

**Policy and Procedures for
Managing Conflict of Interest Requirements
Imposed by Federal Sponsors**

(Public Health Service (PHS/NIH) and National Science Foundation are Currently Covered)

EFFECTIVE AUGUST 24, 2012

POLICY

Caltech is committed to promoting objectivity in research. We support this objective through compliance with National Science Foundation¹ (“NSF”) and Public Health Services² (“PHS”) rules regarding the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interest affecting covered research activities. Caltech has implemented this policy and the following corresponding procedures which establish standards intended to provide a reasonable expectation that the design, conduct and reporting of research funded by the NSF or PHS, including the National Institute of Health (“NIH”), will be free from bias resulting from Financial Conflicts of Interest as defined hereunder. Compliance with these requirements is a condition for submitting a proposal and accepting an award of Federal financial support from the NSF or PHS for all activities conducted under Caltech auspices. This policy and the associated procedures are intended to supplement existing Caltech policies on conflict of interest and conflict of commitment. This policy and these procedures apply to all individuals who meet the definition of Investigator as defined hereunder and, as such, may include faculty, JPL staff, Caltech staff, postdocs, students, external collaborators and co-investigators from other educational institutions or organizations.

¹ Investigator Financial Disclosure Policy -NSF -Federal Register, Vol 60, July 11, 1995, pp. 35820 to 35823.

² Objectivity in Research -DHHS -Federal Register, Vol. 76, August 25, 2011, pp. 53256 to 53293.

PROCEDURES

CONTENTS

The following pages describe the procedures for compliance with Caltech's Policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors. As with all procedures, these may change from time to time to ensure the most efficient processes and effective compliance. To help navigate the complexity of these requirements, we have organized the document as follows:

Definitions

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DEFINITIONS

Investigator is the project director or principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of the research funded by NSF or PHS, or proposed for such funding, which may include faculty, JPL staff, Caltech staff, post-doctoral scholars, students, external collaborators and co-investigators from other institutions or organizations.

Definitions (continued):

Institutional Responsibilities includes an Investigator's professional responsibilities on behalf of Caltech, including activities such as teaching, research, Institute committee or board membership and services and other administrative duties.

Significant Financial Interest (SFI)

The term Significant Financial Interest is defined differently for PHS and NSF. Please review the following carefully to understand the differences and to ensure accurate reporting.

SFI For purposes of PHS funding:

A. Significant Financial Interest means 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 relate to the Investigator's Institutional Responsibilities:

- 1) 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria³); equity interests includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- 2) With regard to any non-publicly traded entity, a significant financial interest exists if the aggregated value of any remuneration received from the entity, in the twelve months preceding the disclosure, 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);

³ Honoraria is considered in determining whether there is a significant financial interest for purposes of PHS and NSF funding disclosures even though they are not under the Institute's general conflict of interest disclosure requirements.
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Definitions (continued):

- 3) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income by the Investigator related to such rights and interests.

B. Included in the definition of Significant Financial Interest is the occurrence of any reimbursed or sponsored travel (i.e. "sponsored travel" is travel which is paid on behalf of the Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's institutional responsibilities.

C. The term significant financial interest does *not* include the following:

- 1) For Caltech employees, salary, royalties, or other remuneration from Caltech, including intellectual property rights assigned to Caltech and agreements to share in royalties related to such rights;
- 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;
- 3) Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;
- 4) Travel reimbursements by Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute;
- 5) Income from service or advisory committees or review panels for Federal, state or local government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

Definitions (continued):

SFI For purposes of NSF funding, Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria⁴); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

- 1) salary, royalties or other remuneration from the applicant institution
- 2) any ownership interests in the business, if the business is an applicant under a Phase I Small Business Innovation Research Program or Small Business Technology Transfer Program;
- 3) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- 4) income from service on advisory committees or review panels for public or non-profit entities;
- 5) an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
- 6) salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve month period.

⁴ Honoraria is considered in determining whether there is a significant financial interest for purposes of PHS and NSF funding disclosures even though it is not under the Institute's general conflict of interest disclosure requirements.
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Definitions (continued):

Disclosure is the submission of the Conflict of Interest Disclosure form through Caltech's Conflict of Interest application which may be accessed at <https://access.caltech.edu> by each Caltech individual who meets the definition of Investigator. The Disclosure should include the details of the nature of any Significant Financial Interest⁵ for the applicable Federal agency, and which is held by the Investigator, his/her spouse and/or dependent children.

