

ADDGENE, INC.
FINANCIAL CONFLICTS OF INTEREST POLICY

I. INTRODUCTION

1.1. Background

- 1.1.1. Certain federal agencies have specific requirements for disclosure and management of personal financial interests related to their sponsored research projects. The focus of these requirements is to ensure responsible stewardship of federal funds and to promote research free from bias resulting from Investigator financial conflicts of interest. Agencies with such requirements include the Public Health Service (PHS) and related components such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) as well as the National Science Foundation (NSF).
- 1.1.2. Addgene is dedicated to maintaining public trust in the integrity of our research-related activities, especially those publicly-funded activities. In establishing this Financial Conflicts of Interest Policy, Addgene will identify and responsibly manage any financial conflicts of interest (FCOI) that may arise during the course of publicly-funded activities. It establishes the requirements for its employee and subrecipient disclosures (on both an annual and an ad hoc basis) of financial interests and professional relationships in outside entities that would reasonably appear to be related to federally-funded research and its related obligations, and for annual certifications of policy compliance.
- 1.1.3. This policy is not only crucial for compliance with federal regulations, but it is consistent with Addgene's position on open science and is vital in safeguarding research objectivity.

1.2. Initial Questions

- 1.2.1. Why does Addgene have this Financial Conflicts of Interest Policy when it is not a university?

As a nonprofit organization, Addgene is dedicated to accelerating research and discovery by improving access to useful research materials and information. In order to continue improving access to useful research materials, Addgene must research and develop new tools and materials for the research community, which can be costly for a nonprofit organization. In some instances, Addgene may supplement its research efforts with federal funds by means of a grant or cooperative agreement which may require that policies like this be in place to ensure the integrity of federally-funded research.

- 1.2.2. Who does this policy apply to?

All Addgene employees are expected to read, understand and abide by the guidelines and procedures set forth in Addgene's Financial Conflicts of Interest Policy. However, due to the nature or position of many Addgenies' employment, this policy primarily concerns the Research and Accounting Teams and any other Addgenies meeting the definitions of "**Investigator**" or "**Senior/ Key Personnel**" defined below.

II. DEFINITIONS

- 2.1. **"Addgene Responsibilities"** mean an Investigator's professional responsibilities on behalf of Addgene, including research and other scholarly activities; outreach or educational activities; and administrative activities.
- 2.2. **"FCOI Team"** means the individual(s) designated by Addgene to review disclosures of significant financial interests (SFI) and determine whether there is a financial conflict of interest.
- 2.3. **"Financial Conflict of Interest (FCOI)"** means a SFI that could directly and significantly affect the design, conduct, or reporting of federally-funded research.
- 2.4. **"Financial interest"** means anything of monetary value, whether or not the value is readily ascertainable. See *also* remuneration.
- 2.5. **"Independent Monitor"** means the individual tasked with overseeing compliance with the Management Plan and to serve as a resource for the individual whose conflicts are under management.
- 2.6. **"Investigator"** means the project director (PD), principal investigator (PI), or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the federal agency, or proposed for such funding, designated by the PI/PD or Addgene management. These individuals could include, for example, the Chief Scientific Officer, Director and Associate Director level positions at Addgene.
- 2.7. **"Management Plan"** 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.
- 2.8. **"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.
- 2.9. **"Remuneration"** means salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interests such as stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
- 2.10. **"Senior/ Key Personnel"** means the PD/PI and any other person identified as senior / key personnel by Addgene in the grant application, progress report, or any other report submitted to the federal funding agency by Addgene under this policy.
- 2.11. **"Subrecipient"** means a third party person, group or organization through which Addgene carries out the publicly-funded research (e.g., subcontractors or consortium members).
- 2.12. **"Significant Financial Interest (SFI)"** means:
 - 2.12.1. 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 appears to be related to the Investigator's Addgene Responsibilities:

