

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

POLICY

Caltech is committed to promoting objectivity in research. We support this objective through compliance with Federal sponsor requirements regarding the disclosure of Significant Financial Interests and the management of Financial Conflicts of Interest affecting covered research activities. Caltech has implemented this policy as a supplement to Caltech's [Policy on Conflicts of Interest](#), [Graduate Student Policy on Conflicts of Interest](#), Caltech's [Policy on Conflicts of Commitment for Researchers](#), and Caltech's [Personnel Memorandum 9-3](#). This policy sets forth standards intended to provide a reasonable expectation that the design, conduct and reporting of research funded by Federal agencies 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 Federal agencies for research at Caltech. This policy, including the procedures implementing the policy and described herein, apply to all individuals who conduct research on Federally sponsored awards and may include faculty, JPL staff, Caltech staff, postdocs, graduate students, external collaborators and co-investigators from other educational institutions or organizations.

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:

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DEFINITIONS

Covered Individual is the project director, co-project director, principal investigator, co-investigators, and any other person, regardless of title or position, who is responsible or contributes in substantive or meaningful way to the proposing, design, conduct or reporting of the research funded by the Federal sponsor, and any other individual as otherwise specified by a Federal sponsor. This may include JPL staff, Caltech staff, post-doctoral scholars, graduate students, external collaborators and co-investigators from other institutions or organizations.

Institutional Responsibilities include a Covered Individual's professional expertise and their professional responsibilities on behalf of Caltech, including activities such as teaching, research, Caltech committee or board membership and services and other administrative duties.

Significant Financial Interest (SFI) may be defined differently for each agency. We have standardized our definition to harmonize among all the agencies.

SFI includes:

1. Financial Interest in a Publicly Traded Entity:
 - a. A financial interest is an SFI if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when combined with all financial interests from the entity, is equal to or exceeds \$5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria);
 - b. An equity interest is an SFI if the equity, including the equity held by the individual, and their spouse, domestic partner and children, when aggregated, as of the date of the disclosure, when combined with all financial interests from the entity, is equal to or exceeds \$5,000 and/or exceeds 5% of the total equity. Equity interests include any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - c. An SFI includes intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income by the Covered Individual related to such rights and interests.
2. Financial Interest in a Non-Publicly Traded Entity:
 - a. A financial interest is an SFI if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when combined with all financial interests from the entity, is equal to or exceeds \$5,000. Remuneration includes salary and other payments for services not otherwise identified as salary (e.g., consulting fees, paid authorships, or honoraria);
 - b. Any equity interest is an SFI, including any equity held by the individual, and their spouse, domestic partner and children. Equity interests include any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
3. Financial Interest related to a Not-for-profit Organizations (excluding Caltech):
 - a. A financial interest is an SFI if it is income from seminars, lectures, or teaching engagements if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when combined with all financial interests from the entity, is equal to or exceeds

\$5,000.

- b. A financial interest is an SFI if it is reimbursed or sponsored travel (i.e., that which is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual so that the exact monetary value may not be readily available) received from the entity in the twelve months preceding the disclosure, when combined with all financial interests from the entity, is equal to or exceeds \$5,000.

A. 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, if the Covered Individual 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 U.S. government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.
- 4) Reimbursed or sponsored travel paid by Federal, state or local U.S. government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute; or
- 5) Income from service or advisory committees or review panels for Federal, state or local U.S. government agency, an Institution of higher education in the U.S. or its affiliated academic teaching hospital, medical center or research institute.

Disclosure is the submission of the financial interests and commitments through Caltech's Disclosure of Financial Interests and Commitments (DFIC) application, which may be accessed at <https://access.caltech.edu> by each Caltech individual who meets the definition of a Covered Individual. The Disclosure should include the details of the nature of any Significant Financial Interest for the applicable Federal agency, and which is held by the Covered Individual, his/her spouse and/or dependent children.

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

- 1) If the collaboration is with a Covered Individual whose institution complies with the applicable Federal Agency COI requirements, including having a compliant FCOI policy, an annual certification from the institution asserting that it complies with agency requirements and has a compliant policy will suffice.
- 2) If the collaboration is with a Covered Individual acting as an individual or through an organization that does not comply with the Federal Agency FCOI requirements, the collaborator Covered Individual(s) must file a Disclosure in the Caltech DFIC. To obtain access to the DFIC system, the non-Caltech Covered Individual must contact the Office of Research Security (researchsecurity@caltech.edu).

Financial Conflict of Interest (FCOI) is a Significant Financial Interest held by a Covered Individual that could directly and significantly affect the proposal, design, conduct, or reporting of Federally funded research. The determination as to whether a Significant Financial Interest constitutes an FCOI is made by the Institutional Official and the Provost or the Provost's designee. For purposes of PHS and NSF funding, 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.

Manage means taking action to address an FCOI, which may include managing, reducing or eliminating the FCOI, to ensure to the extent possible, that the design, conduct and reporting of the research will be free from bias.

Senior/Key Personnel means 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 a Federal Agency by Caltech.

Institutional Official For faculty, the Institutional Official is their Division Chair. For research staff and postdocs, the Institutional Official is the Associate Vice Provost for Research Policy and Compliance, or their delegate. For graduate students the Institutional Official is the Graduate Dean or their delegate. For JPL staff, this term will mean the JPL Ethics Officer, who is to receive Disclosure statements.

