

FOOD ALLERGY SCIENCE INITIATIVE, INC.

CONFLICT OF INTEREST PROCEDURES APPLICABLE TO PUBLIC HEALTH SERVICE FUNDING

The federal Public Health Service (PHS) has adopted regulations ([42 CFR Part 50 Subpart F and 45 CFR Part 94](#)) on *Promoting Objectivity in Research*. These regulations describe the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants). The regulations require that applicants for PHS funding (e.g., funding from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control), prior to the application for PHS funds, disclose to the Food Allergy Science Initiative (FASI) any significant financial interests related to their institutional responsibilities at FASI.

Definitions

Institutional responsibilities means an Investigator's professional activities on behalf of FASI (e.g., teaching, administration, research or clinical care). Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical Service activities such as performing services for FASI
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
- Special Service activities on behalf of FASI including institutional community service.

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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants. FASI's Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

Significant Financial Interest means:

(1) 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 appear to be related to the Investigator's institutional responsibilities on behalf of FASI

- (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 for the investigator, investigator's spouse and dependent children, 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) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- (iv) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed to FASI. 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. This disclosure requirement excludes travel paid for by FASI and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

(2) The term *significant financial interest* does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by FASI to the Investigator if the Investigator is currently employed or otherwise appointed by FASI, including intellectual property rights assigned to the FASI and agreements to share in royalties related to such rights;
- (ii) 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;

- (iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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
- (iv) Income from service on advisory committees or review panels for an U.S. 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.

Disclosure

No later than at the time of an application for PHS-funded research, the Principal Investigator and all other Investigators at FASI must have disclosed to FASI's designated official an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of application for funding from a PHS agency, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the designated official promptly and prior to participation in the project.

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to FASI, pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by FASI's Designated Official

The designated official will conduct reviews of disclosures. The designated official will review any SFI that has been identified in a disclosure; these interests will be compared to each PHS research award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award.

Guidelines for Determining “Relatedness” and Financial Conflict of Interest

The designated official will determine whether an Investigator’s SFI is related to the PHS-funded research and, if so, whether the SFI is a financial conflict of interest. An Investigator’s SFI is related to the PHS-funded research when the designated official reasonably determines that the SFI: could be affected by the research conducted under the award; or is in an entity whose financial interest could be affected by the research. The designated official may involve the Investigator in the determination of whether a SFI is related to the PHS-funded research.

A financial conflict of interest exists when the designated official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator’s SFI is related to PHS-funded research, and if so, whether the relationship creates a FCOI, the designated official considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the designated official may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher’s SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company’s business or financial outlook (excluding Phase I SBIRs and STTRs); or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser’s technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an

- Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the designated official will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this Policy the designated official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

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

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) 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;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts;
- h) For research projects involving human subjects research, use of a data and safety monitoring board;
- i) Double-blind conditions;
- j) Provisions to conduct the work simultaneously at multiple sites;
- k) Written disclosure of the conflict to all individuals working on the research project;
- l) Annual reports on the research progress to the designated official.

If the designated official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on PHS awards will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Designated official necessary to manage the Conflict of Interest. The Designated official will communicate, in writing, with the PHS Agency to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated.

The Designated official will keep a record of Investigator disclosures of financial interests and the Designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for three years from the date the final expenditures report is submitted for grants, for three years from the date of final payment for contracts, or, where applicable, for time periods as otherwise specified in relevant PHS Regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS-funded research project, FASI will ensure public accessibility, via a publicly accessible website or by written response to any requestor within five business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- (i) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by FASI in the grant application, progress report or any other report submitted to the PHS by FASI;
- (ii) FASI has determined that the Significant Financial Interest is related to the PHS-funded research; and
- (iii) FASI has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The information that FASI will make available via a publicly accessible website or in a written response to any requestor within five days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the Significant Financial Interest is held;
- (iv) The nature of the Significant Financial Interest; and
- (v) The approximate dollar value of the Significant Financial Interest in the following ranges: \$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.

If FASI uses a publicly accessible website to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the PHS-funded research project, if it is determined by the Designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If FASI responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the FASI's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via FASI's publicly accessible website for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under a PHS-funded research project, FASI will provide to the PHS Awarding Component an initial FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), FASI will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

Reports will be submitted on the following schedule:

- (i) Within 60 days of identification for an Investigator who is newly participating in the PHS-funded research project;
- (ii) Within 60 days for new, or newly identified, FCOIs for existing Investigators;
- (iii) At least annually (at the same time as when FASI submits any annual progress report, multi-year progress report, if applicable, or at time of extension as required by a PHS agency) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
- (iv) Following a retrospective review to update a previously submitted report, if appropriate.

For any SFI that is identified as conflicting subsequent to an 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), FASI will provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that FASI has implemented

a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator must complete training on *FASI Conflict of Interest Policy Applicable to Public Health Services Funding* prior to engaging in research related to any PHS-funded research and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- 1) FASI revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- 2) An Investigator is new to FASI (training is to be completed prior to his/her participation in the research); or
- 3) FASI finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the designated official).

In fulfillment of the training requirement, FASI requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

Failure to Comply with FASI's Conflict of Interest Policy Applicable to PHS Funding

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by FASI or because an investigator failed to comply with a management plan; then FASI will complete, within 120 days of determining non-compliance, a retrospective review of the investigator's research activities to determine whether any PHS-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

Documentation of a retrospective review will include:

- (i) Project Number
- (ii) Project Title
- (iii) PD/PI or contact PD/PI for multiple PD/PI models (e.g., Program Project Grant)
- (iv) Name of investigator with FCOI
- (v) Reason(s) for retrospective review
- (vi) Detailed methodology used for retrospective review

- (vii) Findings of review; and
- (viii) Conclusions of review

The designated official will appoint one or more individuals to determine if the research was biased. If bias is found, FASI will develop and implement a plan to mitigate the bias. FASI will notify the PHS Agency promptly and will submit a mitigation report within 120 days of the determination of noncompliance.

No expenditures of funds on PHS awards will be permitted unless the Investigator has complied with the Disclosure requirements of this policy and has agreed, in writing, to comply with any FASI FCOI management plan.

Depending on the nature of the FCOI, FASI may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the FCOI is identified and the completion of FASI's independent retrospective review.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action.

In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall 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.

Subrecipient Requirements

FASI shall as part of a written subrecipient agreement with a subrecipient under a PHS award, establish whether the financial conflicts of interest policy of FASI or that of the subrecipient will apply to the subrecipient's investigator(s). If the subrecipient relies on its conflicts of interest policy, the subrecipient shall certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subrecipient agreement will include time periods to meet the disclosure and/or Financial Conflict of Interest reporting requirements of FASI to PHS.