activity**

A Covered Individual using his or her position or authority at TSRI to induce or pressure any other individual in the TSRI community to contribute to, support, or oppose any political group, candidate, issue, or legislation.

**5.4C(1)i Use of TSRI Name**

A Covered Individual utilizing a TSRI trademark or service mark in connection with the promotion, marketing, or sale of a product, service or Business in such a way as to imply TSRI sponsorship or endorsement.

**5.4C(1)j Accepting Gifts**

A Covered Individual or Family member accepting a gift, gratuity, entertainment or favor that creates the appearance that the Covered Individual's exercise of independent and objective judgment related to his/her Institutional Responsibilities would be compromised.

**5.4C(1)k Conflicting Activities**

A Covered Individual engaging in an Outside Professional Activity that conflicts with a business interest of TSRI or engaging in multiple Outside Professional Activities that conflict with each other.

#### **5.4C(1)I Exceptions**

Exceptions to Conflicts of Interest that are generally not allowable arise in extraordinary circumstances, such as the recruitment of a new faculty member, where a Conflict of Interest may be allowed to continue for a finite time period with disclosure and the approval of the CRO.

#### **5.4C(2) Category II: Situations That May Be Allowable With Special Safeguards**

##### **5.4C(2)a Technology Licensing**

A Covered Individual having a Significant Financial Interest in a Business that licenses or seeks to license TSRI Technology.

##### **5.4C(2)b Sponsored Research**

A Covered Individual having a Significant Financial Interest in a Business that has entered into or seeks to enter into an agreement to support Sponsored Research to be conducted under the direction of the Covered Individual.

##### **5.4C(2)c Outside Research**

A Covered Individual conducting research outside TSRI that would ordinarily be conducted within TSRI.

##### **5.4C(2)d Consulting**

A Covered Individual consulting for a Business in which the Covered Individual has a Significant Financial Interest.

##### **5.4C(2)e Disclosure of Unpublished Information**

A Covered Individual sharing confidential, unpublished or proprietary information, research results, or research products of TSRI with a Business in which the Covered Individual has or seeks to have a Significant Financial Interest.

##### **5.4C(2)f Involvement of Laboratory Personnel**

A Covered Individual involving a Scientific Trainee in research supported by and/or relating to a Business in which the Covered Individual has a Significant Financial Interest.

##### **5.4C(2)g Clinical Research**

A Covered Individual participating in Clinical Research on a Technology developed by the Covered Individual, unless the activity falls under the guidelines of [5.4C\(1\)b](#).

##### **5.4C(2)h Founding a Business**

A Covered Individual or Family member participating in the founding of a Business engaging in an activity related to the business of TSRI, provided the Business does not deal or seek to deal with TSRI (see 5.4C(1)a).

##### **5.4C(2)i Sabbatical Leave at a Business**

A Covered Individual working as an employee or independent contractor for a Business while on sabbatical leave from TSRI.

##### **5.4C(2)j Executive Position**



A Covered Individual or Family member serving in an Executive Position for a Business engaging in an activity related to the business of TSRI provided the Business does not deal or seek to deal with TSRI (see [5.4C\(1\)a](#)).

#### **5.4C(2)k Nepotism**

A Covered Individual influencing or having control over TSRI's consideration of employment of a relative as defined in [Section 5.3F](#).

### **5.4C(3) Category III: Situations Usually Allowable With Standard Safeguards**

#### **5.4C(3)a Publication Royalties**

A Covered Individual receiving royalties for published scholarly work and other writings.

#### **5.4C(3)b Invention Royalties**

A Covered Individual receiving royalties under TSRI royalty sharing policies.

#### **5.4C(3)c Scientific Advisory Board**

A Covered Individual serving on the Scientific Advisory Board of a Business in which the Covered Individual has a Significant Financial Interest.

#### **5.4C(3)d Royalties Generated From Non-TSRI Entities**

A Covered Individual conducting sponsored basic research (that is not Clinical Research) relating to a TSRI invention on which the Covered Individual receives, or has the right to receive, royalties and that has been licensed to a Business in which the Covered Individual has a Significant Financial Interest.

### **5.4D Mentor's Obligations to Students and Trainees**

#### **5.4D(1) Principles**

The impact of a mentor's Conflict of Interest or Conflict of Commitment on Scientific Trainees is of special concern to TSRI. The extent and quality of the training experience provided to a Scientific Trainee should not be diminished because of his/her mentor's Outside Professional Activities or Significant Financial Interests. The training experiences of students and postdoctoral fellows are expected to incorporate the values of objectivity in research and the importance of public trust. Scientific Trainees should not participate in research activities that utilize a Business' confidential information or otherwise create unreasonable restraints on the right to publish or communicate freely. Any exceptions to this policy shall be approved in advance by the CRO.