REQUIRED DISCLOSURES

Covered Individuals are required to file a Disclosure in the Caltech Disclosure of Financial Interests and

Commitments (DFIC) application that identifies, or identifies and re-verifies (if previously disclosed), all Significant Financial Interests (SFI). Such Disclosures must be filed at time of hire, **before** any proposal is submitted to a Federal agency, and **within 30 days** of discovering or acquiring a new SFI. 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, all Covered Individuals (including the principal investigator) who must certify that their Disclosure is current, complete and accurate. A Disclosure will be considered current if it was submitted after June 1 of the current disclosure period (June 1 – May 31). The Covered Individual will need to determine whether the Disclosure is complete and accurate. If a Disclosure is not current, complete and accurate, the Covered Individual must submit a Disclosure in the DFIC disclosing all SFI and including a description of the nature of the SFI, the time committed and the amount or value of the SFI. Additionally, in the DFIC, Covered Individuals will be asked to explain how the SFI is related to their Institutional Responsibilities. Per Federal requirements, all such Disclosures must be submitted to the appropriate Institutional Official **before Caltech can forward the proposal** to the covered Federal funding agency.

Each Covered Individual will complete the certifications as part of the Division Approval Form indicating whether Disclosures have been submitted and provide the certification as described, below, under Covered Individual Responsibilities. The Division Chair shall not sign the Division Approval Form until all Covered Individual Disclosures and certifications have been received. 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

For Awards:

Before any expenditure of funds can occur, the Office of Research Security must review the Disclosures and address any financial conflicts of interest related to the Federal award.

The Office of Research Security will review the Disclosure to determine if any disclosed SFI constitutes a Financial Conflict of Interest (FCOI) for purposes of the award. If any actual or potential FCOI is identified, Caltech's Conflict of Interest Manager will work with the Covered Individual(s) to develop a

management plan to manage, reduce, or eliminate any such conflicts before awarded funds are authorized for expenditure. The Covered Individual and the Institutional Official must sign off on any management plans for Faculty Covered Individuals and there must be an approved Outside Activity Approval (See PM 9-3) for Research Staff and Postdoc Covered Individuals.

Copies of the approved management plan or Outside Activity Approval will be made available to the Covered Individual and the plan must be implemented before the activity continues.

As required, the FCOI and management plan will be shared with the Federal agency, in accordance with agency requirements and timelines.

For Annual Reviews or New Financial Interests or Activities Giving Rise to Review (e.g. SRA, Gift, FUA, TSA):

Annual Disclosures will be pre-reviewed as assigned by the DFIC and then reviewed by the appropriate Institutional Official who will determine whether there is an actual or potential FCOI. If an actual or potential FCOI exists, the Director of Research Security, in collaboration with the Institutional Official, will develop and approve the management plan describing the conditions and possible restrictions that Caltech believes are necessary to manage, reduce or eliminate the actual or potential FCOI. The Faculty Member and the Institutional Official must sign off on any management plans for Faculty Covered Individuals and there must be an approved Outside Activity Approval for Research Staff and Postdoc Covered Individuals.

Copies of the approved management plan or Outside Activity Approval will be made available to the Covered Individual and the plan must be implemented before the activity continues.

When required, the FCOI and management plan will be shared with the Federal agency, in accordance with agency requirements and timelines.

Factors to Consider in Management Plans:

The following are examples of conditions or restrictions that may be included in a management plan:

- public disclosure of SFIs;
- monitoring 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 SFI;
- divestiture of SFI;
- 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.

REPORTING

The Office of Research Security will make reports to Federal Agencies, as required.

TRAINING

Covered Individuals will receive training as required by the applicable Federal agency.

Covered Individuals will certify that they have completed all required training.

RECORDKEEPING

As required, Caltech will maintain all 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 the Federal agency 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 Federal agency rules related to the disclosure of SFI and management of FCOI consistent with Federal requirements for covered awards.

PUBLIC ACCESSIBILITY OF FINANCIAL CONFLICTS OF INTEREST

Upon written request to the Office of Research Security (researchsecurity@caltech.edu), Caltech is required to provide, within five (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 SFI is held;
- 4) the nature of the SFI;
- 5) the approximate dollar amount of the SFI 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 the designated principal investigator for an activity that is proposed to be, or actually is, funded by a covered Federal sponsor to:

- 1) Become familiar with this policy for Managing Conflict of Interest Requirements Imposed by Federal Sponsors, and the Federal Sponsor's specific requirements.
- 2) Distribute copies of this document to any individual who either meets or can reasonably be expected to meet the definition of Covered Individual on a Federally sponsored project.
- 3) The principal investigator must also indicate whether he or she knows of any potential Financial Conflicts of Interest between any Covered Individual, including him/herself, arising from a SFI and the proposed Federally sponsored project.
- 4) Notify the Office of Sponsored Research of any external collaborators on Federally sponsored proposals that would qualify as a Covered Individual so that 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 Security 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 and certification requirements for Federally funded awards may result in delays in accessing funds or suspension of expenditures on Federally 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 Office of Research Policy and the Office of Research Security are available to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.