- a) With regard to any **publicly traded entity**, a SFI exists if the value of any remuneration received by the Investigator from the third party-entity in the 12 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;
- b) With regard to any **non-publicly traded entity**, a SFI exists if the value of any remuneration received by the Investigator from the third party-entity in the 12 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
- c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2.12.2. Reimbursed or sponsored travel that reasonably appears related to the Investigator's Addgene Responsibilities may be an SFI. Investigators must disclose the occurrence of any reimbursed or sponsored travel, \$5,000 or more (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 Addgene 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 in the United States, or a United States public or non-profit institution of higher education (as defined at 20 U.S.C. § 1001(a)) or its affiliated hospital, medical center or research institute. The Investigator's disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with Addgene's FCOI policy, the FCOI Teams will decide if further information is needed, including whether a determination or disclosure of monetary value is necessary, in order to determine whether the travel constitutes an FCOI with federally-funded research.

2.13. SFI does **not** mean:

- 2.13.1. the following types of financial interests: salary, royalties, or other remuneration paid by Addgene to the Investigator if the Investigator is currently employed or otherwise appointed by Addgene, including intellectual property rights assigned to Addgene and agreements to share in royalties related to such rights;
- 2.13.2. 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; and
- 2.13.3. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency in the United States, a United States public or non-profit institution of higher education (as defined at 20 U.S.C. § 1001(a)) or its affiliated hospital, medical center or research institute; or income from service on advisory committees or review panels for a Federal, state, or local government agency in the United States, or a United States institution of higher education.

III. DISCLOSURES

3.1. Submissions

- 3.1.1. All Investigators and Senior/ Key Personnel, including both Addgene and any applicable subrecipients (see below) must disclose all SFI, including those of the their spouse and dependent children, that could reasonably be related to their Addgene Responsibilities and their work on the respective federally-funded research by completing the applicable SFI Disclosure Form and submitting it to Addgene's FCOI Team.
- 3.1.2. If the Investigators and Senior/ Key Personnel believe that no SFI exists, they must still complete and return the form while certifying that no SFI exists.
- 3.1.3. Disclosures must be made:
 - a) Prior to engaging in the publicly-funded research,
 - b) Annually during the course of federal sponsored research,
 - c) Immediately if/when:
 - i) Addgene revises its FCOI Policy that affects its Investigator requirements,
 - ii) A new Investigator joins the federally-funded project, or
 - iii) A new SFI is discovered or acquired.
- 3.1.4. Investigators and Senior/ Key Personnel must have a current (within the last 12 months) SFI Disclosure Form on file with Addgene's FCOI Team, or must complete said SFI Disclosure Forms, in order for Addgene to receive funding from PHS, NSF or other sponsors as the prime awardee.

3.2. Review by FCOI Team

- 3.2.1. Addgene has designated its FCOI Team to assume the review responsibility for its Investigators. FCOI Teams will review recurring and transactional/ ad hoc disclosures submitted by applicable Addgene employees and subrecipient Investigators.
- 3.2.2. In the event that a member of the FCOI Team is a named Investigator or Senior/ Key Personnel on the grant application/ award, said Investigator or Senior/ Key Personnel shall be excluded from their FCOI Team duties and responsibilities to the applicable grant.
- 3.2.3. Prior to expenditure of funds, the review and management of any FCOI must be completed. Addgene's FCOI Team will report any identified FCOI to the PHS, NSF or other applicable agency.
- 3.2.4. If the Investigator has certified that he/she has no SFI to disclose, the FCOI Team will sign the SFI Disclosure Form, acknowledging receipt and agreement.
- 3.2.5. When the Investigator has disclosed SFI, the FCOI Team must review the SFI Disclosure Form(s) before the expenditure of funds. This review is to determine whether:
 - a) the SFI reasonably appears to be related to the funded research (e.g., if the SFI could be affected by the research, or is in an entity whose financial interests could be affected by the research); and

- b) the interest constitutes a FCOI (e.g., a SFI that may directly and significantly affect the design, conduct, or reporting of PHS, NSF or other sponsor-supported research).
- 3.2.6. If the SFI is either found to not be related to the funded research, or does not involve a potential FCOI, the FCOI Team will sign the SFI Disclosure Form and no further action is needed.
- 3.2.7. If the SFI is determined to constitute an **actual or apparent** FCOI, the FCOI Team denote the disclosure appropriately and reach out to the applicable technical and/or financial teams for consultation, which may include the submitting Investigator or Senior/ Key Personnel.
 - a) Should the collective review result in a determination that no actual or apparent FCOI exists, the final determination is documented on the SFI Disclosure Form and no further action is required.
 - b) In the event the collective review determines that there is potential for a FCOI but such FCOI can be managed, an appropriate Management Plan will be implemented. This determination is denoted as applicable on the SFI form.
 - c) In the event the collective review determines the FCOI cannot be satisfactorily managed, Addgene will not pursue the grant. The final determination is documented on the SFI Disclosure Form, and no further action is required.

