



FEDERAL RESEARCH CONFLICT OF INTEREST POLICY
September 16, 2013

I. PURPOSE

The purpose of this policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research conducted by this institution or its subcontractors and subrecipients under Public Health Service (PHS) grants, cooperative agreements, and contracts will be biased by any conflicting financial interest of an investigator.

II. APPLICABILITY

This policy applies to:

- A. Research for which this institution applies for or receives a grant, cooperative agreement or contract from PHS and each Investigator being proposed to participate or participating therein.
- B. Research for which this institution has solicited or been issued a subcontract or subaward at any tier under a grant, cooperative agreement or contract from PHS, and Investigators being proposed to participate or participating therein, unless the solicited or issuing institution requires that another research conflict of interest policy apply.

This institution has other policies and procedures relating to conflict of interest which may apply to research and Investigators subject to this policy. This policy is cumulative, and does not replace or supersede any other policy of this institution.

III. DEFINITIONS

- A. "HHS" means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- B. "Financial Interest" means anything of monetary value, whether or not the value is readily ascertainable.
- C. "Financial Conflict of Interest (FCOI)" means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- D. "Institution" means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).
- E. "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the institution and includes research activities, research consultation, and service on panels such as the Institutional Review Board.

F. “Investigator” means the principal investigator or project director (“PI/PD”) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding whether or not they are or are proposed to be employees, collaborators, contractors or agents of this institution. For purposes of the requirements of this policy relating to financial interests, “Investigator” includes the Investigator’s spouse and dependent children.

G. “Manage” 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.

H. “PHS” means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

I. “PHS Awarding Component” means the organizational unit of the PHS that funds the research that is subject to this policy.

J. “Public Health Service Act” or “PHS Act” means the statute codified at 42 U.S.C. 201 *et seq.*

K. “Research” means a systematic investigation designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component, whether authorized under the PHS Act or other statutory authority.

L. “Senior/Key Personnel” means the PI/PD and any other person identified as senior/key personnel by this institution in the grant application, progress report, or any other report submitted to PHS by this institution under the regulations.

M. “Significant Financial Interest” means: (1) A Financial Interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator’s Institutional Responsibilities (i) For publicly traded entities, a *significant financial interest* 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; (ii) For non-publicly traded entities, a *significant financial interest* exists if the value of any remuneration received from an entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. (2) Investigators also must disclose the occurrence of 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 their Institutional Responsibilities. Note: this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources as provided in regulation.

IV. RESPONSIBILITIES OF INVESTIGATORS

Every person who agrees to be proposed to participate in, or who participates in, research covered by this policy agrees to comply with all applicable provisions of the policy in exchange for the benefits of participation. This obligation is independent of any other obligation to comply with this policy which may arise out of a person’s employment relationship or hiring agreement with this institution. An Investigator’s responsibilities under this

policy are personal and may not be assigned or delegated. This institution reserves the right to take appropriate corrective measures and/or disciplinary action in the event of violation of this policy.

Every person who agrees to be proposed to participate in, or who participates in, research covered by this policy must show evidence of completion of Financial Conflict of Interest training as follows: (1) prior to engaging in such research and at least every four years; or (2) immediately if (i) this institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; (ii) An Investigator is new to this institution; or (iii) this institution finds that an Investigator is not in compliance with this policy or the management plan.

V. RESPONSIBILITIES OF DESIGNATED OFFICIALS

A. The Director of Finance shall be this institution's designated official to: (1) receive financial disclosures from Investigators as required by this policy; (2) maintain records of all Investigator financial disclosures, this institution's response to such disclosures, and all actions taken by this institution with respect to each conflicting interest; (3) maintain records for three years from the date of submission of the final expenditure report or, where applicable, from other dates specified in 45 CFR Sec. 74.53(b) and Sec. 92.42(b); (4) make such certifications as may be required by PHS in each funding application; (5) report on conflicts of interest to the PHS Awarding Component; (6) notify the PHS Awarding Component of corrective action taken or to be taken if an Investigator's failure to comply with this policy has biased the design, conduct or reporting of PHS-funded research; (7) make information available, upon request, to HHS regarding all conflicting interests identified by this institution and how those interests have been managed, reduced or eliminated to protect the research from bias; and (8) inform each Investigator of this policy, the Investigator's reporting responsibilities and the applicable federal regulations.

B. The Contracts Manager shall be this institution's designated official to: (1) maintain this policy in compliance with 42 CFR Part 50 and 45 CFR Part 64 as amended from time to time, and any other applicable laws and regulations and make it publicly available; and (2) review statements of Significant Financial Interest to determine whether a conflict of interest exists, and prepare recommendations to the Board of Directors with respect to actions to manage, reduce or eliminate conflicts. The final decision with respect to such actions shall be made by the Board of Directors.

