

# TRUDEAU INSTITUTE

IMPROVING HEALTH THROUGH MEDICAL RESEARCH

## Trudeau Institute, Inc. Financial Conflicts of Interest Policy

### I Purpose

The purpose of the Financial Conflicts of Interest (FCOI) policy is to promote objectivity in research through full disclosure of related financial interests and compliance with standards intended to ensure that the design, conduct, financial management, and reporting of research will not be biased by any related significant financial interest.

Its implementation also ensures compliance with the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94) as published in the Code of Federal Regulations [Federal Register: August 25, 2011 (vol.76, number 165)].

This policy is intended to supplement but not replace any applicable state laws governing conflicts of interest applicable to nonprofit and charitable corporations.

### II Definitions

- A. “Family” means an Investigator’s spouse, domestic partner or dependent children.
- B. “Equity Interest(s)” means stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.
- C. “Financial Conflict of Interest” or “FCOI” means a Significant Financial Interest (as defined in Section G below) that could directly and significantly affect the design, conduct, or reporting of PHS or NSF-funded research.
- D. “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the Institute, including but not limited to, activities such as research, research consultation, teaching, administration, institutional committee memberships, and service on panels such as Institutional Review Boards.
- E. “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.
- F. “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.
- G. “Significant Financial Interest” or “SFI” means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- b. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3. 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.

### III. Procedures

#### A. Duty to Disclose

Investigator(s) (including any person responsible for the design, conduct or reporting of the funded research) must disclose any SFI at the following time(s):

1. at the time of application for PHS-funded research;
2. annually during the period of the award;
3. within thirty (30) days of discovering or acquiring any new SFI during the term of a grant.

The Administration will maintain disclosure forms, to be completed by each Investigator, which will require the Investigator to disclose reportable SFIs, or certify that he or she has no such interests.

#### B. Determining Whether a Conflict of Interest Exists

After disclosure of the financial interest and all material facts, and after discussion with the interested person, the designated official (appointed by the President/Director) will determine if a conflict of interest exists.

#### C. Procedures for Addressing the Conflict of Interest

If it is determined that the SFI is related to the Investigator's PHS or NSF-funded research, the Institute's President/Director will appoint an *ad hoc* committee (the "COI Committee", which generally will include the Institute's Chief Scientific Officer, Chief Financial Officer, and one or more additional members) to determine if such interest could constitute a potential FCOI by directly and significantly affecting the design, conduct or reporting of the funded research, and whether such SFI can be managed. The COI Committee will submit its recommendations to the President/Director, who will determine if the FCOI can be managed or eliminated. If s/he concludes that the FCOI can be managed, the Chief Operating Officer, in consultation with the COI Committee and the Investigator, will develop a FCOI management plan for the President/Director's approval. Examples of conditions or restrictions that might be imposed to manage FCOIs include, but are not limited to:

1. public disclosure of SFIs;
2. monitoring of research by independent reviewers;
3. modification of the research plan;
4. disqualification from participation in all or a portion of the research funded by the granting agency;
5. divestiture of SFIs; or

6. severance of relationships that create actual or potential FCOIs.

The aim of a management plan is to ensure open and timely dissemination of research results, protect trainees, and preserve the integrity of the research. The Investigator will be asked to acknowledge in writing that he or she understands and will comply with any conditions imposed by the President/Director for managing or eliminating a FCOI. Should he or she decline or fail to agree to these conditions, the Institute will take appropriate disciplinary action, including without limitation suspending the Investigator's research and, with requisite approval of NIH, designating a substitute Investigator.

If the President/Director reports an SFI, the chair of the Board of Trustees will be responsible for assembling the COI Committee, in consultation with the Chief Financial Officer, and determining if the financial interest constitutes a potential FCOI. With concurrence of the Executive Committee of the Board of Trustees, the chair will implement measures to manage or eliminate any FCOI of the President/Director.

D. Subrecipients

The PHS rules require the Institute to take reasonable steps to ensure that subcontractors or subrecipients comply with the federal rules. Therefore, when the Institute carries out the PHS-funded research through a subrecipient, the Institute will incorporate, as part of a written agreement with the subrecipient, terms that 1) require the subrecipient to maintain a FCOI policy that complies with federal requirements and 2) establishes whether the Institute's or subrecipient's FCOI policy will apply to the subrecipient Investigators. If the subrecipient's policy will apply, the subrecipient must report any FCOIs to the Institute within forty-five (45) days of identification so that the Institute can report them to the PHS in a timely manner (see Section II.E below for additional information on reporting).