#### **5.4D(2) Mentor Responsibilities**

Scientific Trainees must always be encouraged to conduct research in areas that optimize their training. Special care must be taken to assure that a trainee's research is not primarily designed to (and does not appear to) enhance their mentor's Significant Financial Interest, and is not adversely affected by that interest.

#### **5.4D(3) Required Disclosure to Scientific Trainees**

Before beginning a research project, a Scientific Trainee must be provided by the mentor, a clear description of any Significant Financial Interest the

mentor has in a Business that may be affected by the outcome of research performed by the Scientific Trainee.

#### **5.4D(4) Prior Approval for Graduate Students, Research Associates, and Senior Research Associates**

Written approval from the Dean, Graduate and Postdoctoral Studies, must be obtained before a graduate student, research associate, or senior research associate can be assigned to conduct research which is sponsored by and/or relates to a Business in which the mentor has a Significant Financial Interest.

### **5.4E Conflicts of Commitment**

#### **5.4E(1) Definition**

A Conflict of Commitment is a situation where a commitment to Outside Professional Activities of a Covered Individual adversely affects his or her capacity to meet his or her responsibilities at TSRI. A Conflict of Commitment is perceptible because of a reduction of the Covered Individual's time and intellectual energies devoted to TSRI activities. Whenever a Covered Individual's Outside Professional Activities exceed permitted limits, or whenever a full-time faculty member's primary professional loyalty is not to TSRI, a Conflict of Commitment exists.

#### **5.4E(2) Outside Professional Activity Time Allowance**

Covered Individuals who are full-time employees owe their primary professional allegiance to TSRI, and their primary commitment of loyalty, time and intellectual energies should be directed to their TSRI research, teaching, training and administrative responsibilities. Accordingly, TSRI full-time employees should arrange Outside Professional Activities to minimize any interference with their responsibilities at TSRI. TSRI's Policy allows full-time Faculty employees to devote a limited amount of time for Outside Professional Activities, unless an exception has been granted for more than the normal allowance of time. Full-time Faculty employees are allowed ten percent (10%) of their total professional effort to be directed to Outside Professional Activities, not to exceed the equivalent of 36 days per year. Unless a special exception has been arranged in advance, part-time employees are not eligible for the 10% time allowance for Outside Professional Activities and are required to commit to TSRI 100% of the time agreed in accordance with the terms of their employment with TSRI.

### **5.4F Conflicts of Commitment Policy Implementation Guidelines**

Failure to complete the necessary forms may result in disciplinary action, including, without limitation, limiting the individual's research privileges and termination of employment.

Category I: Situations that are generally not allowable because they represent Conflicts of Commitment that are inconsistent with TSRI Policy.

Category II: Situations that may be allowable, provided that special safeguards appropriate for the circumstances can be implemented.

Category III: Situations that are usually allowable, provided that standard policies and safeguards are followed.

#### **5.4F(1) Category I: Situations Generally Not Allowable**

##### **5.4F(1)a Prolonged Absence**

A Covered Individual having a commitment outside of TSRI that involves frequent or prolonged absence from TSRI on non-TSRI business. The allowable exceptions are instructional or research activities performed in the course of normal faculty sabbatical leave that are routinely subject to disclosure and approval processes.

##### **5.4F(1)b Engagements Limiting the Scope of Activity at TSRI**

A Covered Individual, as part of an arrangement with a non-TSRI affiliated entity, agreeing to any limitations on the Covered Individual's performance of research or other instructional duties for TSRI (e.g. through agreements containing exclusive provider, non-competition or right of first refusal clauses).

#### **5.4F(2) Category II: Situations That May Be Allowable With Special Safeguards**

##### **5.4F(2)a Executive Position**

A Covered Individual serving in an Executive Position for a Business. Such service is not generally allowable if it falls within Section [5.4C\(1\)a](#).

#### **5.4F(3) Category III: Situations That Are Usually Allowable With Standard Safeguards**

##### **5.4F(3)a Activities for Governmental, Non Profit or Professional Organizations**

A Covered Individual providing services to outside governmental, educational, professional, scientific, artistic, cultural, civic businesses or other organizations that enhance the value of the Covered Individual to TSRI and do not adversely affect the Covered Individual's primary commitment to TSRI.

