

**Allen Institute**  
**Investigator Financial Conflict of Interest Policy**

We are committed to conducting our research with the highest level of objectivity and integrity and to complying with applicable laws and regulations. In order to affirm these commitments, this *Investigator Financial Conflict of Interest (“FCOI”) Policy* and the [Investigator FCOI Procedures](#) describe circumstances that may give rise to an FCOI and establish standards for disclosure and management of such conflicts.

This policy applies to “Investigators,” (referred to as “you”) which includes anyone who is responsible for the design, conduct, or reporting of Research, regardless of funding source (internal or external). This policy is intended to establish compliance with the policies of the U.S. Public Health Service (“PHS”) and U.S. National Science Foundation (“NSF”) requiring that grantee institutions adopt, maintain and enforce written policies pertaining to researchers' FCOIs.

The existence of an FCOI does not indicate wrongdoing, and disclosing potential conflicts promotes transparency and preserves both our and your reputation. Although we may have to eliminate some FCOIs, we can often work with you to manage the conflict so that the Research can continue in a way that minimizes the possibility of bias and preserves the objectivity of the Research. Proper management depends on full and prompt disclosure. See Section 11 for definitions of capitalized terms.

**1. Summary for Investigators.** The following is a short summary of Investigator responsibilities under this policy. As an Investigator, you have an obligation to be familiar with and abide by the provisions of this policy, which includes:

- timely completing required FCOI training;
- timely disclosing whether you or your spouse or dependent child has a financial interest that reasonably appears to be related to your Institutional Responsibilities and otherwise meets the definition of a Significant Financial Interest (“SFI”); these SFIs may include compensation and/or equity from a publicly traded company in excess of \$5,000 over a 12 month period, compensation from a non-publicly traded company in excess of \$5,000 over a 12 month period, any non-publicly traded equity, certain intellectual property interests, and sponsored or reimbursed travel that exceeds \$5,000 over a 12 month period from a single organization; and
- cooperating with the Institutional Official (“IO”) and COI Committee as they (a) evaluate your SFI to determine if it constitutes an FCOI (b) implement a Management Plan or conduct additional reviews, (c) report FCOIs to funding agencies, as appropriate, and (d) perform other oversight and implementation activities under this policy.

Each of these requirements is described in further detail below.

**2. Training Requirements.** You must complete the FCOI training offered by the Allen Institute prior to engaging in Research and at least every 4 years thereafter. In addition, you must complete training within 30 days when any of the following circumstances apply:

- you are a new Investigator at the Allen Institute;
- this policy and/or the *Investigator FCOI Procedures* change in a manner that affects your requirements as an Investigator; or
- you are not in compliance with this policy, the *Investigator FCOI Procedures*, or a Management Plan.

The training will describe your responsibilities for disclosure of SFIs. Grants Administration will provide you with information regarding how to complete the required training and will maintain records of your training. See the *Investigator FCOI Procedures* for more on training.

**3. Disclosure of Significant Financial Interests.** You must submit disclosures of SFIs to Grants Administration for review in accordance with the [Investigator FCOI Procedures](#). Grants Administration provides Disclosure Forms that guide you through the necessary elements of disclosure. You must have an up-to-date disclosure on file prior to submission of an application for funded Research.

