

Financial Conflict of Interest Policy

Purpose

Photozig, Inc. (Photozig) strives to promote objectivity in research by implementing standards such that the design, conduct and reporting of Public Health Service (PHS, which includes NIH) funded research is free from bias resulting from financial conflict of interest (FCOI).

Policy Statement

Photozig follows a written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which PHS funding is sought or received.

Photozig requires and enforces Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests.

Photozig identifies and manages FCOIs and provides initial and ongoing FCOI reports to the PHS consistent with this Policy to comply with the requirements of 42 CFR 50, Subpart F.

Photozig makes information available, promptly upon request, to the PHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest.

Photozig takes all necessary steps to fully comply with the requirements of the regulation.

Definitions

Disclosure of Significant Financial Interests means an Investigator's disclosure of significant financial interests to Photozig.

FCOI Report means the Photozig's report of a financial conflict of interest to a PHS Awarding Component.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

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.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, Investigator includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation 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 and product development. As used in this subpart, 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.

Significant Financial Interest (SFI) means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) Salary, royalties, or other remuneration from the applicant institution;
- (2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
- (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (4) Income from service on advisory committees or review panels for public or nonprofit entities;
- (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
- (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

Responsibilities

1. Disclosure, Review and Monitoring

Investigators who are planning to or participating in research activity that is either partially or wholly supported by PHS funds must disclose their SFI in a timely fashion, either to a member of the Photozig Management Team (PMT) or the designated Photozig FCOI Official. If the disclosure is provided to a member of the PMT, it will be forward to the designated Photozig FCOI Official who will determine whether the SFI constitutes an FCOI, based on guidance set by this FCOI Policy.

Each Investigator is required to disclose SFIs (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI: a) no later than at the time of application for PHS-funded research; b) at least annually during the period of the award; and c) within 30 days of discovering or acquiring a new SFI.

The FCOI Official will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities. Consistent with Policy, if the SFI is determined to be an FCOI, the PMT and the Photozig FCOI Official will take actions to discuss and approve the implementation of an FCOI management plan consistent with government regulation and, furthermore, to promptly notify the PHS funding component (e.g. NIH) via a FCOI report.

As a part of the FCOI management plan, the PMT will decide one or more actions depending upon the situation, including requiring certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that create financial conflicts. Employees with an identified FCOI must comply with the FCOI management plan.

Investigators shall use Disclosure Forms to report SFIs, which will include the following information:

- Name of Investigator
- Project Name and title and project PD/PI (or contact PD/PI for projects with multiple PD/PIs) name and title for each sponsored research project.
- Investigator's title and role within each sponsored research projects.
- Reason for disclosure (Annual or description of event that triggered Ad-Hoc disclosure)
- Details of each Investigator significant financial interests in the preceding 12 months including:
 - Name of entities with which the Investigator has significant financial interests.
 - Nature of the significant financial interests (i.e., stock, non-stock equity, honorarium, consulting fee, payment for services, paid authorship, tenure on advisory panels, intellectual property, fee-splitting agreements for referrals or other investment/payment)
 - Amount of significant financial interests or a statement that value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- Details of sponsored or reimbursed travel including:
 - Purpose of trip
 - Identity of sponsor/organizer
 - Destination of trip
 - Duration of trip
 - Value (actual for reimbursed travel or estimated in cases of sponsored travel).
- In cases where value is not immediately ascertainable, Investigator will provide information on the covered services including but not limited to class and carrier of air travel, type and location of accommodation and number and type of meals provided.
- Details of other, potentially non-quantifiable interests including but not limited to:
 - Gifts of goods or services.
 - Outstanding agreements that contain provisions restricting the Investigator's ability to speak, publish or otherwise undertake activities contrary to a company's commercial interest.

FCOI Official will review all significant financial disclosures and supporting documentation to determine whether a significant conflict of interest exists that requires management to preserve objectivity in the design, conduct or reporting of the research and if that research is from a sponsor requiring reporting (such as the PHS). This determination will be made when an Investigator, or the Investigator's spouse, domestic partner or dependent children have significant financial interest(s) that may compromise, or have the appearance of compromising, an Investigator's professional judgment that could directly and significantly affect the design, conduct, or reporting of the research, proposed or funded.

If the FCOI Official determines that there is a conflict that can be managed, a management plan will be developed in the best interest of Photozig, in consultation with the Investigator and an assigned Conflict Manager. An interim management plan may be developed for time critical situations and approved by the PMT. The plan should be updated as more information becomes available. This management plan will be instituted before a new Investigator joins a research project or within 60 days from when Photozig discovers an undisclosed SFI or one not previously reviewed for whatever reason.