#### **5.4G How and When to Make Disclosures and Certifications**

##### **5.4G(1) Responsibility of Covered Individuals**

All Covered Individuals have the responsibility for disclosing Conflicts of Interest, Significant Financial Interests and Conflicts of Commitment. In addition, all Covered Individuals shall annually certify to TSRI their compliance with this Policy. Both the disclosure and certification requirements are met when a Covered Individual has accurately completed, signed and filed with the CRO the applicable disclosure form. Disclosure forms are available at: (<http://coi.scripps.edu>).

All Covered Individuals have the responsibility to respond fully and in a timely manner to inquiries from the CRO in connection with a disclosure under this policy. Failure to follow the certification and/or disclosure procedures set forth below may result in disciplinary action, including but not limited to limiting the Covered Individual's research privileges, or termination of employment.

##### **5.4G(2) Timing of Disclosures and Certifications**

The disclosure and certification requirements described in [5.4G\(1\)](#) must be met at each of the following times:

- when a Covered Individual is hired or begins using TSRI facilities;
- when a Covered Individual applies to an outside entity for funding to support Sponsored Research;
- no more than 30 days after either a new Significant Financial Interest arises or there is a change in a previously disclosed Significant Financial Interest which results in a Covered Individual's most recent disclosure and certification becoming incomplete or inaccurate; and
- within the time period for response to the CRO's annual request for recertification.

#### **5.4G(3) Research Funding (Grant) Application Requirements**

Many aspects of this Policy are designed so that TSRI and its Faculty comply with Federal Conflict of Interest regulations relating to application for and administration of Federal research and educational activities sponsored by PHS or the National Science Foundation (NSF). TSRI generally applies these Federal requirements to all research funding applications that are submitted to an outside entity. Thus, the Principal Investigator must certify to TSRI's Office of Sponsored Programs that all the Investigators on the federal grant application have updated their Conflicts of Interest and Commitment Disclosure Form they have on file with the CRO and thus is complete and accurate as of the date the research funding application is sent to the outside entity. More specific requirements related to disclosure obligations for Investigators engaged in PHS-supported Sponsored Research are set forth in [Appendix A](#) of this Policy.

#### **5.4G(4) An Award of Research Funding Creates Responsibilities**

The Office of Sponsored Programs and the Research Services identify Significant Financial Interests disclosed by Covered Individuals relating to Sponsored Research supported by an award. The CRO ensures that all Covered Persons performing Sponsored Research supported by the award either have no Financial Conflicts of Interest, or, if they do, that the Financial Conflicts of Interest have been appropriately managed.

#### **5.4G(4)a Subrecipients of an Award of Research Funding**

The Office of Sponsored Programs ensures that all subrecipients under an award execute an appropriate sub-award agreement. In situations where TSRI carries out Sponsored Research through a subrecipient (e.g., subgrantees, contractors, or collaborators), TSRI will take reasonable steps to ensure that (1) the entity has its own policies in place that meet the requirements of this Policy or (2) Investigators working for such entities follow applicable provisions of this Policy. Subrecipients that rely on their own policy must provide to TSRI a copy of such policy upon request. More specific requirements related to subrecipients engaged in Sponsored Research funded by PHS are set forth in [Appendix A](#).

#### **5.4G(5) Disclosures in Presentations and Publications**

TSRI requires that publications of research results contain acknowledgment to all sources of funding used in the research. TSRI recommends the

disclosure of a Covered Individual's Significant Financial Interests in verbal presentations of research results.

#### 5.4H Outside Professional Activities

##### **5.4H(1) Approval Required for Paid Outside Professional Activities**

A Covered Individual who is a member of TSRI's Professional Staff (Faculty and Scientific Staff) or holds an Executive Position at TSRI shall first obtain approval from the CRO before engaging in any Outside Professional Activity for which the individual will receive compensation (excluding reimbursement for out-of-pocket expenses). The form entitled, "Approval Request for Outside Professional Activities," is available at <http://intranet.scripps.edu/compliance>. Such approval is not required for seminars, lectures, or service on advisory committees or review panels for government or organizations (although in some circumstances these activities may require approval pursuant to the Conflict of Interest provisions of this Policy). Approval of such requests will be based on compliance with this Policy and all other relevant policies of TSRI.

##### **5.4H(2) Approval Required for Service in an Executive Position**

A Covered Individual shall first obtain approval from the CRO before beginning service in an Executive Position for a Business.