- 3.1. Annual Disclosure.** You must complete an annual disclosure of SFIs each year. If you are a new Investigator, you must complete an annual disclosure upon hiring and prior to engaging in any Research activities. Grants Administration will remind you when annual disclosures are due.
  - 3.2. New/Updated Disclosure.** To make sure your annual disclosure is current, you must disclose new SFIs within 30 days and promptly update information regarding any previously disclosed SFIs.
    - 3.2.1. Updating disclosure within 30 Days of new SFI.** You must submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI (e.g., through purchase, sale, marriage, or inheritance, or travel).
    - 3.2.2. Updating disclosure for previously disclosed SFI.** If you have already disclosed an SFI but there has been a change in the value of the SFI, your Institutional Responsibilities, or the Research that may impact or relate to the SFI, you must promptly update your disclosure.
- 4. Review of Disclosures.**
- 4.1. Institutional Official and COI Committee.** The IO or his/her designee will review disclosures of SFIs. The IO may appoint up to five COI Committee members to assist with reviewing SFIs, creating Management Plans or other reports, resolving disputes, and/or managing policy violations. The IO may delegate responsibilities to the COI Committee, Grants Administration, or others as appropriate.
  - 4.2. Review of SFIs.** The IO will review SFI disclosures to determine whether an SFI is related to Research and, if so related, whether the SFI is an FCOI. An SFI is related to Research when the IO reasonably determines that the SFI could be affected by the Research or is in an Entity whose financial interest could be affected by the Research. As the Investigator, you may be involved in this determination. An FCOI exists when the IO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Research. The IO may consult with or rely upon the determination of the COI Committee for review of disclosures.
  - 4.3. Review of Disclosures Prior to Expenditure of Funds.** Prior to the expenditure of funds under a Research project, the IO will review disclosures to determine (1) whether any SFIs relate to the proposed Research, (2) whether an FCOI exists, and if so, (3) develop and implement a Management Plan that specifies the actions that have been or will be taken to manage the FCOI.
    - 4.3.1.** If an FCOI exists and the funder is a PHS Awarding Agency, Grants Administration will submit an FCOI Report to the PHS Awarding Agency prior to the expenditure of funds (as described in Section 7) and ensure that the IO has implemented a Management Plan. Thereafter, Grants Administration will submit FCOI Reports to the PHS Awarding Agency annually or as otherwise specified by the Awarding Agency. In cases in which the IO identifies an FCOI related to PHS-funded Research and you are able to eliminate it prior to the expenditure of funds, Grants Administration will not submit an FCOI Report.
  - 4.4. Review of Disclosures Related to Ongoing Research.** If you are new to a Research project and you disclose an SFI, or if you are currently working on a Research project and you disclose a new SFI, the IO will, within 60 days, review the SFI to determine whether it is related to the Research and whether an FCOI exists. If an FCOI exists, the IO will implement, on at least an interim basis, a Management Plan that will specify the actions that we have taken or will take to manage the FCOI. Depending on the nature of the SFI, the IO may require additional interim measures with regard to your participation in the Research project between the date of disclosure and the completion of the IO's review.
    - 4.4.1.** If an FCOI exists and the funder is a PHS Awarding Agency, Grants Administration will submit an FCOI Report to the PHS Awarding Agency within the same 60-day period provided for review and ensure that we have implemented a Management Plan. Thereafter, Grants Administration will submit FCOI Reports annually, as specified in the [Investigator FCOI Procedures](#).

## 5. Failure to Disclose/Review and Retrospective Review.

**5.1. Late SFI Review.** Whenever the IO identifies an SFI that an Investigator did not timely disclose or the IO or COI Committee did not timely review for whatever reason, the IO will follow Section 4.4 regarding “Review of Disclosures Related to Ongoing Research.”

**5.2. Retrospective Review.** Whenever the IO identifies an FCOI that was not timely identified or managed, the IO or his/her designee will, within 120 days of the determination of noncompliance, complete a Retrospective Review to determine whether the FCOI caused bias to any Research conducted during the time period of noncompliance. The IO will complete a Retrospective Review when, for example, an Investigator fails to disclose an SFI that constitutes an FCOI, the IO or COI Committee fails to review or manage such FCOI, or an Investigator fails to comply with a Management Plan. The Retrospective Review must include certain elements outlined in the [Investigator FCOI Procedures](#).

**5.2.1.** If the funder is a PHS Awarding Agency, Grants Administration will update any previously submitted FCOI Report, as appropriate, specifying the actions that will be taken to manage the FCOI going forward based on the results of the Retrospective Review.

**5.2.2.** If the IO finds bias during the course of a Retrospective Review and the funder is a PHS Awarding Agency, Grants Administration will notify the Awarding Agency promptly and submit a Mitigation Report, as described in Section 7.5.

**6. Management of Financial Conflicts of Interest.** When the IO identifies an FCOI, s/he will develop and implement a Management Plan that specifies the actions that have been and will be taken to manage the FCOI. The Management Plan must include the following:

- The role and principal duties of the conflicted Investigator in the Research project;
- Conditions or restrictions 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; and
- How the Management Plan will be monitored to ensure Investigator compliance

The Management Plan may also include conditions or restrictions, such as:

- Public disclosure of FCOIs (e.g., when presenting or publishing the Research results);
- For Research involving human subjects, disclosure of the FCOI 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 FCOI;
- Modification of the Research plan;
- Change of Investigator or Investigator responsibilities, or disqualification of Investigator from participation in all or a portion of the Research;
- Reduction or elimination of the FCOI (e.g., sale of an equity interest); or
- Severance of relationships that create the FCOI.

The IO may consult with or rely upon the COI Committee to develop the Management Plan. The IO or his/her designee will monitor Investigator compliance with the Management Plan on an ongoing basis until completion of the Research project.