VI. REPORTING OF SIGNIFICANT FINANCIAL INTERESTS

A. Each Investigator who is planning to participate in PHS-funded research shall submit to the appropriate designated official a statement on the prescribed form of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

- (i) that would reasonably appear to be related to the Investigator's institutional responsibilities;
- (ii) that would reasonably appear to be affected by the research for which PHS funding is sought; and
- (iii) in entities whose Financial Interests would reasonably appear to be affected by the research.

An Investigator who determines that he/she does not have any reportable known Significant Financial Interests must submit a negative declaration on the prescribed form.

B. Investigators shall submit their financial interest statements on or before the date on which this institution:

- (i) submits an application for PHS-funded research to PHS;
- (ii) submits a proposal to PHS for a research contract whether in response to a solicitation from PHS or otherwise; or
- (iii) assumes the legal obligation to carry out research required under a PHS-funded research contract.

C. If an individual first plans to participate or participates as an Investigator in PHS-funded research after the dates specified in subsection B., he or she shall promptly submit a statement of his/her known Significant Financial Interests as required by subsection A.

D. Investigators who are required to submit or have submitted a statement of known Significant Financial Interests shall submit an updated statement annually or whenever new reportable significant financial interests are obtained.

VII. MANAGING CONFLICTING INTERESTS

A. The appropriate designated official shall do all the following before this institution expends any federal funds for PHS-funded research:

(1) Review all statements of Significant Financial Interest received to date to determine whether such interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

(2) Notify the Investigator if he/she finds that a conflict of interest exists and then meet and confer as necessary and appropriate with the Investigator and the project's PI/PD. The appropriate designated official will also determine what actions should be taken by this institution to manage, reduce or eliminate the conflict of interest. Conditions or restrictions that this institution may impose to manage conflicts of interest include, but are not limited to: (i) public disclosure of significant financial interests, (ii) monitoring of research by independent reviewers, (iii) modification of the research plan, (iv) disqualification from participation in all or a portion of the research funded by the PHS, (v) divestiture of significant financial interests, or (vi) severance of relationships that create actual or potential conflicts.

(3) Report the existence of any identified conflict of interest (but not the nature of the interest or other details) to the PHS Awarding Component and provide it with assurances that the interest has been managed, reduced or eliminated in accordance with this policy.

B. The appropriate designated official shall conduct a similar review whenever any additional or updated statements of financial interest are received after the initial expenditure of federal funds. If a conflict of interest is identified, within 60 days, the conflicting interest shall be managed, reduced, or eliminated as provided above, at least on an interim basis, and a report shall be made to the PHS Awarding Component as provided above.

C. If the failure of an Investigator to comply with this policy has biased the design, conduct, or reporting of the PHS-funded research, the appropriate designated official shall within 60 days notify the PHS Awarding Component of the corrective action taken or to be taken.

D. If this institution does not in a timely manner identify or manage a financial conflict of interest, it shall, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The appropriate designated official shall document this retrospective review by creating a report that includes all of the following: (i) Project number; (ii) Project title; (iii) PI/PD or contact PI/PD if a multiple PI/PD model is used; (iv) Name of the Investigator with the Financial Conflict of interest; (v) Name of the entity with which the Investigator has a Financial Conflict of Interest; (vi) Reason(s) for the retrospective review; (vii) Detailed methodology used for the retrospective review; (viii) Findings of the review; and (ix) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, this institution shall update the previously submitted financial conflict of interest report, specifying the actions to be taken to manage the financial conflict of

interest going forward. If bias is found, the institution shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report shall include, at a minimum, the key elements documented in the retrospective review as well as 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 (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). Thereafter, this institution will submit financial conflict of interest reports annually. Depending on the nature of the financial conflict of interest, the institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of the institution's retrospective review.

E. If HHS determines that a PHS-funded project of clinical research 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 conflicting interest that was not disclosed or managed as required by this policy, this institution shall require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research and request an addendum to previously published presentations.

VIII. PUBLIC ACCESSIBILITY

A. The appropriate designated official shall ensure that this institution publicly posts its Financial Conflict of Interest policy on its publicly accessible web site. Prior to the expenditure of any PHS-funded research project, this institution shall post on its publicly accessible web site information concerning any Significant Financial Interest disclosed to this institution that meets the following three criteria.

- (i) The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel for the PHS-funded research project identified by this institution in the grant application, progress report, or any other required report submitted to the PHS Awarding Component;
- (ii) This institution determines that the Significant Financial Interest is related to the PHS-funded research; and
- (iii) This institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

B. The appropriate designated official shall ensure that the following information listed below is posted on this institution's publicly accessible web site. This institution will update its publicly accessible web site annually, or within 60 days of a newly identified financial conflict of interest, and will keep the information available for three years from the date the information was most recently updated.