#### 5.4I Review and Management of Conflict of Interest, Significant Financial Interests, and Conflict of Commitment Disclosures

##### **5.4I(1) Disclosure Review and Reporting Obligations**

All disclosures shall be reviewed by the CRO in a timely and objective manner to determine if a Conflict of Interest or Commitment appears to exist. If a Conflict of Interest or Commitment is identified, the CRO shall develop a plan to properly eliminate or manage the Conflict of Interest or Commitment, as specified in [section 5.4I\(4\)](#) of this Policy.

In those instances where Sponsored Research is involved, TSRI will make reports to appropriate external sponsors to the extent required by and in accordance with its funding agreement with the sponsor and applicable law and regulation. For PHS-funded research and activities, the notification shall be in the manner specified in Appendix A. For NSF-funded research and educational activities, TSRI will keep NSF's Office of General Counsel appropriately informed if TSRI finds that it is unable to satisfactorily manage a conflict of interest..

No activity can commence relating to new situations without approval from the CRO. In those instances where Clinical Research is involved and a Conflict of Interest arises, TSRI will notify the Institutional Review Board accordingly.

##### **5.4I(2) Implementing Guidelines for Conflicts of Interest**

When implementing this Policy, the CRO shall consider the purposes for managing Conflicts of Interest. The first purpose is to maintain the integrity of professional judgment. In the research context, this means to prevent significant financial interests from affecting the design, conduct, or reporting of research. The second purpose is to maintain public confidence in professional judgment by minimizing conditions that would cause

reasonable persons to believe that professional judgment has been improperly influenced, whether or not it has.

The CRO's obligation is to implement this Policy in a way that creates an environment of integrity and confidence. The management technique applied to a Conflict of Interest situation will depend on, among other things, the severity of the Conflict. The CRO assesses the severity of a Conflict by examining both the possibility for bias and the seriousness of the possible harm. Factors affecting the possibility for bias may include, for example;

- value of financial interest;
- nature of relationship;
- length of time it has existed;
- role of the individual in the activity.

Factors affecting the possibility for harm may include, for example :

- direct or indirect possibility for harm;
- nature of activity;
- research - basic vs. clinical;
- scope of consequences;
- will the Conflict affect research of others or harm TSRI;
- extent of accountability.

#### **5.4I (2)a Implementing Guidelines for Financial Conflicts of Interest in Sponsored Research**

For Sponsored Research, the CRO will review disclosures and make the determinations set forth in this Section. For each disclosed Significant Financial Interest, the CRO will determine (a) whether the Significant Financial Interest is related to the Sponsored Research and, if so related, (b) whether the Significant Financial Interest is a Financial Conflict of Interest. A Covered Individual's Significant Financial Interest is related to the Sponsored Research when the CRO reasonably determines that the Significant Financial Interest could be affected by the Sponsored Research or is in an entity whose financial interest could be affected by the research. A Financial Conflict of Interest exists when the CRO reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the Sponsored Research. The CRO's determination should be made before Sponsored Research funds are expended on research, or upon receipt of the disclosure.

#### **5.4I (3) Implementing Guidelines for Conflicts of Commitment**

When implementing this Policy, the CRO shall consider the purposes for managing Conflicts of Commitment. The CRO shall assess a Covered Individual's disclosure of Outside Professional Activities to determine whether the Covered Individual's responsibilities to TSRI have been or reasonably appear to be compromised or may potentially be compromised. The evaluation is made to ensure that a Covered Individual's Outside Professional Activities are not so demanding of time and attention that they interfere with the Covered Individual's responsibilities to TSRI.

#### **5.4I (4) Management Techniques**

The CRO shall impose such conditions or restrictions as the CRO deems appropriate to manage, reduce or eliminate identified Conflicts of Interest or Commitment. All Covered Individuals shall promptly comply with any management plan and other directives imposed by the CRO. Where Sponsored Research is funded by a Federal agency, such management plan shall be developed and implemented prior to the expenditure of award funds. The management plan shall specify the actions that have been or will be taken to manage, reduce or eliminate the Conflict of Interest. Examples of conditions or restrictions that might be imposed to manage a Conflict of Interest include, but are not limited to: (i) public disclosure of the Conflict of Interest; (ii) for Clinical Research, disclosure of Conflicts of Interest directly to participants; (iii) monitoring of research by independent reviewers; (iv) modification of research plans; (v) change of personnel or personnel responsibilities, or disqualification from participation in Federally funded research; (vi) reduction or elimination of the Significant Financial Interest; and (vii) severance of relationships that create the Conflict of Interest.