Additional guidance on management of FCOIs

**7. Reports to the Awarding Agency.** The FCOI Reports referred to in this section apply to PHS-funded Research only. Grants Administration will make any FCOI Reports to non-PHS Awarding Agencies in accordance with such Awarding Agencies’ policy or instructions. In cases where you eliminate the FCOI prior to the expenditure of PHS-funded Research, Grants Administration will not submit an FCOI Report to the PHS Awarding Agency.

- 7.1. FCOI Reports - Required Information.** All FCOI Reports will include sufficient information to enable the PHS Awarding Agency to understand the nature and extent of the FCOI and to assess the appropriateness of the Management Plan. The FCOI Report must include certain required elements as outlined in the [Investigator FCOI Procedures](#).
- 7.2. Method of Reporting.** Grants Administration will submit FCOI Reports in the manner specified by the Awarding Agency.
- 7.3. Timing of Submitting FCOI Reports.** Grants Administration will submit FCOI Reports prior to expenditure of any funds under a PHS-funded Research project. Additionally, Grants Administration will submit an FCOI Report within 60 days after a determination that you have an FCOI, whether you are an Investigator who is newly participating in a project or an existing Investigator who disclosed a new SFI during the period of award. Whenever you do not timely disclose a previously existing FCOI or the IO or COI Committee fails to timely review a previously existing SFI during an ongoing PHS-funded project, the IO must, within 60 days, review the SFI as provided in Section 4.4 on "Review of Disclosures Related to Ongoing Research." If an FCOI exists, Grants Administration will submit the FCOI Report within the same 60-day period provided for review.
- 7.4. Annual FCOI Reports.** Grants Administration will submit an annual FCOI Report to the PHS Awarding Agency for any previously-reported FCOIs for an ongoing PHS-funded Research project. The annual FCOI Report will address the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded Research project.
- 7.5. Mitigation Reports.** If the IO and/or COI Committee find bias in the course of a Retrospective Review, Grants Administration will notify the PHS Awarding Agency promptly and submit a Mitigation Report. The Mitigation Report must include the key elements as described in the [Investigator FCOI Procedures](#). Thereafter, Grants Administration will submit FCOI Reports annually as described above.
- 8. Subrecipient Requirements.** We must take reasonable steps to ensure that all subrecipients that receive PHS funds from or through the Allen Institute comply with FCOI regulations. To that end:
- We require subrecipients who rely on their own FCOI policy to certify as part of the subcontract with us that their policy complies with the regulations. Additional information can be found in the [Investigator FCOI Procedures](#).
  - If the subrecipient cannot provide such certification, the subcontract must state that their Investigators are subject to our FCOI policy and procedures for disclosing SFIs that are directly related to their work for us.
  - The subcontract will include time periods to meet SFI disclosure or FCOI reporting requirements, as applicable, and will set forth requirements to make any FCOI information publicly available pursuant to Section 10 on "Public Accessibility."
- 9. Violations of Policy.**
- 9.1. PHS Remedies.** If an Investigator fails to comply with this policy or procedures, and such failure appears to bias the design, conduct or reporting of PHS-funded Research, we must promptly notify the PHS Awarding Agency of our completed or planned corrective action. The PHS Awarding Agency will consider the situation and, as necessary, take appropriate action, or refer the matter to us for further action, which may include directions on how to maintain appropriate objectivity in the Research project. The PHS Awarding Agency may determine that imposition of special award conditions or suspension of funding or other enforcement action is necessary until the matter is resolved.
- 9.1.1.** If HHS determines that a PHS-funded clinical Research project 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, the Investigator involved must disclose the FCOI in each public presentation of the results of the Research and to request an addendum to previously published presentations.

**9.2. Internal Remedies.** In addition to any reports to or remedies required by the Awarding Agency, the IO will report an Investigator's violations of this policy or procedures to the COI Committee for appropriate action, which may include disciplinary action up to and including termination of employment, suspension of Research activities, and/or other remedies as appropriate to the violation.

## **10. Public Accessibility.**

**10.1. Policy on Website.** This policy is available via our publicly accessible website.

**10.2. Public Availability of Certain FCOI Information.** Prior to the expenditure of funds for PHS-funded Research, we must ensure public accessibility of information concerning any SFI disclosed to the Allen Institute that meets the following criteria:

- The SFI was disclosed and is still held by the Senior/Key Personnel;
- The IO has determined that the SFI is related to the PHS-funded Research; and
- The IO has determined that the SFI is an FCOI.

We will make information about the FCOI publicly available as described in the [Investigator FCOI Procedures](#).

