Managing Conflict of Interest Requirements Under Federal Sponsored Awards

INTRODUCTION

Certain Federal Agencies^{1,2} have issued specific guidelines governing policies and procedures on financial disclosure and potential conflict of interest that recipients of Federal awards must follow in order to continue to receive research funding. The Institute has reviewed the existing guidelines and has determined that in the interests of uniformity in accepting and administering any Federal awards it will implement the following policies and procedures as a condition for submitting a proposal and/or accepting an award of Federal financial support for all activities conducted under Institute auspices. These policies and procedures are intended to be a supplement to the existing Institute policies on Conflict of Interest, Conflict of Commitment and Technology Transfer that are covered in Chapter 7 of the Faculty Handbook. These procedures and policies are to cover all individuals who meet the definition of Investigator under the Federal guidelines and, as such, may cover faculty; staff, including members of JPL; students; and co-investigators from other educational institutions or organizations.

DEFINITIONS

Investigator means the principal investigator; co-investigators; and any other person including research faculty, JPL staff, Institute professional staff, post doctoral scholars, students, and external collaborators who could be considered to be responsible for the design, conduct, or reporting of research or other activities funded or proposed for funding by a Federal agency. For the

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

²Objectivity in Research - DHHS - Federal Register, Vol. 60, July 11, 1995, pp. 35810 to 35819.

purposes of determining whether an Investigator has a financial interest the term "Investigator" also includes the Investigator's spouse and dependent children.

Significant Financial Interest for the purposes of these policies and procedures means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees, major gifts, or honoraria); 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) For Institute employees, salary, royalties, or other remuneration from the Institute; or any ownership interests in a business or commercial enterprise, if the business or enterprise is an applicant under the Small Business Innovative Research (SBIR) Program or the Small Business Technology Transfer (STTR) Program;
- 2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- 4) 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 five percent ownership interest in any single entity; or
- 5) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Disclosure means the written statement filed with the appropriate Institute official by each and every individual that meets the definition of Investigator when such individual is listed as a participant in a proposal for an activity that is proposed to be supported with Federal funds or subsequently actively participates in the role of an Investigator on an on-going activity supported with Federal funds. The Disclosure should include the details of the nature of any financial interest of the individual and, if applicable, that of any spouse and dependent children, that would appear to be significantly affected by the activities. For National Science Foundation and Public Health Service proposals involving external collaborators who meet the definition of Investigator and have a financial interest of the type covered by these guidelines, Disclosure can take one of two forms:

- 1) If their collaboration is through an organization that complies with National Science Foundation or Public Health Service Policies, then a certification from their institution that it complies with National Science Foundation and Public Health Service policy will suffice.
- 2) If their collaboration is as an individual or through an organization that is not required to comply with National Science Foundation or Public Health Service policies, the collaborator(s) must file a Disclosure, if required, with the Provost's Office of the Institute.

<u>Division Chair</u> used throughout this document refers to the head of the Division to whom the individual meeting the requirements of the definition of Investigator is administratively responsible. For JPL staff this term will mean the individual, designated by the Director of the Laboratory, who is to receive Disclosure statements. For any other campus employees who do not report administratively directly to a Division Chair, the term is to mean the Provost or the Provost's designee.

POLICY

Federal policy requires that the Institute identify Significant Financial Interests of the following types that are attributable to any individual meeting the definition of Investigator and ensure that these are managed, reduced, or eliminated prior to allowing the expenditure of any funds under a Federal award for financial support of the activity:

- Any Significant Financial Interest of the Investigator that would reasonably appear to be directly and significantly affected by the activity funded by, or proposed to be funded by Federal funds, and
- 2) Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be directly and significantly affected by the activity funded by, or proposed to be funded by Federal funds.