For NSF and PHS proposals or awards involving an external collaborator who meets the definition of Investigator and who has a Significant Financial Interest, Disclosure can take one of two forms:

- 1) If the collaboration is with an Investigator whose institution complies with NSF or PHS policies, an annual certification from the institution asserting that it complies with NSF and PHS policy will suffice.
- 2) If the collaboration is with an Investigator acting as an individual or through an organization that does not comply with NSF or PHS policies, the collaborator Investigator(s) must file a Disclosure. To obtain access to the Disclosure system, the non-Caltech Investigator must contact the Office of Research Compliance (orc@caltech.edu).

Financial Conflict of Interest a Significant Financial Interest held by an Investigator that could directly and significantly affect the design, conduct, or reporting of his/her PHS or NSF funded research. The determination as to whether a Significant Financial Interest constitutes a Financial Conflict of Interest is made by the Institutional Official and the Provost or the Provost's designee. For purposes of PHS and NSF, any ownership interests (whether SFI or not) in a business will not constitute an FCOI if the business is an applicant under a Phase I Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer (STTR) Program.

⁵ SFI as defined by the applicable Federal agency.
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Definitions (continued):

Manage taking action to address a financial conflict of interest, which may include reducing or eliminating the financial conflict of interest, to ensure to the extent possible, that the design, conduct and reporting of the research will be free from bias.

Senior/Key Personnel the project director or principal investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to PHS by Caltech.

Institutional Official the Division Chair to whom the Investigator is administratively responsible. For campus employees who do not report administratively to a Division Chair, or for the Division Chair, the Institutional Official is the Provost or the Provost's designee. For JPL staff, this term will mean the individual, designated by the Director of the Laboratory, who is to receive Disclosure statements.

End Definitions.

REQUIRED DISCLOSURES

Investigators are required to identify and disclose, or identify and re-verify, if previously disclosed, Significant Financial Interests **before** an application is submitted to either NSF or PHS, and **thereafter within 30 days** of discovering or acquiring a new Significant Financial Interest. Disclosures must also be updated at least annually in connection with Caltech's annual Conflict of Interest disclosure process.

At the time a proposal is being prepared, the individual serving as principal investigator should alert any other individuals who may meet the definition of Investigator of the need to comply with these procedures. All individuals who are considered to be Investigators (including the principal investigator) are to determine if they have any Significant Financial Interests and, if so, each must file an electronic Disclosure of the nature and magnitude of the financial

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interest. According to Federal requirements, all such Disclosures must be submitted with the appropriate Institutional Official **before Caltech can forward the proposal** to the covered Federal funding agency (NSF or NIH).

The principal investigator will complete the Division Approval Form indicating whether Disclosures have been submitted and making the certification as described, below, under Principal Investigator Responsibilities. In cases where a Disclosure has been indicated as being submitted, the Division Chair shall not sign the Division Approval Form until any related Disclosures have been received. Before any expenditure of funds can occur, the Institutional Official must review the Disclosures and address any conflicts of interest. Proposals will only be processed by the Office of Sponsored Research if the appropriate certifications have been made on the Division Approval Form and the Disclosures are on file.

DISCLOSURE REVIEW AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

Caltech will review disclosures of Significant Financial Interests in accordance with these procedures to determine whether an actual or potential Financial Conflict of Interest exists. Caltech's Institutional Official will review and work with the Investigator(s) to develop a management plan for any such conflicts before awarded funds are expended. Compliance with Caltech's governing policies and these procedures is an ongoing requirement that Caltech must fulfill in order to be eligible to receive funding from NSF and PHS.

Institutional Officials and the Office of the Provost are designated by Caltech as responsible for reviewing disclosures of Significant Financial Interests and determining whether a Financial Conflict of Interest exists for purposes of covered Federal funding. When a Financial Conflict of Interest is identified, these individuals also are responsible for determining what steps need to be taken to manage the conflict prior to the expenditure of covered funding.

The Institutional Official receiving a Disclosure will: review the disclosure to determine if the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest for purposes of the award. If any actual or potential Financial Conflict of Interest is identified, the Institutional Official will work with the Investigator to determine the steps that should be taken to manage the conflict and will prepare a proposed written management plan. The proposed management plan will be forwarded to the Provost's Office along with the original copy of the Disclosure and a copy of the corresponding Division Approval Form.

The Provost's Office will review the Disclosure in the context of the proposed activity along with the management plan proposed by the Investigator and Institutional Official. Before permitting any expenditure of funds from the Federal sponsor, the Provost, in collaboration with the Institutional Official, will approve the management plan describing the conditions and possible restrictions that Caltech believes are necessary to manage the actual or potential Financial Conflict of Interest. The following are examples of conditions or restrictions that may be included in a management plan:

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modifications to the research plan;
- disqualification from participation in all or a portion of the activity funded by the Federal agency that would impact the significant financial interest;
- divestiture of significant financial interests;
- severance of relationships that create potential or actual conflicts; or
- require placing of shares or other forms of equity ownership documents in a blind trust.