- (i) Investigator's name; title and role with respect to the research project;
- (ii) Name of the entity in which the Significant Financial Interest is held;
- (iii) Nature of the Significant Financial Interest; and
- (iv) Approximate dollar value of the significant financial interest in the following dollar ranges: \$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.

IX. SUBCONTRACTORS, SUBRECIPIENTS, AND COLLABORATING INSTITUTIONS

If this institution plans to carry out or carries out PHS-funded research through subgrantees, subcontractors or collaborators, it shall require that such entities provide it with written assurances that they have in effect a written,

enforced policy on conflict of interest that complies with the requirements of 42 CFR Part 50, 45 CFR Subpart F and other applicable laws and regulations. If an entity fails to provide such assurances, this institution shall require Investigators working for such entity to comply with this policy.

X. EFFECTIVE DATE

This policy takes effect September 16, 2013.

STATEMENT OF SIGNIFICANT FINANCIAL INTERESTS BACKGROUND INFORMATION AND INSTRUCTIONS

This institution has a research conflict of interest policy as required by the U.S. Public Health Service (NIH, CDC, etc.). The policy requires all Investigators to complete a statement of significant financial interests and return it to the ChangeLab Solutions prior to submission of a proposal. This institution may not submit a proposal to a PHS component until all proposed Investigators submit their statements. You can obtain a copy of ChangeLab Solutions' research conflict of interest policy and the applicable federal regulations from the Contracts Manager.

Who must submit a statement:

Anyone who plans to participate or is participating at this institution as an Investigator (i.e., PI/PD or other position with responsibility for the research design, conduct and reporting) on PHS-funded research must submit a statement of significant financial interest. Follow-up statements may also be required (see below).

Consultants and unpaid Investigators:

This institution's policy applies to all Investigators, including current and prospective employees of this institution, consultants, unpaid Investigators whose time is contributed, etc. If you work for a proposed or current subcontractor, subrecipient, or collaborating institution on this institution's PHS-funded research, special rules may apply. Contact ChangeLab Solutions for more details.

What information must be disclosed:

You must disclose all your known *significant financial interests* (and those of your spouse and dependent children): (1) that would reasonably appear to be related to your institutional responsibilities including the research for which PHS funding is being sought; and (2) in entities whose financial interests would reasonably appear to be related to your institutional responsibilities or to be affected by the research.

Disclosures must be made on the attached form. If you don't have any reportable significant financial interests, you must complete the statement with a negative declaration.

"Significant financial interest" means:

(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 institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* 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;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* 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 the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of 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 their institutional 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. The Investigator's disclosure to the Institution's shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institution's appropriate designated official 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.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.”

When a statement should be submitted

You must submit a financial interest statement on or before the date on which this institution: (1) submits an application for PHS-funded research to PHS; (2) submits a proposal to PHS for a research contract whether in response to a solicitation from PHS or otherwise; or (3) assumes the legal obligation to carry out research required under a PHS-funded research contract.

Sometimes an individual doesn't initiate plans to participate or begin participating as an investigator until after this institution has submitted an application or proposal. In that case, you should submit a statement as soon as your plans to participate or your participation is initiated.

Updated statement

Investigators who are required to submit or have submitted a statement of known significant financial interests are required to submit an updated statement annually or within 30 days of acquiring or discovering a new reportable significant financial interests are obtained.

STATEMENT OF SIGNIFICANT FINANCIAL INTERESTS

If you determine that you have no reportable significant financial interests, complete Section I Negative Declaration. Return this form to the Director of Finance.

If you determine that you have reportable significant financial interests, complete Section II. Report each interest separately. Specify the owner of the interest (e.g. investigator, spouse, dependent child) and nature of the interest (e.g., "250 shares of Biotech Co., fair market value \$12,000" or "expected annual salary of \$36,000 from Techno Corporation"). Do not report financial interests not within the definition of "Significant Financial Interest." For travel, report the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. Specify how each Significant Financial Interest would reasonably appear to be related to the Investigator's institutional responsibilities or to be affected by the PHS-funded research, or how the financial interests of the entity in which you have a significant financial interest would reasonably appear to be affected. Do not report Significant Financial Interests that do not reasonably appear to be affected. Sign the declaration and return this form to the Director of Finance. Fax and scanned submissions are acceptable.

I. NEGATIVE DECLARATION

I declare that to the best of my knowledge and belief I have no reportable Significant Financial Interests:

Name (print or type)

Signature

Date

II. AFFIRMATIVE DECLARATION

I declare to the best of my knowledge and belief I have the following reportable Significant Financial Interests:

Name (print or type)

Signature

Date

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