3.3. Timing of Review and Requirements

- 3.3.1. Newly Funded Research Project. Prior to Addgene's expenditure of any federal grant funds, the FCOI Team shall review all SFI disclosures and:
 - a) determine whether the SFI relates to PHS-funded research;
 - b) determine whether a FCOI exists;
 - c) if there is an FCOI, either take steps to eliminate the conflict or develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI; and
 - d) if an FCOI is not eliminated and a management plan is implemented, Addgene must file an FCOI report with the appropriate PHS awarding component.
- 3.3.2. Ongoing Federally-Funded Research (timely disclosure). In the course of an ongoing federally-funded research project (timely disclosure), should an Investigator who is new to participating in the research project disclose a SFI or should an existing Investigator disclose a new SFI to Addgene, the FCOI Team shall, within 60 days, review the disclosure of the SFI and:
 - a) determine whether the SFI relates to federally-funded research;
 - b) determine whether a FCOI exists;
 - c) if there is an FCOI, either take steps to eliminate the conflict or develop and implement, on at least an interim basis, a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI. Depending on the nature of the SFI, Addgene may determine that additional interim measures are necessary with regard to the

- Investigator's participation in the federally-funded research project between the date of disclosure and the completion of the FCOI Team's review; and
- d) if an FCOI is not eliminated and a management plan is implemented, Addgene must file an FCOI report (or update an existing one) with the appropriate federal awarding agency component within 60 days.

3.3.3. Ongoing Federally-Funded Research (failure to timely disclosure or review). In the course of an ongoing federally-funded research project, should Addgene identify an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Addgene during an ongoing federally-funded research project, the FCOI Team shall, within 60 days, review the SFI and:

- a) determine whether the SFI relates to federally-funded research;
- b) determine whether a FCOI exists;
- c) if there is an FCOI, either take steps to eliminate it or develop and implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
- d) if there is an FCOI, complete a retrospective review, within 120 days. Depending on the nature of the FCOI, Addgene may determine that additional interim measures are necessary with regard to the Investigator's participation in the federally-funded research between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of Addgene's retrospective review; and
- e) If an FCOI is not eliminated and a management plan is implemented, Addgene must file an FCOI report (or update an existing one) with the appropriate appropriate federal awarding agency component within 60 days

3.4. Management of Financial Conflicts of Interest

3.4.1. Prior to expenditure of funds, Addgene's FCOI Team, in conjunction with the affected Addgene technical and/or financial teams, will develop a Management Plan that contemplates the conditions and/or restrictions to eliminate, reduce, or manage the FCOI. The Investigator, Chief Financial Officer, the Executive Director and Legal may also be involved in drafting the plan, including conditions such as:

- a) publicly disclosing the conflict when publishing or presenting research;
- b) appointing an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the conflict;
- c) modifying the research plan;
- d) changing personnel or their responsibilities, or disqualifying participation in all or a portion of the research;
- e) reducing or eliminating the SFI; or
- f) severing relationships that pose a FCOI.

3.4.2. In consultation with Addgene's FCOI Team and the affected technical and/or financial teams, the Management Plan shall include the following (where possible):

- a) the role and principal duties of the conflicted Investigator;
- b) the conditions of the Management Plan;
- c) how the plan is designed to safeguard objectivity in the research;

- 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) any other information relevant to the management of the FCOI.

3.4.3. The FCOI Team signs the Management Plan, and appoints an individual to monitor the project until completion of the funded research. A copy of the approved Management Plan will be held by Addgene's FCOI Team who will report all instances of FCOI to PHS, NSF or other sponsor.

