

BacStitch DNA Financial Conflict of Interest Policy

Policy Statement

As a professional research and development corporation, BacStitch DNA is committed to protecting the integrity and objectivity of its research activities by ensuring that the design, conduct, and reporting of research will not be biased or appear to be biased by a personal financial conflict of interest. BacStitch DNA has implemented this policy to identify, manage, reduce, or eliminate financial conflicts of interest.

The procedures described in this policy were created and designed primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research but are also intended to provide a basic framework and standards for identifying, evaluating, and managing potential financial conflicts of interest relating to BacStitch DNA's other research activities. For non-PHS research, the specific steps, timing, determinations, documentation, and notifications may be tailored as appropriate but will remain focused on maintaining BacStitch DNA's high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

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.

Definitions

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

Designated Official is the individual designated by BacStitch DNA 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 BacStitch DNA 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 BacStitch DNA project responsibilities, including:

1. 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;
2. 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

3. 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 BacStitch DNA 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 BacStitch DNA (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by BacStitch DNA, including that paid for intellectual property rights assigned or licensed to BacStitch DNA and agreements to share in royalties related to such rights;
- Any ownership interest in BacStitch DNA (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 BacStitch DNA's Designated Official

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

- Informing BacStitch DNA Investigators of their obligations under this policy and any related regulations;

- Reviewing disclosures of significant financial interest with BacStitch DNA's Administrator 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, BacStitch DNA'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 BacStitch DNA with sufficient assurances to enable BacStitch DNA's compliance with all applicable laws or regulations. To this end, the written agreement between BacStitch DNA and the subrecipient will specify whether BacStitch DNA'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 BacStitch DNA's policy and the applicable regulations (absent such certification, BacStitch DNA's policy will apply to the subrecipient's Investigators, and
 - Establish time periods for subrecipient reporting of financial conflicts of interest to BacStitch DNA that enable BacStitch DNA to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If BacStitch DNA's policy will apply to the subrecipient Investigators, BacStitch DNA 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 in particular, 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 and submit the SFID Form to BacStitch DNA's

Administrator. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available. BacStitch DNA's Administrator will review SFID submissions with the Designated Official. 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.

BacStitch DNA Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to BacStitch DNA's Administrator. Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). The annual update will typically be done in conjunction with completion of the annual training. 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 BacStitch DNA 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, BacStitch DNA may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements

BacStitch DNA will disclose financial conflicts of interest as required by applicable laws or 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 BacStitch DNA has implemented a plan to manage the conflict.

Initial Reports

Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator Significant Financial Interest found by the Institution to be a Financial Conflict of Interest in accordance with the regulation. The Institution must also provide an FCOI report whenever an Investigator does not timely disclose a Significant Financial Interest or whenever the Institution, for whatever reason, does not review a disclosed Significant Financial Interest and the Institution then determines that a Financial Conflict of Interest exists.

Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project

The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award. The reports must also be submitted on an annual basis.

All FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the Institution's management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the Financial Conflict of Interest;
4. Name of the entity with which the Investigator has a Financial Conflict of Interest;

5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. 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 the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
8. A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

Institutional Retrospective Review Requirements

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest, or failure by the Institution to review or manage such a Financial Conflict of Interest, or failure by the Investigator to comply with a Financial Conflict of Interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. 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.

At least the following key elements will be documented in the retrospective review:

1. Project number
2. Project title
3. PD/PI or contact PD/PI if a multiple PD/PI model is used

4. Name of the Investigator with the FCOI
5. Name of the entity with which the Investigator has a financial conflict of interest Reason(s) for the retrospective review
6. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.)
7. Findings of the review
8. Conclusions of the review

If bias is found, BacStitch DNA will promptly notify the PHS Awarding Component and submit the mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a “Revised FCOI Report.” 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 the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., 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). Thereafter, BacStitch DNA will submit FCOI reports annually as prescribed by the regulation. Upon request, BacStitch DNA will provide HHS with information relating to any Investigator disclosure of significant financial interests.

Confidentiality

BacStitch DNA will, to the extent possible, protect the confidentiality of disclosures. In every instance, BacStitch DNA 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 BacStitch DNA staff only on a need-to-know basis and will not be disclosed outside of BacStitch DNA unless necessary to comply with contractual, legal, or regulatory requirements.

Investigator or Institutional (BacStitch DNA) Noncompliance

If an Investigator or anyone at BacStitch DNA knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), BacStitch DNA may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator or individuals 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 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, BacStitch DNA shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;

- BacStitch DNA 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, BacStitch DNA 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

Investigators receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the NIH Web site.

BacStitch DNA requires Investigators to complete such training annually, and when any of the following occurs:

- BacStitch DNA revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to BacStitch DNA; or
- BacStitch DNA finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

Retention of Records

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with BacStitch DNA's Record Retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by BacStitch DNA 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 Part 75.361 .

Point of Contact

If you have a conflict of interest or if you have a question to discuss, contact the BacStitch DNA Administrator.