



Financial Conflicts of Interest Policy Statement

This document establishes Arc Bio, LLC's (Arc Bio), policies on individual financial conflicts of interest. It is Arc Bio's policy to ensure that personnel avoid situations in which personal financial interest may affect, or have the appearance of affecting, their professional judgement in exercising their duties or responsibilities, or in conducting or reporting research. This policy was developed to guide personnel in managing their personal affairs and financial activities that may appear to conflict with their responsibilities and to ensure that Arc Bio and its employees comply with applicable federal laws when participating in research funded by the Public Health Service (PHS). Arc Bio's personnel should promptly disclose the circumstances of any situation that might be covered by this policy. This policy applies to any Arc Bio member acting as an Investigator or as a Senior/Key personnel on any PHS research project and any Sub-recipient of that project.

Reason for Policy

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. The policy was written to be in conformance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought^[1] and 45 CFR Part 94, Responsible Prospective Contractors.

[1]These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II.

Definitions

For purposes of this policy, the following definitions shall apply:

Designated Official is the individual designated by Arc Bio to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

Equity interest includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by Arc Bio through the Designated Official.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Immediate family refers to an Investigator's spouse and dependent children.

Investigator means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.

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

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

PHS-funded Research means research funded under PHS grants, cooperative agreements, or contracts.

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

Remuneration includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

Significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Arc Bio project responsibilities, including:

- With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
- With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Significant financial interests also include any reimbursed or sponsored travel (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 the Investigator's Arc Bio project 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; 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.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Arc Bio (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Arc Bio, including that paid for intellectual property rights assigned or licensed to Arc Bio and agreements to share in royalties related to such rights;

- Any ownership interest in Arc Bio (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan);
- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a 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
- Income from service on advisory committees or review panels for a 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.

Procedures

Responsibilities of Arc Bio's Designated Official

The Designated Official or his/her designee shall be responsible for the following:

- Informing Arc Bio's Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, Arc Bio's review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Arc Bio with sufficient assurances to enable Arc Bio's compliance with all applicable laws or regulations. To this end, the written agreement between Arc Bio and the subrecipient will specify whether Arc Bio's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
- Obtain certification from the subrecipient that its policy complies with Arc Bio's policy and the applicable regulations (absent such certification), Arc Bio's policy will apply to the subrecipient's Investigators, and
- Establish time periods for subrecipient reporting of financial conflicts of interest to Arc Bio that enable Arc Bio to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Arc Bio's policy will apply to the subrecipient Investigators, Arc Bio will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

Internal Reporting Requirements

For PHS-funded research, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form (Exhibit 1) and submit it to the Designated Official. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

Determination and Management of Financial Conflicts of Interest

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Arc Bio determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or

- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Arc Bio may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements

Arc Bio will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Arc Bio will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Arc Bio has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Arc Bio will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involve a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Arc Bio (e.g., not reviewed or reported by a subrecipient in a timely manner), Arc Bio will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Arc Bio will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Arc Bio will provide HHS with information relating to any Investigator disclosure of significant financial interests; Arc Bio's review of, and response to, such disclosure; and whether the disclosure resulted in Arc Bio's determination of a financial conflict of interest.

Confidentiality

Arc Bio will, to the extent possible, protect the confidentiality of disclosures. In every instance, Arc Bio will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Arc Bio staff only on a need-to-know basis and will not be disclosed outside of Arc Bio unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator Noncompliance

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Arc Bio may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In

addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Arc Bio shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Arc Bio will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded 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 a financial conflict of interest that was neither disclosed nor managed, Arc Bio shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

Training and Education

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, consultants and employees engaged in NIH-funded research or its compliance.

The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Upon completion of the training, a certificate of completion must be turned into the Designated Official. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the Company due to changes in the FCOI policy, non-compliance of the Investigator/Key Personnel or new to the Company. At a minimum, the FCOI training shall be taken every three (3) years.

Retention of Records

For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Arc Bio with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the Arc Bio Designated Official.

Exhibit 1:



Financial Conflict of Interest Disclosure Form

Persons completing this form are expected to have read and understood the Arc Bio’s Financial Conflict of Interest Policy on Federal Grants and Contracts. If you have any questions regarding that policy contact the Arc Bio Designated Official prior to signing this document.

1. Do you, your spouse, or dependent children have a “significant financial interest (SFI)” (as defined on the Arc Bio’s Company Policy Financial Conflict of Interest (FCOI) Policy) that would reasonably appear to be affected by your “Research”?

Yes No

If yes, please describe in the space below the nature and extent of your/their affiliation.

2. Do you, your spouse or dependent children have a “significant financial interest” in any business or legal entity whose financial interests would reasonably appear to be affected by this covered “Research”?

Yes No

If yes, please describe in the space below the nature and extent of your/their affiliation.

Description of your “significant financial interest”, if applicable in Sections 1 and 2 above.

I certify that:

I have read Arc Bio’s Policy on Financial Conflict of Interest on Federal Grants and Contracts. I have made all required financial disclosures.

(If the program leader, principal investigator or project director) I have made every effort to ensure that all Investigators (see policy for definition) responsible for the design, conduct or reporting of the research have submitted required disclosures.

Signature _____ Date: _____

Typed/Printed name: _____

Disclosure Type:

- First time _____
- Annual update _____
- Project specific _____ Project title: _____ Sponsor: _____

Special Notes (if any):