

# **THE FORSYTH INSTITUTE** **RESEARCH CONFLICT OF INTEREST POLICY**

## **I. INTRODUCTION**

As an independent academic research institution, The Forsyth Institute (“Forsyth”) encourages its staff to seek and participate in sponsored research in order to foster Forsyth’s core mission of advancing human health and wellbeing through scientific discovery and education. While the complexity of the research relationships that Forsyth and its scientific staff have with industry, government and other entities is increasing, the overriding principle that financial and other personal considerations cannot compromise, or appear to compromise, a staff member’s professional judgment in conducting or reporting research results remains a priority at Forsyth. Forsyth is committed to ensuring that the objectivity of its staff members is never threatened by obligations owed to companies or organizations that sponsor research at Forsyth.

Many of the Forsyth staff conduct research that is supported by public funds and thus incur a specific obligation to preserve the public trust. The Federal Government requires that Forsyth ensure that such members of its staff are aware of potential conflicts of interest arising from interrelationships with Federal agencies and commercial sponsors and their obligation to notify Forsyth of all outside activities that may have conflict of interest implications.

To further these goals in compliance with all applicable Federal policies, Forsyth has developed this policy which establishes clear guidelines and principles to enable its staff to appropriately structure and maintain their relationships with industry in a manner that is ethically and legally appropriate and in no way whatsoever compromises the integrity of the research conducted at Forsyth. This Policy is designed to increase awareness of the Forsyth staff of the potential for financial conflicts of interest, and to establish procedures for identifying and addressing financial conflicts of interest.

## **II. DEFINITIONS**

For the purposes of this Forsyth Institute Conflict of Interest Policy (“Policy”) the following definitions shall apply.

“Clinical Trial” means any research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

“Conflict of Interest Committee” (“COI Committee”) means Forsyth’s committee or individual that advises the Institutional Official on conflict of interest matters.

“Entity” is any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (defined below) or any member of his/her family receives remuneration or in which any such person has an ownership or equity interest.

“Family” means any member of an Investigator’s immediate family, specifically, any dependent children and spouse.

“Financial Conflict of Interest” or “FCOI” occurs when Forsyth, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a research project that he or she is conducting at Forsyth and could directly and significantly affect the design, conduct or reporting of such research project.

“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 Forsyth;
- 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 institutional 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. With respect to any such reimbursed or sponsored travel, Investigators must disclose the (i) purpose of the trip, (ii) identity of the sponsor/organizer, (iii) destination and (iv) duration.

“Institutional Official” means the individual within Forsyth that is responsible for the solicitation and review of disclosures of Investigator’s Significant Financial Interests, including those of the Investigator’s Family, related to the Investigator’s Institutional

Responsibilities. For the purposes of this Policy, the Institutional Official is designated as Paul McDonough, the Vice President of Operations.

“Institutional Responsibilities” an Investigator’s professional responsibilities on behalf of Forsyth, including, but not limited to, research, research consultation, teaching, mentoring, professional practice, Institutional committee memberships, and services on panels such as institutional review boards and data/safety monitoring boards.

“Investigator” is the Project Director/Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of a research project at Forsyth. 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, graduate students or laboratory technicians. The definition may also include collaborators, visiting scientists or consultants, as appropriate.

“Public Health Service” or “PHS” is the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

“Senior/Key Personnel” are the Project Director/Principal Investigator and any other person identified as senior/key personnel by Forsyth in the grant, application, progress report or any other report submitted to the NIH by the Institution.

“Significant Financial Interest” includes the following:

Financial Interest consisting of one or more of the following interests of the Investigator or Investigator’s Family that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

- a) with regard to a publicly traded Entity, a Significant Financial Interest exists if the value of any remuneration received from such Entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the Entity as of the date of disclosure, when aggregated, exceeds five thousand U.S. dollars (\$5,000). For purposes of this definition, remuneration includes salary and 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 a non-publicly traded Entity, a Significant Financial Interest exists if the value of any remuneration received from the Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds five thousand U.S. dollars (\$5,000) or is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- c) income related to intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income by the Investigator related to such rights and interests.

### **III. PRINCIPLES**

#### **a) General Principles**

Forsyth's Investigators must ensure the integrity of their research by taking steps to avoid conflicts of interest or even the appearance of conflicts of interest. It is recognized that due to the complexity and diversity of personal relationships as well as the fact that the perception of a conflict of interest varies from one individual to another, the most effective means to address conflicts of interest at Forsyth is to establish a system under which employees disclose their conflicts of interests and Forsyth evaluates them.

