

# Point Designs' Conflict of Interest Policy Statement

## I. BACKGROUND

Point Designs is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. Point Designs has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to Point Designs' other research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining Point Designs' high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

## II. PURPOSE

Point Designs has a duty to ensure that work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm patients, the reputation of Point Designs, the governmental agency providing the funding, or External Partners. In addition, Point Designs must comply with government regulations when making expenditures with Government Awards. This policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. It is intended to comply with the requirements of federal regulations, including , but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service ("the PHS FCOI Rules") as found in [42 C.F.R. Part 50, Subpart F](#) (titled Promoting Objectivity in Research) and [45 C.F.R. Part 94](#) (titled Responsible Prospective Contractors) and the Federal Acquisition Regulation [FAR 52.203-16](#) (collectively referred to as the "Financial Conflict of Interest Rules").

## III. DEFINITIONS

- A. **Disclosure of Significant Financial Interests** means an Investigator disclosing information about a Significant Financial Interest (SFI) to Point Designs.
- B. **External Partner**: a consultant, subcontractor, or subrecipient performing work under a Government Award who is not employed by Point Designs.
- C. **Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- D. **FCOI Report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- E. **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

- F. **HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- G. **Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
- H. **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- I. **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 (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.
- J. **Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- K. **PD/PI** means a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.
- L. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- M. **PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to [42 C.F.R. Part 50, Subpart F](#).
- N. **Public Health Service Act (PHS Act)** means the statute codified at [42 U.S.C. 201](#) et seq.
- O. **Research** means a systematic investigation, study or experiment designed to develop or 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). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- P. **Senior/key personnel** means the PD/PI and any other person identified as senior/key personnel by Point Designs in the grant application, progress report, or any other report submitted to the PHS by Point Designs.
- Q. **Significant Financial Interest (SFI)**
- a. 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:
    - i. 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;
- ii. 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
  - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. 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 details of this disclosure will include, at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Chief Executive Officer 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.
- c. The term significant financial interest does **not** include the following types of financial interests:
- i. 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;
  - ii. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - iii. 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;
  - iv. 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
  - v. 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.

- R. **Small Business Innovation Research (SBIR) Program** means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of [42 C.F.R. Part 50, Subpart F](#), the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

## IV. RESPONSIBILITIES OF INSTITUTIONS REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

Point Designs shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with [42 C.F.R. Part 50, Subpart F](#), and make such policy available to any requestor within five business days of a request.

Point Designs shall inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and renew training **every four years**, and immediately when any of the following circumstances apply:

- A. Revision of financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
- B. An Investigator is new to Point Designs; or
- C. An Investigator is not in compliance with its financial conflict of interest policy or management plan.

### Subrecipient Requirements

Awardee Institutions are responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the National Institute of Health (NIH).

Point Designs will take reasonable steps to ensure that any subrecipients (i.e., subcontractors or consortium members) performing work under a PHS-funded research project comply with the PHS Financial Conflict of Interest regulations by:

- A. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
  - a. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with [42 C.F.R. Part 50, Subpart F](#). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of Point Designs for disclosing significant financial interests that are directly related to the subrecipient's work for Point Designs;
  - b. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Point Designs. Such time period(s) shall be sufficient to enable Point

Designs to provide timely FCOI reports, as necessary, to the PHS as required by the FCOI policy;

- c. Alternatively, if the subrecipient's Investigators must comply with Point Designs' financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Point Designs. Such time period(s) shall be sufficient to enable Point Designs to comply timely with its review, management, and reporting obligations under the FCOI policy.
- B. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with 42 C.F.R. 50, Subpart F, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

## V. DISCLOSURE, REVIEW, AND MONITORING OF FINANCIAL INTERESTS DISCLOSED BY INVESTIGATORS

Point Designs designates the Chief Executive Officer as the institutional official to solicit and review disclosures of significant financial interest from each investigator who is planning to participate in, or is participating in, sponsored research. In the event the Chief Executive Officer has a conflict of interest, the President of Point Designs shall fulfill the duties typically performed by the Chief Executive Officer.

Each Investigator who is planning to participate in the PHS-funded research is required to:

- A. Disclose to the Chief Executive Officer the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
- B. Submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by Point Designs, during the period of the award. Such disclosure shall include any information that was not disclosed initially to Point Designs, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution) and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- C. Submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Each FCOI disclosure will be reviewed by the Chief Executive Officer or the President. The Chief Executive Officer is responsible for determining when an actual or potential conflict of interest exists in a given situation — that is, when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research — and for taking action as necessary to manage such conflicts of interest, including development and implementation of a management plan.

If it is found that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the federally funded research, the Director of Research will take actions as necessary to manage financial conflicts of interest, including any financial conflicts of a

subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to [§50.605\(a\)](#).

## MANAGEMENT AND REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Prior to the expenditure of any funds under a PHS-funded research project, the Chief Executive Officer shall:

- A. Review all Investigator disclosures of significant financial interests;
- B. Determine whether any significant financial interests relate to PHS-funded research;
- C. Determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

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

For any significant financial interest that Point Designs identifies as conflicting subsequent to Point Designs' initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Point Designs shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI report regarding the financial conflict of interest and ensure that Point Designs has implemented a management plan in accordance with [42 C.F.R. Part 50, Subpart F](#). Pursuant to [§50.605\(a\)\(3\)\(ii\)](#), where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by Point Designs (e.g., was not timely reviewed or reported by a subrecipient), Point Designs also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. If bias is found, Point Designs is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Point Designs' management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for Point Designs' determination that the financial interest conflicts with such research; and
- A description of the key elements of Point Designs' management plan, including:
  - Role and principal duties of the conflicted Investigator in the research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

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

## VII. RECORD MANAGEMENT

Point Designs shall maintain records relating to all Investigator disclosures of financial interests and Point Designs' review of, and response to, such disclosures (whether or not a disclosure resulted in Point Designs' determination of a financial conflict of interest) and all actions under Point Designs' policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 C.F.R 75.361 for different situations.