## **11. Definitions.**

**Awarding Agency or Agency** is the organization that funds a Research project with either federal or private funds.

**COI Committee** is a group of authorized Allen Institute personnel that oversees the application of the FCOI Policy.

**Disclosure Forms** or Forms are the following forms used by the Institutional Official and the COI Committee to evaluate SFIs that may result in an FCOI: 1) *Annual Disclosure Form*, 2) *SFI Disclosure Form*, and 3) *Travel Disclosure Form*.

**Entity** is any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (or their spouse or dependent children) receives remuneration or has an ownership or equity interest.

**Equity** means any interest in the ownership or profits of a business enterprise, including stock, stock options, or other equity security.

**Family Member** is the spouse and dependent children of an Investigator.

**Financial Conflict of Interest (FCOI)** is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

**FCOI Report** is the Allen Institute's report of an FCOI to the PHS Awarding Agency.

**FCOI Reporting Summary** is an Allen Institute-developed summary that can be used by Investigators and the IO to guide compliance with mandatory PHS disclosure requirements.

**Institutional Official (IO)** is the Allen Institute individual(s) appointed by the CEO to be responsible for appointing COI Committee members, reviewing and evaluating SFI disclosures to determine if an FCOI exists, preparing Management Plans for identified FCOIs, and conducting additional activities pursuant to this policy and the *Investigator FCOI Procedures*.

**Institutional Responsibilities** are the Investigator's professional responsibilities on behalf of the Allen Institute, including but not limited to Research, Research consultation, teaching, professional practice, clinical activities, purchasing, institutional committee membership, and service on advisory or review panels or boards.

**Investigator** is either 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, which may include, for example, subrecipients, collaborators or consultants.

**Management Plan** is the Allen Institute's documented plan that specifies the actions that we have taken or will take to manage an FCOI.

**Mitigation Report** is a report prepared by the IO and/or COI Committee for submission to the PHS Awarding Agency after the IO or COI Committee has found bias in the course of a Retrospective Review.

**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), including any such activity for which research funding is available from a PHS funding agency 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.

**Retrospective Review** is the documented process where the IO and/or COI Committee determine whether there was any bias in the design, conduct or reporting of Research. A Retrospective Review is conducted whenever an FCOI is not identified or managed in a timely manner.

**Senior/Key Personnel** means the project director, principal investigator, and any other person identified as senior/key personnel by the Allen Institute in the grant application, progress report or any other report submitted to PHS.

**Significant Financial Interest (SFI)** is:

- A financial interest consisting of one or more of the following interests of an Investigator or Investigator's Family Member (i.e., spouse or dependent child) **that reasonably appears to be related to the Investigator's Institutional Responsibilities**:
  - With regard to any publicly traded Entity, an SFI 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;
  - With regard to any non-publicly traded Entity, an SFI 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 Family Member holds any equity interest (e.g., stock, stock option, or other ownership interest);
  - Intellectual property rights and interests (e.g., patents, copyrights, royalties), upon receipt of income related to such rights and interests;
- Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities where the aggregate value of such reimbursed or sponsored travel received from a single outside organization **exceeds \$5,000** in the twelve months preceding the disclosure. (Sponsored travel is travel that is paid on behalf of the Investigator and not reimbursed to the Investigator.)

Reimbursed or sponsored travel does not include travel expenses reimbursed by or sponsored by a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

- **For Investigators applying for or receiving NSF Funding only:** SFI includes salary, royalties or other payments related to the Investigator's Institutional Responsibilities that, when aggregated for the Investigator and the Investigator's Family Member, are expected to exceed \$5,000 during the next twelve month period (prospectively).

**Significant Financial Interest** does not include the following types of financial interests:

- Salary, royalties or other remuneration from the Allen Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Allen Institute, including intellectual property rights assigned to the Allen Institute 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 (or Family Member, as applicable) does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures or teaching engagements sponsored by a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- Income from services on advisory committees or review panels for a U.S. federal, state, or local government agency, an accredited, domestic institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

## 12. References.

- [Investigator FCOI Procedures](#)
- [42 CFR 50 Subpart F and 45 CFR Part 94](#)
- [NIH FAQs on FCOI Regulation](#)
- [NSF Conflict of Interest Policy](#)

**13. Records Retention.** All records relating to SFI disclosures and the Allen Institute review of or response to such disclosures (whether or not an SFI is determined to be FCOI) and all action taken under this policy will be maintained for at least three (3) years from the date of the final expenditures report, or as otherwise required by law, whichever is longer. Grants Administration will maintain these records.

## 14. Administration of Policy.

**Subject Matter Expert.** Please direct questions of interpretation or specifics concerning this policy to the Legal Department.

**Effective Date.** This version is effective as of March 31, 2016 and supersedes previous versions (including version effective August 24, 2012) to the extent that they are inconsistent with this policy.