The PMT will review managed conflicts annually (or as relevant information arises) to monitor the conduct of the activity, and to ensure scientific objectivity and timely dissemination of the research results.

Prior to expenditure of funds, as part of the periodical process described above, the designated FCOI Official is required to: a) review all Investigator SFI disclosures; b) determine if any SFIs relate to PHS-funded research; c) determine if an FCOI exists; and d) develop and implement management plans to manage FCOIs.

The process to review disclosures of SFIs, make determination of FCOIs, and implement a management plan will depend on the nature of the disclosure/SFI: (a) new Investigator; (b) an existing Investigator who discloses a new SFI; or (c) whenever Photozig identify an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution. All cases will involve the release by the Investigator of the Disclosure Form, collection of data, review, and implementation of management plans to manage FCOIs. Whenever Photozig identifies a significant financial interest that was not disclosed within the allotted time requirements by an Investigator, i.e. case (c), the Investigator will be referred to the PMT for non-compliance management and mitigation. The PMT shall, within 60 days, review the significant financial interest and determine whether a financial conflict of interest exists. If the FCOI exists, the PMT shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward. At this time the PMT shall also determine if the FCOI is related to PHS-funded research, if so, the PMT will notify the NIH promptly regarding the nature of the FCOI and including the Management report. Within 120 days of Photozig's determination of noncompliance, the PMT shall complete a retrospective review of the Investigator's activities to determine whether any research was biased in design, conduct or reporting. Based upon the retrospective review, the PMT shall, if appropriate, update the previously submitted FCOI report, and, if bias was found, submit a mitigation report to the PHS Awarding Component.

As part of the process to take actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project, the PMT at least annually or at important project milestones to review disclosures of significant financial interests and determine if a plan is warranted to eliminate, reduce, or manage any conflict. The FCOI Official will send the determination of whether a plan is required or not, in writing, to the Investigator (or other relevant party). The written decision must include a rationale for the decision, and a plan of action will be implemented, which may include certain disclosure in public presentations, employee role reassignment, reduction or elimination of the financial interest sanctions (e.g., sale of an equity interest) or severance of relationships that created financial conflicts. Managed conflicts will be reviewed by the PMT annually, at key project steps, or as new information arises.

2. Enforcement Mechanisms and Remedies and Noncompliance

If an Investigator operating under a management plan is non-compliant with the plan, the FCOI Official must report non-compliance to the PMT, who must meet within 60 days to determine if continued non-compliance has occurred. If continued non-compliance has occurred, and the PMT determines that the research is funded through the PHS, the PMT is to promptly notify the PHS Awarding Component.

Non-compliance to either disclosure policies or to management plans may cause administrative actions in accordance with company policies, in addition to any legal penalty(ies) under state and federal laws that may be appropriate (e.g., oral admonishment; written reprimand; reassignment; demotion; suspension, or separation; denial of eligibility to engage in research funded through Photozig; or other appropriate penalties).

Photozig shall complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

In any PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required, Photozig must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research and to request an addendum to all previously published presentations.

3. Reporting

Based on the FCOI management plan, the designated FCOI Official will submit an initial FCOI report to the PHS-funding component, for example NIH. The report will be submitted, for example using eRA Commons for NIH, and consist of all elements required by the regulation.

The FCOI report for will be submitted prior to the expenditure of funds under the Notice of Award. FCOIs identified during the period of award will be submitted to NIH within sixty (60) days of identification, including for new investigators joining an ongoing PHS-funded project.

Annual FCOI reports (or revised reports as a result of retrospective reviews) will also be submitted and will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

Prior to expenditure of PHS funds under an award, Photozig will report to the PHS awarding component the existence of any conflicting interest found and assure that the interest has been managed, reduced or eliminated in accordance with regulations. Photozig will make available upon Sponsor's request how those interests have been managed, reduced, or eliminated to protect the research from bias.

FCOI reports will be sent to the PHS in the following circumstances:

- Prior to the expenditure of funds.
- Within 60 days of the identification for an Investigator who is newly participating in the project.
- Within 60 days for new, or newly identified, FCOIs for existing investigators
- Annually along with the required progress reports.
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report.

Photozig will report the existence of any actual or potential conflicting interest influencing federal awards that the company has been unable to manage prior to expenditure of funds. Photozig will report on the existence of any actual or potential conflicting interest influencing external sponsor awards as required by sponsors.

For any interests that are identified subsequent to the initial annual report under the award, a report will be made and the conflicting interest will be managed, reduced or eliminated, at least on an interim basis, within sixty days of that identification.