The managing of Significant Financial Interests of individuals meeting the definition of Investigator is an ongoing requirement that the Institute must fulfill as long as the activity is supported with Federal funds. In turn, individuals who satisfy the definition of Investigator on a given Federal award are required to notify the Division or other designated office of any financial interests, or changes thereof, as long as they participate as an Investigator on a proposal or Federally funded activity.

INSTITUTE RESPONSIBILITIES

The Office of the Provost is designated as the Institute office responsible for reviewing financial disclosures that are judged significant. The Office of Sponsored Research, acting on behalf of the Institute, must be in a position to certify on proposals submitted to selected Federal agencies that the Institute has in place a policy and procedures to identify and manage, reduce or eliminate

Significant Financial Interests of the type described in the Policy Section. For awards from the Public Health Service, the Office of Sponsored Research will have to report to the Public Health Service awarding unit, prior to expenditure of any funds under the award, the existence of any significant conflicting interests found by the Institute in its review and assure the awarding unit that the interests have been managed, reduced, or eliminated. Further, the Office of Sponsored Research may have an obligation to notify certain funding agencies if changes occur in the status of the financial interests of an individual or individuals who satisfy the definition of Investigator. Notification of the National Science Foundation is required if the Office of the Provost judges that the Institute is unable to satisfactorily manage an actual or potential conflict of interest. Finally, the Office of the Provost will maintain the required records of all Disclosures and of all actions taken to resolve actual or potential conflicts of interest until at least three (3) years after the termination or completion of the activity to which such conflicts relate or until the resolution of any government action involving these records, whichever is later. To fulfill these responsibilities the Institute must rely on the assistance of the individual that is designated as the Principal Investigator on a Federally supported activity.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The individual that is designated as Principal Investigator for an activity that is proposed to be, or actually is, funded by a Federal sponsor is required to:

- Become familiar with the current Institute policy and procedures for managing conflicts of interest (the current version of this document).
- 2) Distribute copies of the policy and procedures to all individuals who will participate as an Investigator on an activity that is proposed to be, or actually is, Federally funded and who either satisfy or can reasonably be expected to satisfy the definition of Investigator.

- 3) Assure the Division Chair and the Office of Sponsored Research, through certification on the Division Approval Form accompanying all proposals, that all individuals, including themselves, who satisfy the definition of Investigator have reviewed their individual involvement in the activity to determine if they have a financial interest as defined in these guidelines and, if they do, have filed a Disclosure with their Division Chair or other appropriate Institute administrative official.
- 4) Notify the Office of Sponsored Research of those external collaborators on National Science Foundation or Public Health Service proposals, that would fulfill the role of Investigator so that institutional certifications can be obtained, where appropriate.
- 5) Assume responsibility for seeing that all those individuals who meet the definition of Investigator: (a) who have a financial interest are reminded of the requirement to file an annual update of their Disclosure with their Division Chair; (b) who during the course of the project have any change in the status of their financial interests are aware of the requirement to notify the Division Chair of the change at the time the change occurs.
- 6) Agree to abide by any conditions imposed by the Institute as a result of a review of the nature of the financial interests of those individuals filing a disclosure related to a given proposed Federally funded activity.

PROCEDURES

The following steps are presented as guidelines to assist individuals in working with the Institute to satisfy Federal requirements regarding compliance with Conflict of Interest regulations:

1) The Institute will make copies of these policies and procedures available to Division Offices, the Office of the Dean of Graduate Studies, Human

Resources, JPL, and any other unit or individual that may have personnel engaged on a Federally funded activity. All current and future personnel are required to become familiar with this policy and associated procedures.

2) 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 this policy on Conflict of Interest. All individuals who are considered to be Investigators (including the Principal Investigator) are to determine if they have any financial interests according to these guidelines and, if so, must file a written Disclosure of the nature and magnitude of the financial interest with the Division Chair responsible for the Investigator's compliance with Institute policies and procedures.

According to Federal requirements all such Disclosures must be on file with the appropriate Division Chair before the Institute can forward the proposal to the Federal funding agency.