Alternatively, if the Institute's FCOI policy will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFIs to the Institute. Such time periods shall be sufficient to enable the Institute to comply with timely review, management, and reporting obligations under the federal rules as described in Section II.G.

If the Institute is a subrecipient of PHS funds, this policy will apply to the required FCOI review, rather than the policy of the subawarding organization.

E. Violations of the Conflicts of Interest Policy

If an Investigator fails to comply with the provisions of this policy, or with any conditions for managing or eliminating a FCOI mandated by the President/Director, the President/Director will discuss the violation with the Investigator and attempt to remedy it informally. If the President/Director is unable to reach a resolution, he or she shall impose appropriate sanctions up to and including suspension or termination of the Investigator.

#### F. Public Access

The Institute will make available to the public upon request, information concerning any SFI disclosed to the Institute that meets the following three criteria:

1. The disclosed SFI is still held by an Investigator of an active PHS-funded project;
2. The Institute determines that the SFI is related to the PHS-funded research; and
3. The Institute determines that the SFI is a FCOI.

The Institute will respond within five (5) business days of receipt of a request for public disclosure. The response 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 SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges, as set forth in the PHS rules, may be used), 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. The Institute will note in its written response that the information provided is current as of the date of correspondence and is subject to updates on at an annual basis, or within sixty (60) days of the identification of new FCOI. The requester must ask for any such updates if s/he desires them. FCOI information will remain available for three (3) years from the date the information was most recently updated.

#### G. Reporting

Prior to the Institute's expenditure of grant funds from the PHS, it will report to the PHS any FCOIs found by the Institute that have not been eliminated, and, along with certain other details required by the PHS, will provide assurance that the FCOI has been managed.

When FCOIs are identified during the term of the grant for an Investigator newly participating in the project, or the Institute identifies a new FCOI for an existing Investigator, the Institute will report such FCOIs to the PHS within sixty (60) days of identification.

Upon submission of annual progress reports, multi-year progress reports, if applicable, or at the time of extension, the Institute shall provide the PHS with the status of a reported FCOI and any changes to the management plan, if applicable, until the completion of the project.

Each report to the PHS must include sufficient information to enable the agency to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The required information includes:

1. project number;
2. project title;
3. name of Principal Investigator or contact PI if multiple PD/PI model;
4. name of Investigator with FCOI;
5. name of the entity in which the Investigator has a FCOI;
6. reason for the retrospective review;
7. detailed methodology used for the retrospective review;

8. findings of the review; and
9. conclusions of the review.

#### H. Reviews

Whenever the Institute identifies a SFI that was not disclosed in a timely manner by the Investigator, or for whatever reason was not timely reviewed by the Institute, the Institute will determine whether the SFI constitutes a FCOI within sixty (60) days thereafter and implement an appropriate management plan.

If the FCOI was not identified or managed in timely manner, as when 1) the Investigator failed to disclose a SFI that subsequently was found by the Institute to constitute a FCOI, 2) the Institute failed to review or manage such FCOI, or 3) the Investigator failed to comply with the FCOI management plan, the Institute shall complete a retrospective review of the Investigator's activities and the PHS-funded research project. The purpose of the retrospective review, which must occur within 120 days of the Institute's determination of noncompliance, is to determine whether any PHS-funded research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

The Institute will document the retrospective review, which documentation must include, but not necessarily be limited to, all of the following key elements: project number and title; name of principal investigator, name of the Investigator with the FCOI; the name of the entity with which the Investigator has a FCOI; reasons for the retrospective review; detailed methodology used for the retrospective review, review findings and conclusions.

As appropriate, the Institute will update any previously submitted FCOI report with information describing how the FCOI will be managed going forward.

If bias is found after a retrospective review, the Institute will promptly notify the PHS and follow up with a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

#### I. Training

Prior to engaging in any research project, all Investigators must complete training on the Investigator's obligations under this policy and repeat the training at least every four years. Training must be completed immediately (i) if this policy is revised to the extent that it affects Investigators' obligations; (ii) when an Investigator is new to the Institute; or (iii) when the Institute finds an Investigator to have violated this policy or any applicable management plan.