

People Designs Policy on Financial Conflicts of Interest Related to PHS/NIH-Funded Research

Purpose

This policy is intended to ensure the design, conduct, and reporting of PHS/NIH-funded research performed by People Designs are free from bias resulting from Investigator financial conflicts of interest.

Definitions

An **Investigator** is a person in a PHS grant application or progress report who can directly or materially influence the research, or who is responsible for the design, conduct, and reporting of such research.

A **SFI** (significant financial interest) is one or more of the following interests of an Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, remuneration received from the entity in the preceding 12 months and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any other payment for services (e.g., consulting fees, honoraria, paid authorship; sponsored travel); 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;
- With regard to any non-publicly traded entity, remuneration (includes salary and any other payment for services, such as consulting fees, honoraria, paid authorship; sponsored travel) received from the entity in the 12 months preceding the disclosure exceeds \$5,000, or the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests in excess of \$5,000.

The following types of financial interests are not a SFI:

- Salary, royalties, or other remuneration paid by People Designs to the Investigator if the Investigator is currently employed or otherwise appointed by People Designs, including intellectual property rights assigned to People Designs and agreements to share in royalties related to such rights;
- 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;
- Remuneration from seminars, lectures, teaching engagements, or service on advisory committees or review panels for or sponsored by a domestic federal, state, or local

government agency, or a domestic institution of higher education as defined in U.S.C. Code 20 U.S.C. 1001(a). Note that remuneration from a foreign institution of higher education or the government of another country is NOT excluded.

A **FCOI** is a SFI that:

- Could be affected by , or is in an entity whose financial interest could be affected by the PHS/NIH- funded research; and
- Could reasonably be determined to have the potential to directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

The **Regulation** means 42 CFR Part 50 Subpart F.

Assignment of FCOI Management Responsibilities

A FCOI Manager (AKA “Designated Official”) will be designated to notify, solicit, review, and manage FCOI-related information and activities as described in this policy.

Notification of Policy

Investigators will be notified of this policy when they are first designated as an Investigator and when there is a material change to this policy that effects requirements of Investigators.

Training

Investigators will complete an approved FCOI training course that covers FCOI Regulation and Investigator responsibilities prior to first engaging in research related to a PHS/NIH-funded grant.

Investigators will complete an approved FCOI training course in each of these instances:

- Upon hiring or promotion to a position where they are or are expected to be an Investigator;
- When it is determined the investigator is not in compliance with this policy or a FCOI management plan;
- When it has been more than 3 years since prior training.

Investigators will review this policy and clarify any questions regarding FCOI with the FCOI Manager within 60 days of being notified of a material change to this policy that effects requirements of Investigators.

Disclosure of SFIs

Investigators will disclose or update SFIs in each of these instances:

- Upon hiring or promotion to a position where they are or are expected to be an Investigator;
- Prior to submission of applications for PHS/NIH-funded research;
- At least annually for as long as they are an Investigator.

Investigators will disclose new SFIs within 30 days of discovering or acquiring the new SFI.

Review of SFIs and FCOIs

The FCOI Manager will review SFIs:

- Prior to the expenditure of funds on a new PHS/NIH-funded grant; and
- Within 60 days of receipt of each new SFI disclosure.

The FCOI Manager will review SFI disclosures to:

- Determine whether each SFI relates to any PHS/NIH-funded research; and
- Determine whether each related SFI is a FCOI; and
- Develop and implement a management plan for each FCOI.

A retrospective review of related SFIs and FCOIs will be conducted within 120 days of determination of any of these events:

- Failure by an Investigator to disclose a SFI that is determined to constitute a FCOI; or
- Failure by People Designs to review or manage a FCOI; or
- Failure by an Investigator to comply with a FCOI management plan.

A retrospective review will include the project identifier(s), project title(s), PI/PD contact information, Investigator name(s), FCOI entity(ies), reasons for the retrospective review, a detailed description of the methodology used for the retrospective review, review findings, review conclusions, and any other elements required by the Regulation.

Management of FCOIs

A management plan will be developed to manage each FCOI. The management plan may include conditions or restrictions as determined by the FCOI Manager (for example, full public disclosure, appointment of an independent monitor, modification of the research plan, etc.).

The FCOI Manager will monitor Investigator compliance with FCOI management plans.

Reporting FCOIs

FCOIs will be reported to the funder (including NIH), including all required information defined in the Regulation in each of these instances:

- Prior to the expenditure of funds on a new PHS/NIH-funded grant;
- Within 60 days of identification of a new Investigator in a project;
- Within 60 days of determination of a FCOI;
- Annually as a component of progress reports;
- As part of an update to a prior report when an FCOI existed but was undisclosed at the time of the prior report.

If bias is found with the design, conduct or reporting of PHS/NIH-funded research, the funder will be notified promptly, and a Mitigation Report submitted (including entity name, name of the investigator, nature of SFI(s), value of the SFI(s), and all other elements required by the Regulation).

If an investigator fails to comply with the FCOI regulations or a FCOI management plan, or appears to have biased the design, conduct, or reporting of the research, the funder will be notified promptly, and corrective action taken.

If DHHS determines that a PHS/NIH-funded research project of People Designs that includes clinical research whose purpose is/was to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by People Designs as required by the Regulation, People Designs will require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research; and
- Request an addendum to previously published presentations.

Enforcement

Employees who fail to follow this policy or other FCOI requirements will be sanctioned and may be terminated.

Non-employees covered by this policy who fail to follow this policy or other FCOI requirements will be reported to their institution and their contract/relationship with People Designs may be terminated.

Management of Sub-recipients

A written agreement will be established with subrecipients of grants to People Designs stipulating whether the subrecipient will follow the People Designs FCOI policy or the FCOI policy of the subrecipient.

If the subrecipient will follow the People Designs FCOI policy, subrecipient Investigators will follow and complete the same People Designs FCOI policies and procedures as People Designs Investigators.

If the subrecipient will follow the FCOI policy of the subrecipient, People Designs will obtain a certification from the subrecipient that its FCOI policy complies with the PHS regulations.

Maintenance of Public Access

This FCOI policy will be posted on People Design' website.

Up-to-date FCOI information (including at least the minimum required elements in the Regulation) for requested investigators and grants for which such information was updated within the last 3 years will be provided within 5 days of a written request.

Retention of Records

FCOI-related records, including documents and reports referred to in this policy, will be maintained for at least 3 years following the final expenditures report for the related research grant.

Where CFR or other legal or contractual requirements specify longer than 3-year retention of specific records that overlap with FCOI-related records, records will be retained for at least the longer period.

Materially revised 2022-8-12