#### **b) Areas in which Financial Conflicts of Interest may arise**

A Financial Conflict of Interest may arise in the relations of a Forsyth Investigator with any Entity:

1. that supplies goods and services to Forsyth;
2. from whom Forsyth leases property and equipment;
3. with whom Forsyth is dealing or planning to deal in connection with a gift, purchase or sale of real estate, securities or other asset;
4. that donates funding or otherwise supports Forsyth; or
5. that sponsor or support research at Forsyth.

#### **c) External Consulting Arrangements**

Forsyth recognizes and agrees that its Investigators may be engaged by industry to provide external consulting services in connection with the design, development, testing, evaluation, regulatory review and approval of products or to be a member of a scientific advisory board or other such safety board or to make presentations. The performance of such external consulting services in compliance with this Policy is permitted provided that the Forsyth staff member does not utilize Forsyth's equipment or resources, or violate Forsyth's policies.

### **IV. DISCLOSURES**

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

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual Financial Conflict of Interest or be perceived to present a Financial Conflict of Interest.

#### **a) Annual Disclosures**

All Investigators must disclose their Significant Financial Interests to Forsyth, through the Institutional Official, on an annual basis in accordance with the policies established by Forsyth..

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 sponsored research projects or applications for sponsored research projects, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. Forsyth will not submit a research proposal or enter into a research agreement unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional 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.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities. 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. This disclosure requirement does not apply to any travel that is reimbursed or sponsored by a federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher learning.

**V. CLINICAL TRIALS**

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

Financial Conflicts of Interest related to research involving human subjects pose special concerns. Forsyth and its Investigators have ethical obligations to honor the rights and protect the safety of persons who participate in research conducted at Forsyth. Where the proposed research project involves human subjects, the presumption against permitting a related startup company to sponsor the research is particularly strong. Any equity interest in the startup company (including stock options, warrants and instruments convertible into equity) or non-equity interest over \$5,000 in a year will almost always preclude the financially interested Investigator from conducting a human subjects research project sponsored by the startup company. The presumption may be overcome only in rare and compelling circumstances, as judged by the Conflict of Interest Committee and the Institutional Official, and where effective controls are implemented in order to mitigate any possible effects of such Financial Conflict of Interest. Such circumstances may include, for example, that the Investigator is uniquely qualified to perform the experimental procedure.

## **VI. REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL**

If a disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate. The Institutional Official may consult the COI Committee for guidance in specific cases, or in the application of this Policy to particular situations.

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 that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator or the COI Committee is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

## **VII. REPORTING TO PHS**

a) For all PHS funded awards, prior to the expenditure of any funds under the award, Forsyth shall submit to the funding agency a report of any Financial Conflict of Interest. Forsyth is required to submit additional reports annually during the award period, and within sixty (60) days of any subsequently identified Financial Conflict of Interest. If the funding for the research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

b) If a proposed PHS funded research project is to be carried out in whole or part by a subrecipient, Forsyth will incorporate as part of a written agreement with such subrecipient terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators, as well as the time frames within which the subrecipient must provide to Forsyth information necessary to ensure that Forsyth is meeting its reporting obligation to the relevant PHS funding agency.

## **VIII. 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 is implemented.

An Institutional 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 Institutional Official, will be described in a written explanation of the decision to the Investigator, COI Committee, and, where applicable, the IRB, and will notify the Investigator of the right to appeal the decision.

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, a committee appointed by the Institutional Official will 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, PI, 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, 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 PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including 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.

**IX. TRAINING**

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional 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 the Investigator has not complied with this policy or with a management plan related to their activities.

**X. RECORD RETENTION**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee.

**XI. CONFIDENTIALITY**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Forsyth may make such information available to an agency funding research of an Investigator, 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 Forsyth, if requested or required by law. If Forsyth is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **XII. PUBLIC ACCESSIBILITY**

Prior to the expenditure of funds, Forsyth 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 Investigator;
- 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 policy.

## **XIII. REGULATORY AUTHORITY**

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

## **XIV. REVISION OF THIS POLICY**

This Policy may be revised at any time by action of the authorized officials of Forsyth. Such revisions shall not affect the rights accrued prior to the date of such action.