IV. REPORTING AND RECORDKEEPING

4.1. FCOI Reports to Federal-Sponsor

4.1.1. Prior to expenditure of funds, Addgene shall report all findings of FCOI to the applicable federal sponsor. The report shall include sufficient information to allow the agency to understand the nature of the conflict and appropriateness of the Management Plan. It shall include:

- a) project number; project director or principal Investigator;
- b) the name of Investigator and/or Senior/ Key Personnel with the conflict, and the entity involved;
- c) nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium, etc.);
- d) 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 value is not readily determined;
- e) description of how the SFI relates to the funded research and the basis for determining that the SFI conflicts with the research;
- f) description of the key elements of the Management Plan including:
 - i) the role and principal duties of the conflicted Investigator and/or Senior/ Key Personnel in the research project;
 - ii) conditions of the Management Plan;
 - iii) how the Management Plan is designed to safeguard objectivity in the research project;
 - iv) confirmation of the Investigator and/or Senior/ Key Personnel's agreement to the Management Plan;
 - v) how the Management Plan will be monitored to ensure Investigator and/or Senior/ Key Personnel compliance; and
 - vi) other information as needed.

4.1.2. On an annual basis, Addgene reports to the applicable federal sponsor the status of any previously identified FCOI, and any changes to the Management plan.

4.1.3. Addgene submits a Retrospective Review (see "Compliance and Remedial Measures" below) and mitigation reports promptly to the applicable federal sponsor as necessary.

4.2. Recordkeeping

4.2.1. Records of all disclosures of SFI and of all actions taken to review and manage conflicts will be maintained by Addgene until at least three (3) years after the later of the termination or

completion of the award to which they relate, or the resolution of any governmental action involving these records.

- 4.2.2. The disclosure and supporting documents filed in compliance with this policy will be maintained as confidential to the extent possible under applicable state and federal requirements. Whenever requests for such information are requested by any external entity, the individual will be notified.

V. COMPLIANCE & REMEDIAL MEASURES

5.1. Retrospective Review

- 5.1.1. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator and/or Senior/ Key Personnel to timely disclose a SFI that is later determined by Addgene to constitute a FCOI; failure by Addgene to timely review or manage such an FCOI; or failure by the Investigator and/or Senior/ Key Personnel to comply with a FCOI Management Plan, Addgene shall, within 120 days of Addgene's determination of noncompliance, complete a retrospective review of the Investigator's and/or Senior/ Key Personnel's activities and the federally-funded research project to determine whether any federally-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- 5.1.2. Under PHS's federal sponsorship policy, Addgene is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
 - a) Project number and title;
 - b) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - c) name of the Investigator and/or Senior/ Key Personnel with the FCOI;
 - d) name of the entity with which the Investigator and/or Senior/ Key Personnel has a FCOI;
 - e) reason(s) for the Retrospective Review;
 - f) detailed methodology used for the Retrospective Review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - g) findings of the review; and
 - h) conclusions of the review.
- 5.1.3. Based on the results of the retrospective review, if appropriate, Addgene shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
- 5.1.4. If bias is found, Addgene is required to notify the sponsoring federal agency promptly and submit a mitigation report to the applicable awarding component. The mitigation report must include, at a minimum, the key elements documented in the Retrospective Review, above, and a description of the impact of the bias on the research project and Addgene's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