Photozig will notify PHS promptly if bias is found with the design, conduct or reporting of PHS-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation, which shall include all reporting elements required by the regulation.

If an Investigator fails to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Photozig will also notify PHS promptly and take corrective action for noncompliance with the Institution's policy or the management plan.

Unless otherwise required by sponsors, the FCOI report will include the following information:

- Project Number
- PD/PI (or contact PD/PI if multiple PD/PI model is used)
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a FCOI
- Nature of the financial interest (i.e., stock, non-stock equity, honorarium, consulting fee, payment for services, paid authorship, tenure on advisory panels, intellectual property, fee-splitting agreements for referrals or other investment/payment)
- The approximate dollar value of the significant financial interest within the following ranges:
 - \$0 – \$4,999
 - \$5,000 – \$9,999
 - \$10,000 – \$19,999
 - \$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 funded research and the basis for the Institution's determination that the financial interest conflicts with such research.
- A copy of the Management Plan with key elements, including: a) the role and principal duties of the conflicted Investigator in the research project; b) the conditions of the management plan; c) how the management plan is designed to safeguard objectivity in the research project; d) confirmation of the Investigator's agreement to the management plan; e) how the management plan will be monitored to ensure investigator compliance; and f) other information as needed.

4. Maintenance of Records

Photozig will retain all disclosure forms, conflict management plans and related documents for a period of at least 3 years from the date the final expenditures report is submitted to the PHS (NIH), or at least 3 years from the date the conflict has ended, whichever is longer, and for other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

5. Subrecipient

Photozig will establish, where applicable, via a written agreement, whether the subrecipient will follow the FCOI Policy of Photozig or the FCOI Policy of the Subrecipient, including a requirement for the Subrecipient to report identified FCOIs for its Investigators in a time frame that allows Photozig to report identified FCOIs to PHS as required by the regulation.

If Subrecipient will follow its own FCOI Policy, Subrecipient must provide a FCOI Policy that complies with the requirements of 42 CFR 50, Subpart F. Photozig shall obtain a certification from the subrecipient that its FCOI policy complies with the regulation.

Alternatively, if applicable, Photozig may include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable Photozig to identify, manage and report identified FCOIs to PHS.

6. Public Accessibility

Photozig FCOI policy shall be publicly accessible:

- FCOI Policy shall be posted in Photozig web site
- If there is not current presence on publicly accessible web site, the FCOI Policy will be made within 5 business days of a request.

Photozig shall make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. The information will meet these requirements:

- Include the minimum elements as provided in the regulation.
- Be posted on a Public Website or made available within 5 calendar days of a written request.
- Be updated, at least annually (Web site only but any response to a written request should include the updated information).
- Be updated, within 60 days of a newly identified FCOI (Web site only but any response to a written request should include the updated information).
- Remain available for three years from the date the information was most recently updated.

In the event of a formal request from the public for information of FCOIs Photozig will provide a Public FCOI Report in writing within 5 working days provided the FCOI meets the following criteria:

- The significant financial interest is related to publicly funded research.
- The significant financial interest was disclosed and is still held.
- The Institution determines that the significant financial interest is a financial conflict of interest.

The Public FCOI Report will include the following information:

- Investigator's Name
- Investigator's Title and Role with respect to the research project
- The name of the entity in which the significant financial interest is held
- Nature of the financial interest (i.e., stock, non-stock equity, honorarium, consulting fee, payment for services, paid authorship, tenure on advisory panels, intellectual property, fee-splitting agreements for referrals or other investment/payment)
- The approximate dollar value of the significant financial interest within the following ranges:
 - \$0 – \$4,999
 - \$5,000 – \$9,999
 - \$10,000 – \$19,999

- \$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.

7. FCOI Training

Photozig will be responsible for providing formal and information education on federal regulations and requirements related to Financial Conflict Interest (FCOI training). In this training, Photozig will inform each Investigator of Photozig FCOI Policy, Investigator's disclosure responsibilities, and the Federal regulation.

Each PHS-supported Investigator is required to complete FCOI training prior engaging in any PHS-funded research, periodically at least every 4 years, and immediately after FCOI policy revision, new investigator, or non-compliance. Training for new Investigators will occur before they submit their first disclosure forms (i.e. within 60 days of appointment or before they join a sponsored research project, whichever occurs first). Refresher courses must be taken every four years thereafter and automatically in cases of noncompliance. Researchers with lapsed or revoked status must complete courses before engaging or continuing sponsored research.

New Investigators will be required to provide training certification upon completion which may be provided to sponsors. Questions involving regulations, guidelines, precedents, and practice in this context, and particularly as they may relate to sponsored programs, may be directed to Photozig.