The CRO shall monitor Covered individual compliance with a management plan until completion of the research project.

Determination of the existence of a Conflict of Interest and the means identified for eliminating or managing the conflict will be communicated in writing to the affected Covered Individual and other appropriate personnel. When applicable, for Sponsored Research, the appropriate manager responsible for grant and contract administration will also be notified of pertinent facts needed for grant administration and regulatory compliance.

Failure to complete the necessary forms or comply with a management plan may result in disciplinary action, including, without limitation, limiting the individual's research privileges, reassignment, demotion, and termination of employment.

#### **5.4I (5) Review of CRO Decisions**

Any determination and/or recommendation made by the CRO with respect to a Covered Individual is subject to review by the President, or by the Board of Trustees on recommendation of the Professional Affairs Committee.

#### **5.4I (6) Record Retention**

Records of TSRI's actions and of all disclosures under this Policy will be maintained for at least three (3) years. For actions and disclosures related to Sponsored Research, the three (3) year period begins after submission of the final award expenditure report or as otherwise required by the external agreement or applicable regulations. Upon authorized request of a sponsoring entity, disclosure documents and related records pertaining to the specific Sponsored Research will be made available to appropriate officials.

### **APPENDIX A: Additional Provisions Applicable to U.S. Public Health Service (PHS) Sponsored Research [1](#)**

Research funded by or proposed for funding by the U.S. Public Health Service (PHS), including the National Institutes of Health, is subject to certain requirements imposed by PHS regulations, as amended from time to time (see <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). Such research is also subject to the Policy and this Appendix A. To the extent of any conflict between a provision of the Policy and a provision of this Appendix A, the provision of this Appendix A shall govern.

TSRI has implemented the PHS requirements in the Policy, and as follows.

### **1. Disclosure Obligations**

In addition to the obligation to disclose Significant Financial Interests as set forth in Section 5.4G of the Policy, Investigators seeking to engage in or engaged in PHS-funded research also must disclose the occurrence of any reimbursed or sponsored travel received in the preceding 12 months related to their Institutional Responsibilities, unless the travel is reimbursed or 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. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration. Sponsored travel means travel that is paid on behalf of the Investigator and not reimbursed to the Investigator (so that the exact monetary amount may not be readily determined). Investigator travel meeting these criteria must be disclosed at <https://travel.scripps.edu>.

### **2. Review of Disclosed Interests**

If, during the course of an ongoing PHS-funded project, a Significant Financial Interest is disclosed by a new Investigator or an existing Investigator discloses a Significant Financial Interest not previously reported, or it comes to the attention of TSRI officials that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by an Investigator, the interest shall be reviewed pursuant to Section 5.4I(2) of the Policy within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a Financial Conflict of Interest. If the CRO determines that a Financial Conflict of Interest exists, the CRO shall implement, on at least an interim basis, a management plan, as set forth in Section 5.4I(4) of the Policy, that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

### **3. Retrospective Review**

Whenever a Financial Conflict of Interest involving PHS-funded research is not identified in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined by the CRO to constitute a Financial Conflict of Interest, failure by the CRO to review or by TSRI to manage such a Financial Conflict of Interest, or failure by the Investigator to comply with a management plan, the CRO shall, within 120 days of his/her determination of noncompliance, complete a retrospective review of the Investigator's activity and the PHS-funded research to determine whether any PHS-funded research, or portion thereof, conducted during the time period of noncompliance was biased in design, conduct, or



reporting of such research.

The CRO will document the retrospective review. Such documentation shall include the following elements: (i) Project/Contract number and title; (ii) principal investigator/project director; (iii) name of the Investigator with the Conflict of Interest; (iv) name of entity in which the Investigator has a Significant Financial Interest that gives rise to the Financial Conflict of Interest; (v) reason for the retrospective review; (vi) detailed methodology used for the retrospective review; (vii) findings of the review; and (viii) conclusions of the review.

#### **4. Financial Conflict of Interest Reports to PHS**

Prior to TSRI's expenditure of any funds under a PHS-funded research project, TSRI will provide the PHS Awarding Component with a Financial Conflict of Interest Report (Report) regarding any Significant Financial Interests, including Significant Financial Interests of subrecipient Investigators, related to the PHS-funded research that TSRI finds to be a Financial Conflict of Interest and, to the extent required by regulation, will ensure that TSRI has implemented a management plan as set forth in Section 5.41(4) of the Policy. In addition, during the course of a PHS-funded research project, TSRI will provide the PHS Awarding Component with a Report within 60 days of identifying any Significant Financial Interest that TSRI identifies as a Financial Conflict of Interest subsequent to its initial Report.