- 3) The Principal Investigator will complete the Division approval form and certify: (a) that the proposed activity has been reviewed for potential conflicts of interest and; (b) if any have been identified, that the required Disclosures have been filed with the Division or other appropriate office. In cases where a Disclosure is indicated, the Division Chair shall not sign the Division Approval Form until the Disclosure has been received. The proposal 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.
- 4) The Division or other appropriate Institute Office receiving a Disclosure will: (a) review the disclosure to determine if the disclosed financial interests are considered significant and, (b) if any significant interests are

identified, make a recommendation as to the steps that are to be taken to reduce or eliminate the potential conflict. This review and recommendation 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. If a change in the status of the financial interest of an individual who meets the definition of Investigator and who is a participant in a pending or a funded Federally supported project occurs, the required new or revised Disclosure will be reviewed by the Division, and forwarded, with appropriate recommendations to the Office of the Provost for review and action. This supplemental Disclosure shall reference the Federally funded activity to which it applies.

- 5) The Provost's Office will review the Disclosure in the context of the proposed activity along with any recommendations and actions proposed by the Division. Before permitting any expenditure of funds from the Federal sponsor the Provost in collaboration with the Division Chair or other equivalent administrative official will state the conditions and possible restrictions that the Institute believes are necessary to manage, reduce, or eliminate actual or potential conflicts of interest so that the Institute can allow expenditure of any funds from the award. Copies of these decisions will be sent to the investigator(s), the Principal Investigator and the Office of Sponsored Research. For Public Health Service awards the Office of Sponsored Research will send an assurance to the Public Health Service awarding unit that a significant financial interest was identified and it has been managed, reduced, or eliminated as appropriate. Examples of such conditions or restrictions include:
 - 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.

In those rare cases where an offer of an award is received from a Federal agency and no formal proposal has been processed through the Office of Sponsored Research, the same procedures for review and certification on a Division Approval Form and, when required, Disclosure will be followed prior to accepting the award. Should a significant financial conflicting interest be identified, no expenditure of funds will be permitted until the conflict is resolved according to the procedures outlined previously.

6) For all awards except those emanating from the Public Health Service if the Provost, with the concurrence of the President and the Institute Administrative Council, determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the activity may be allowed to go forward without imposing such conditions or restrictions.

SANCTIONS

Individuals who fail to adhere to this policy and associated procedures may be subject to any one or more of the following sanctions:

- Removal from the activity;
- Letter of reprimand;
- · Special monitoring of future work;
- Probation or enhanced supervision;
- · Salary, rank reduction, or demotion; and
- Termination of employment.

ASSISTANCE

The Office of the Provost welcomes comments and suggestions on modifying these procedures to simplify their implementation. The Division Chairs, the Provost's Office and the Office of Sponsored Research are willing to provide advice and assistance to any individual on the interpretation of these requirements and the applicability to a specific situation.

Interoffice Memorandum

CALIFORNIA INSTITUTE OF TECHNOLOGY

Division of Chemistry and Chemical Engineering

To:	David L. Goodstein, Vice Provost		
From:	Peter B. Dervan	Extension: 3646	Mail Code: 164-30
Subject:	Managing Conflict of Interest Requirements		
Agency:			
	with the Division of Grant/Contract.	Chemistry and Chemica	has filed a financial disclosure al Engineering in connection with
I have revie are signific		statement to determine	e if the disclosed financial interests
☐ The disc proposal.	closed financial inte	rests are not deemed s	ignificant with respect to the above
☐ The disc managed b	closed financial inte by the Principal Inve	rests may be deemed s stigator.	ignificant but can be adequately
☐ The disc recommend	closed financial inte dations are suggest	rests may be deemed s ed as steps to reduce o	ignificant, and the following or eliminate the potential conflict:
			igned:

Encs: Original Disclosure Statement Copy, Divisional Approval Form