

## **INSTITUTE FOR PROTEIN INNOVATION FINANCIAL CONFLICT OF INTEREST POLICY**

### **INTRODUCTION**

The Institute for Protein Innovation (IPI) was created to forge new models of collaboration between industry and academia. Many societal, institutional and individual benefits emerge from academic scientists working with industry partners. For example, collaborations/interactions allow new technologies to be created and commercialized more rapidly and novel therapeutics to be fully developed. At the same time, these relationships can give rise to conflicts that compromise the integrity and objectivity of research.

IPI is therefore committed to creating a research environment that ensures the design, conduct and reporting of research that is partially or wholly funded by the US Public Health Service (PHS) (which includes the National Institutes of Health (NIH)) is free from any bias resulting from financial conflicts of interest.

This policy augments IPI's Research Misconduct and IPI's Conflict of Interest Policies for the Board of Directors, Officers and Key Employees, who have a fiduciary duty of loyalty to IPI.

### **DEFINITIONS**

**Conflict of Interest Committee** (COI Committee) is the committee chartered by the Board of Directors to advise the Board of Directors, Institute and the Institutional Official on conflict of interest matters.

**Family** means any member of the Investigator's immediate family, specifically, any dependent children or 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 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, and 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 IPI;
- b) income from the authorship of academic or scholarly work;

- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for US Federal, state or local governmental agencies; US institutions of higher education; 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 institutional responsibilities. This travel may have been paid on behalf of the Investigator or reimbursed. Excluded is travel reimbursed or sponsored by US Federal, state or local governmental agencies; US institutions of higher education; research institutes affiliated with institutions of higher education; academic teaching hospitals; and medical centers.

**Financial Conflict of Interest** means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of the Institution's research.

**Institution** is the Institute for Protein Innovation (IPI), a non-profit 501(c)(3) medical research organization, incorporated in the Commonwealth of Massachusetts, with offices and laboratories at 4 Blackfan Circle, Suite 921, Boston, MA 20115.

**Institutional Official** means the individual within the Institution, responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's Family related to the Investigator's institutional responsibilities. For this Policy, the Institutional Official is designated as the Director of Finance.

**Institutional Responsibilities** means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration and institutional, internal and external professional committee service.

**Investigator** means any individual responsible for the design, conduct or reporting of research or proposals for such funding. This definition is not limited to those titled or budgeted as Principal Investigator or Co-investigator on a particular proposal and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants, as appropriate.

**Public Health Service** means the Public Health Service of the US Department of Health and Human Services (HHS) and any PHS components 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, 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, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

**Significant Financial Interest** means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 months preceding the disclosure, and the value of any equity interest during the 12 months 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 months 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 months preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e) is reimbursed or sponsored travel related to their institutional responsibilities.

### **CONFLICT OF INTEREST:**

This policy is predicated on the expectation that Investigators should conduct their affairs to avoid or minimize conflicts of interest and 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 Institution to manage those conflicts of interest that arise, and describes prohibited situations. Every Investigator must become familiar with and abide by the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

## 1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests, as defined above, to the Institution on an annual and *ad hoc* basis, as described below. The Institutional Official is responsible for distributing, receiving, processing, reviewing, and retaining disclosure forms.

### a) Annual Disclosures

All Investigators must disclose Significant Financial Interests that are related to the Investigator's institutional responsibilities through the Institutional Official on an annual basis. All forms should be filed annually to the Institutional Official or Designee by January 1 (reflecting the previous calendar year) or some other date as determined by the Institute or when there is a change in required information.

### b) Ad hoc Disclosures

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

Prior to entering into PHS-sponsored projects or applications for PHS- sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an *ad hoc*, updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such *ad hoc* disclosures.

All Investigators must also submit to the Institutional Official an *ad hoc* disclosure of any Significant Financial Interests acquired or discovered during the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

### c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant 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 Institutional 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.

## 2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, the case will be reviewed promptly by the Institutional Official or Designee to determine whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest is determined to exist, the Institutional Official will manage the financial Conflict of Interest, including the reduction or elimination of the conflict, as appropriate. The Institutional Official may consult the Executive Director, Chairman of the Conflict of Interest Committee of the Board of Directors or an independent consultant for guidance in specific cases.

A Financial Conflict of Interest will exist when the Institutional Official or Designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of research. If the Institutional Official determines a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategy and sign the written management plan before any related research resumes.

The Institutional Official will periodically review ongoing activity and monitor conduct (including use of students and postdoctoral appointees) to ensure the open and timely dissemination of research results and to otherwise oversee compliance with the management plan.

## 3) REPORTING TO PHS

The Institutional Official will report Financial Conflicts of Interest or non-compliance to the PHS in accordance with its regulations. If the funding for the research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest such that the prime awardee may fulfill their reporting obligations to the PHS.

## 4) INVESTIGATOR NON-COMPLIANCE

### a) Disciplinary Action

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

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to abide by the decision of the Institutional official, will be described in a written explanation of the decision to the Investigator and will notify the individual of the right to appeal the decision to the Executive Committee. The Institution will promptly

inform the Awarding Organization of the action taken or to be taken. If funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) **Retrospective Review**

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official will conduct a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. All such determinations must be reviewed by an Ad Hoc Review Committee or the Board of Director's Conflict of Interest Committee. If the Review Committee determines that the Institutional Official failed to adequately address the conflict in the initial review, the Institute will engage an independent reviewer to complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, Principle Investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, the detailed methodology used for the retrospective review and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the sponsoring organization or the prime awardee relating to the research, specifying the actions taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the timeframe established in the Awarding organization regulations. If bias is found, IPI will promptly notify the Awarding Organization and submit a mitigation report in accordance with the Awarding Organization's regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5) **TRAINING**

Prior to engaging in research funded by PHS and at least every four years thereafter, each Investigator must complete training on this Policy, as well as his or responsibilities regarding

disclosure and PHS regulations. Investigators must complete training within a reasonable period, as determined by the Institutional Official, if this Policy is substantively amended in a manner that affects the requirements of Investigators; the Investigator is new to the Institution; or the Investigator has not complied with this Policy or with a management plan related to his or her activities.

#### **6) RECORD RETENTION**

The Institutional Official will retain all disclosure forms, conflict management plans and related documents for three years, beginning from the date that the final expenditure report was submitted to the Awarding Organization or the prime awardee, unless any litigation claim, financial management review or audit is begun before the expiration of the three years. The records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action is taken.

#### **7) CONFIDENTIALITY**

All disclosure forms, conflict management plans, and related information will be confidential to the extent permitted by law. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS; 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 Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans and related information to an outside entity, the Investigator will be informed of this disclosure.

#### **8) PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, the Institution will publish on a publicly accessible website or respond to any requestor within five business days of the request information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) a determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

#### 9) **REGULATORY AUTHORITY**

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Adopted by the Institute for Protein Innovation on March 19<sup>th</sup>, 2017 and amended on January 6<sup>th</sup>, 2021.