The Report will contain all elements required by regulation, which may include: (i) Project/Contract number; (ii) principal investigator/project director; (iii) name of the Investigator with the Financial Conflict of Interest; (iv) name of entity in which the Investigator has Significant Financial Interest that gives rise to the Financial Conflict of Interest; (v) nature of the financial interest; (vi) value of the financial interest, within dollar ranges, or if the value cannot be readily determined through reference to public prices or other reasonable measures, a statement to that effect; (vii) a description of how the financial interest relates to the PHS-funded research and the basis for TSRI's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of the management plan, including (a) the role and principal duties of the conflicted Investigator in the research project, (b) conditions of the management plan, (c) how the management plan is designed to safeguard objectivity in the research project, (d) confirmation of the Investigator's agreement to the management plan, (e) how the management plan will be monitored to ensure Investigator compliance, and (f) other information as needed.

If a retrospective review is performed as provided for in Section 3 of this Appendix A, previously submitted Reports affected by the review will be updated to specify the actions taken to manage the Financial Conflict of Interest going forward. If the retrospective review finds that the PHS-funded research was biased, TSRI will promptly notify the PHS Awarding Component and submit a mitigation report, which shall include: (i) the key elements documented in the retrospective review; (ii) a description of the impact of the bias on the research project; and (iii) TSRI's plan of action or actions taken to eliminate or mitigate the effect of the bias.

TSRI will submit updated Reports annually to PHS, addressing the status of previously identified Financial Conflicts of Interest and any changes to management plans, including whether the Financial Conflict of Interest is still being managed or, if it no longer exists, an explanation as to why it no longer exists. Reports will be submitted for the duration of the PHS-funded project period.

#### **5. Subawardees and Collaborators**

If TSRI carries out PHS-funded research through a subrecipient (e.g., subgrantees, contractors, or collaborators), TSRI will include in its written agreement with the subrecipient a statement as to whether the financial conflicts of interest policy of TSRI or that of the subrecipient applies to the subrecipient's Investigators.

If the subrecipient's financial conflicts of interest policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. If the subrecipient cannot make such a certification, TSRI's policy and this Appendix A as applied to TSRI Investigators in Sponsored Research will apply to subrecipient Investigators.

If the subrecipient's financial conflict of interest policy applies, TSRI will include in the subrecipient agreement time periods for the subrecipient to report all identified Financial Conflicts of Interest to TSRI. Such time periods must provide TSRI with sufficient time to review the reports and make timely reports to PHS, as necessary.

If subrecipient Investigators are subject to TSRI's policy, the subrecipient agreement will specify time periods for the subrecipient Investigators to submit Investigator disclosures of Significant Financial Interests to TSRI so that TSRI has sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under this Policy related to Sponsored Research.

#### **6. Public Disclosure of Information**

TSRI shall make this policy available via a publicly accessible website. In addition, prior to the expenditure of any funds under a PHS-funded research project, TSRI will make available, either via a publicly accessible website or by responding within five (5) days to any written request, information concerning any Significant Financial Interests determined by TSRI to be a Financial Conflict of Interest held by a principal investigator or project director or any other individual who has been identified by TSRI as key personnel on the PHS-funded project. Such information will remain available, for response to written requests or disclosure via TSRI's publicly accessible website, for at least three years from the date that the information was most recently updated.

In situations where the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by TSRI as required by this Policy, TSRI 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.

#### **7. Notification to PHS**

TSRI will promptly notify the PHS Awarding Component if failure of an Investigator to comply with this Policy as it relates to Financial Conflicts of Interest in Sponsored Research or a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research.

#### **8. Training**

Prior to engaging in PHS-funded research, Investigators will be required to complete training regarding the requirements set forth in this Policy. Training shall be updated every four (4) years, and immediately when any of the following circumstances apply: (i) TSRI revises its policy in a manner that affects the requirements for Investigators with regard to financial interests; (ii) an Investigator is new to TSRI; or (iii) TSRI finds that an Investigator is not in compliance with the Policy or management plan implemented thereunder. TSRI has established on-line training that is available at <http://coitraining.scripps.edu>.

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<sup>1</sup> The term "research" as used in this Appendix A includes any activity for which research funding is available from a PHS Awarding Component, including a research grant, career development award, center grant, individual fellowship award, institutional training grant, program project, or research resources award.