Copies of the approved management plan will made available to the Investigator and the plan must be implemented before the expenditure of funds.

For PHS funded activities, all SFI must be reviewed by the Institutional Official and all potential FCOI completely addressed prior to expenditure of funds. Should an SFI arise during the term of the award, the Investigator must file a Disclosure within 30 days and the SFI must be

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reviewed by the Institutional Official and all potential FCOI completely addressed within 60 days of the Disclosure. If an Investigator does not file his/her Disclosure in a timely manner, additional compliance action by the Institutional Official and the Institute will be required pursuant to 42 CFR 50.605.

REPORTING

The Office of Research Compliance will make any required reports to PHS and NSF. In the case of PHS, the PHS will review the reported Financial Conflict of Interests to determine if additional information is needed. PHS may decide that further action is needed to ensure the objectivity of the research or that the Financial Conflict of Interest has not been appropriately managed, reduced or eliminated. PHS may also require suspension of funding until the matter is resolved.

TRAINING

For PHS funded or proposing Investigators, Caltech will provide Investigators with training regarding the requirements of these procedures and the governing policy and any changes thereto:

- 1) prior to an Investigator's engagement in research related to any PHS funded project;
- 2) every four years; and
- 3) whenever an Investigator is found to be out of compliance with these procedures, their governing policy, or an applicable management plan.

The principal investigator will be responsible for certifying that all investigators have undergone the required training prior to their engagement in the covered research.

NSF funded or proposing Investigators should familiarize themselves with the Institute Conflict of Interest Policy and these procedures and the governing policy relative to obligations required by NSF.

RECORDKEEPING

The Institute will maintain required records of all Disclosures and of all actions taken to manage actual or potential conflicts of interest for at least three (3) years from the date the final expenditure or project report is submitted to PHS or NSF or until the resolution of any legal or government action involving these records, whichever is later.

SUBRECIPIENT REQUIREMENTS

Caltech will include provisions in all covered subawards requiring subrecipients to comply with NSF and PHS rules related to the disclosure of Significant Financial Interests and management of Financial Conflict of Interests consistent with Federal requirements for covered awards.

PUBLIC ACCESSIBILITY OF FINANCIAL CONFLICTS OF INTEREST

Upon written request to the Office of Research Compliance (orc@caltech.edu), Caltech is required to provide, within 5 business days, a written disclosure of Financial Conflicts of Interest held by Senior and Key Personnel proposing for funding or funded by PHS, including:

- 1) the Investigator's name;
- 2) the Investigator's title and role with respect to the research project;
- 3) the name of the entity in which the Significant Financial Interest is held;
- 4) the nature of the Significant Financial Interest;
- 5) the approximate dollar amount of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

Caltech requires that the designated principal investigator for an activity that is proposed to be, or actually is, funded by a covered Federal sponsor is required to:

- 1) Become familiar with these procedures and the governing policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors
- 2) Distribute copies of this document to any individual who either meets or can reasonably be expected to meet the definition of Investigator and who will participate on any covered activity that is proposed to be, or is, Federally funded by NSF or PHS.
- 3) Assure the Institutional Official and the Office of Sponsored Research, through certification on the Division Approval Form accompanying all proposals, they, themselves, and to the best of their knowledge, all individuals who satisfy the definition of Investigator:
 - (a) have reviewed their responsibilities with respect to this document and the Caltech Policy on Conflicts of Interest,
 - (b) have determined whether they have any Significant Financial Interests as defined in this document,
 - (c) have submitted a Disclosure(s) to Caltech or their own Institution, as required; and
 - (d) have completed all required Col training.

The principal investigator must also indicate whether he or she knows of any potential Financial Conflicts of Interest between any Investigator, including him/herself, arising from a Significant Financial Interest and the proposed work.

- 4) Notify the Office of Sponsored Research of those external collaborators on NSF or PHS proposals that would fulfill the role of Investigator so that institutional

certifications can be obtained, where appropriate.

POSTING OF THE POLICY AND PROCEDURES

Caltech will post these procedures and the governing policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors on its public Office of Research Compliance website. All current and future personnel receiving or proposing to receive funds from the covered federal sponsors are required to become familiar with these procedures and the governing policy.

SANCTIONS

Failure to timely comply with Disclosure requirements for PHS funded awards may result in delays in accessing funds or suspension of expenditures on PHS funded activities.

Individuals who fail to adhere to these procedures and the governing policy may be subject to suspension of funds, to removal from participation on the covered award and disciplinary action up to and including termination of employment.

ASSISTANCE

The Division Chairs, the Provost's Office and the Office of Research Compliance are available to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.