5.2. Disciplinary and Remedial Measures

- 5.2.1. Addgene's Executive Team and FCOI Team are responsible for the interpretation and overall coordination of this policy. Violation of any part of this policy shall be subject to disciplinary procedures, which may include suspension and termination of employment. Moreover, any Addgene employee who has received financial benefit from transactions in violation of this policy shall be liable for repayment (to the appropriate entity) of all financial benefits resulting from such violation.
- 5.2.2. Whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator and/or Senior/ Key Personnel to disclose a SFI that is determined by Addgene to constitute a FCOI; failure by Addgene to review or manage such a FCOI; or failure by the Investigator and/or Senior/ Key Personnel to comply with a FCOI Management Plan, Addgene shall, within 120 days of Addgene's determination of noncompliance, complete a Retrospective Review (as described above) of the Investigator's and/or Senior/ Key Personnel's activities and the federally-funded research project to determine whether any federally-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- 5.2.3. If the failure of an Investigator and/or Senior / Key Personnel to comply with Addgene's FCOI Policy or a FCOI Management Plan appears to have biased the design, conduct, or reporting of the federally-funded research, Addgene shall promptly notify the federal agency awarding component of the corrective action taken or to be taken.
- 5.2.4. The federal awarding component will consider the situation and, as necessary, take appropriate action to maintain appropriate objectivity in the research project, which may require Addgene to:
 - a) submit records,
 - b) submit to on-site review,
 - c) accept special award conditions,
 - d) suspend funding, accounts,
 - e) rescind contracts entered into violation of this policy or state law;
 - f) bring legal action for restitution to the appropriate entity or entities of the amount of financial benefit received by the Addgene employee as a result of the employee's violation of this policy; and/or
 - g) any other enforcement actions necessary to resolve the matter.

VI. SUBRECIPIENTS

6.1. Disbursement of Sponsor Funds to Subrecipients

- 6.1.1. If Addgene carries out the publicly-funded research through a subrecipient (e.g., subcontractors or consortium members), Addgene (the sponsored entity) shall take reasonable steps to ensure that any subrecipient Investigator complies with this FCOI.
- 6.1.2. Addgene shall incorporate, as part of a written agreement with the subrecipient, terms that establish whether Addgene's FCOI Policy or that of the subrecipient will apply to the subrecipient's Investigator.

- a) If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to Addgene's FCOI Policy for disclosing SFI that are directly related to the subrecipient's work for Addgene.
 - b) Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Addgene. Such time period(s) shall be sufficient to enable Addgene to provide timely FCOI reports, as necessary, to the sponsoring federal agency.
 - c) Alternatively, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to Addgene. Such time period(s) shall be sufficient to enable Addgene to provide timely FCOI reports, as necessary, to the sponsoring federal agency.
- 6.1.3. Addgene shall provide FCOI reports to the applicable federal agency's reporting department, regarding all FCOI of all subrecipient Investigators prior to the expenditure of sponsor funds and within 60 days of any subsequently identifying FCOI.

VII. PUBLIC ACCESSIBILITY

7.1. Public Accessibility Requirement

- 7.1.1. PHS, NSF and other sponsors require Addgene to ensure public accessibility of SFI information related to PHS, NSF and other federally sponsored research, including an obligation to respond to any requestor within 5 business days, with information concerning any SFI that meets all the following criteria:
 - a) The SFI was disclosed and is still held by the Investigator or Senior/ Key personnel;
 - b) A determination has been made that the SFI is related to the funded Research; and
 - c) A determination has been made that the SFI constitutes an FCOI.
- 7.1.2. The information to be made available shall include the Investigator and/or Senior/ Key Personnel, name, title and role in Research, name of entity involved with the FCOI, nature of the interest, approximate dollar amount of interest, or statement that the value is not readily determined.
- 7.1.3. The information must be made available for a period of three (3) years from the date that it was most recently updated.

7.2. Website

- 7.2.1. This Addgene FCOI Policy is available on this publicly accessible website.

VIII. EDUCATION & TRAINING

8.1. Investigator and Senior/ Key Personnel Training

- 8.1.1. Each Investigator and Senior/ Key Personnel must complete training regarding Addgene's policy on financial conflicts of interest, the Investigator's and Senior/ Key Personnel's responsibilities regarding disclosure of SFI, and of these specific federal sponsor requirements.
- 8.1.2. Training must be completed prior to engaging in research related to any federally-funded grant and refreshed at least every 4 years.
- 8.1.3. Additional training must be completed when:
 - a) financial conflict of interest policies are revised in a manner that changes researcher requirements;
 - b) a new Investigator and/or Senior/ Key Personnel is added to the federally-funded research; and
 - c) a researcher is non-compliant with financial conflict of interest policies and procedures.

POLICY HISTORY

If you have any questions about Addgene's Financial Conflicts of Interest Policy, please email fcoi@addgene.org

New: April 07, 2021