

Bolder BioTechnology Financial Conflict of Interest Policy

Introduction

This Financial Conflict of Interest Policy was created to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research. The policy was written to conform 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. The policy outlines procedures to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest for PHS-sponsored research.

Definitions

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

Designated Official is the individual designated by Bolder BioTechnology to oversee the financial conflict 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 Bolder BioTechnology 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, whether domestic or foreign, 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 Bolder BioTechnology 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and Interests

Significant financial interest also includes any reimbursed or sponsored travel (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), whether domestic or foreign, related to the Investigator's Bolder BioTechnology 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. Disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Bolder BioTechnology's Designated Official and / or the Designated Officials designee(s) and Bolder BioTechnology's Administrator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the PHS-funded research.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Bolder BioTechnology (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Bolder BioTechnology, including remuneration paid for intellectual property rights assigned or licensed to Bolder BioTechnology and agreements to share in royalties related to such rights;
- Any ownership interest in Bolder BioTechnology (or a subrecipient as applicable) held by the Investigator (e.g., Bolder Biotechnology employee stock options);
- 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;
- 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 Bolder BioTechnology's Designated Official

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

- Informing Bolder BioTechnology Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with Bolder BioTechnology's Financial Conflict of Interest 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, Bolder BioTechnology'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 Bolder BioTechnology with sufficient assurances to enable Bolder BioTechnology's compliance with all applicable laws or regulations. To this end, the written Consortium Agreement between Bolder BioTechnology and the subrecipient will specify whether Bolder BioTechnology's or the subrecipient's financial conflict 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 Bolder BioTechnology's policy and the applicable regulations (absent such certification, Bolder BioTechnology's policy will apply to the subrecipient's Investigators, and
 - Establish time periods for subrecipient reporting of financial conflicts of interest to Bolder BioTechnology that enable Bolder BioTechnology to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If it is decided that Bolder BioTechnology's Financial Conflict of Interest policy will apply to the subrecipient's Investigators, Bolder BioTechnology 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 and submit the SFID Form to Bolder BioTechnology'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 their training and will otherwise be made

available. Bolder BioTechnology'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.

Investigators are expected to submit an updated SFID Form at least annually for PHS-funded research and as otherwise necessary. 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, Bolder BioTechnology's Administrator, working in conjunction with Bolder BioTechnology's Designated Official or his/her designee(s) 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 Bolder BioTechnology determines that a financial conflict of interest exists, a financial conflict 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, Bolder BioTechnology may require the management of conflicting financial interests in other ways as it deems appropriate.

External Reporting Requirements

Bolder BioTechnology will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Bolder BioTechnology will ensure public accessibility by posting its Financial Conflict of Interest Policy 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 conflicts of interest that have not been eliminated and will ensure that Bolder BioTechnology has implemented a plan to manage the conflicts.

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, Bolder BioTechnology 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 conflict of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Bolder BioTechnology (e.g., not reviewed or reported by a subrecipient in a timely manner), Bolder BioTechnology 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, Bolder BioTechnology will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Bolder BioTechnology will provide HHS with information relating to any Investigator disclosure of significant financial interests; Bolder BioTechnology's review of, and response to, such disclosure; and whether the disclosure resulted in Bolder BioTechnology's determination of a financial conflict of interest.

Confidentiality

Bolder BioTechnology will, to the extent possible, protect the confidentiality of disclosures. In every instance, Bolder BioTechnology 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 Bolder BioTechnology staff only on a need-to-know basis and will not be disclosed outside of Bolder BioTechnology 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), Bolder BioTechnology may take appropriate disciplinary action, which may include, without limitation, termination of the

Investigator's participation in the research. 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 conflict of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Bolder BioTechnology shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Bolder BioTechnology 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, Bolder BioTechnology 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 are required to 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 Financial Conflict of Information page: <https://grants.nih.gov/grants/policy/coi/index.htm>.

Bolder BioTechnology requires Investigators to complete such training at least once every four years, and when any of the following occurs:

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

Retention of Records

The Designated Official will retain financial conflict of interest disclosure forms and other supporting information consistent with Bolder BioTechnology'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 Bolder BioTechnology 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 or 48 CFR Part 4, Subpart 4.7.