Conflict of Interest in Research - Other Federal (Non-DOE) Sponsors

BRIEF

Policy Summary

Berkeley Lab employees responsible for the design, conduct, or reporting of research sponsored by certain federal (non-DOE) sources must disclose financial interests related to their institutional responsibilities periodically over the life cycle of the research project.

Who Should Read This Policy

All researchers responsible for the design, conduct, or reporting of research sponsored by certain public agencies

To Read the Full Policy, Go To:

The POLICY tab on this wiki page

Contact Information

Research and Institutional Integrity Office
RIIO@lbl.gov

Policy

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<th>Conflict of Interest in Research – Other Federal (Non-DOE) Sponsors</th>
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<tr>
<td>Publication date:</td>
<td>4/9/2013</td>
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<tr>
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<td>3/1/2011</td>
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POLICY

A. Purpose

Investigators conducting research sponsored by certain public agencies are subject to specific requirements regarding the disclosure and management of financial conflicts of interest to ensure a reasonable expectation that such research will be conducted free of bias.

B. Persons Affected

All Lawrence Berkeley National Laboratory (Berkeley Lab) researchers who are responsible for the design, conduct, or reporting of research sponsored by the National Science Foundation (NSF), UC Discovery Grants and University of California Office of the President Special Programs, and research sponsored by other public agencies that have adopted these requirements

C. Exceptions

Not applicable

D. Policy Statement
1. **Introduction.** The National Science Foundation (NSF) published regulations in the Federal Register, effective October 1, 1995, requiring principal investigators and participants who are responsible for the design, conduct, or reporting of the research to disclose project-related significant financial interests at the time of proposal submission. Other agencies that have also adopted the federal requirement are UC Discovery Grants and University of California Office of the President (UCOP) Special Programs (which include the California Breast Cancer Research Program and the Tobacco-Related Disease Research Program).

2. **Process**
   a. Principal investigators (PIs) and other researchers who are responsible for the design, conduct, or reporting of the research must complete financial disclosures for all new, amendment, non-competing continuation, and renewal proposals.
   b. The principal investigator must identify individuals responsible for the design, conduct, and reporting of the proposed research.
      i. The PI, and those researchers identified by the PI, must disclose whether or not they have Significant Financial Interests (SFIs) related to the research project. If so, each researcher including the PI as applicable will complete an addendum (a "positive disclosure") providing further information about the SFI and its relationship to the research.
   c. The Research and Institutional Integrity Office (RIIO) will review positive disclosures, and the Deputy Laboratory Director will make a determination.
   d. For research involving human subjects, see the RPM policy, *Conflict of Interest in Research – Human Subjects.*

3. **Work for Others from NSF Flow-Through Funding.** Disclosure is required when Berkeley Lab is proposing a Work for Others agreement with an entity that is receiving its funding from NSF (except for Phase I SBIR/ STTR) or the other agencies mentioned above. In such cases, federal and state forms are to be completed as in the following examples:
   a. Berkeley Lab receives funding from Chiron. Chiron receives its funding for the project from NSF. Berkeley Lab must collect both the state disclosure (Form 700-U) from the Berkeley Lab PI, and federal disclosures of financial interest from the PI and all participants. Chiron is a nongovernmental entity and is not exempt.
   b. Berkeley Lab receives funding from the University of Texas, which receives its funding from NSF. Berkeley Lab must collect the disclosures of financial interest (Principal Investigator's List of Participants, Individual Certification, and Positive Disclosure, if applicable). The University of Texas is a governmental institution, so the state disclosure (Form 700-U) does not need to be completed.

3. **Research and Institutional Integrity Office (RIIO) Process**
   a. The RIIO will review positive disclosures, and the Deputy Laboratory Director will make a determination.
   b. For research involving human subjects, see the RPM policy, *Conflict of Interest in Research – Human Subjects.*

4. **Work for Others from NSF Flow-Through Funding.** Disclosure is required when Berkeley Lab is proposing a Work for Others agreement with an entity that is receiving its funding from NSF (except for Phase I SBIR/ STTR) or the other agencies mentioned above. In such cases, federal and state forms are to be completed as in the following examples:
   a. Berkeley Lab receives funding from Chiron. Chiron receives its funding for the project from NSF. Berkeley Lab must collect both the state disclosure (Form 700-U) from the Berkeley Lab PI, and federal disclosures of financial interest from the PI and all participants. Chiron is a nongovernmental entity and is not exempt.
   b. Berkeley Lab receives funding from the University of Texas, which receives its funding from NSF. Berkeley Lab must collect the disclosures of financial interest (Principal Investigator's List of Participants, Individual Certification, and Positive Disclosure, if applicable). The University of Texas is a governmental institution, so the state disclosure (Form 700-U) does not need to be completed.

**E. Roles and Responsibilities**

<table>
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<th>Responsibilities</th>
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| Investigators         | • Investigators – including the principal investigator, co-investigators, collaborators, consultants, and any other individual who is responsible for designing, conducting, or reporting research funded by NSF or proposed for such funding – are responsible for the design, conduct, or reporting of the results of work performed or to be performed under the NSF-sponsored project.  
                         • Must disclose to the Laboratory all SFIs related to the proposed research no later than the time of application for NSF funding |
| Principal investigators| • Principal investigators – as well as co-investigators, collaborators, consultants, and any other individual who is responsible for designing, conducting, or reporting research funded by NSF or proposed for such funding – are responsible for the design, conduct, or reporting of the results of work performed or to be performed under the NSF-sponsored project.  
                         • Have primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project  
                         • Must fully identify all investigators on the award who are required to disclose SFIs under the terms of this policy |

**F. Definitions/Acronyms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Financial conflict of interest</td>
<td>A Significant Financial Interest related to the NSF-funded research activity in which the investigator is engaged, and that could directly and significantly affect the design, conduct, or reporting of the NSF-funded research activity</td>
</tr>
<tr>
<td>Key personnel</td>
<td>An NSF research project director, principal investigator, and any other personnel considered essential to work performance and identified as key personnel in the contract proposal and award</td>
</tr>
<tr>
<td>Research</td>
<td>As used in this policy, any activity for which research funding is available from a NSF-awarding agency, including but not limited to research grants, cooperative agreements, career-development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards, conference grants, Phase II Small Business Innovative Research (SBIR), and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this policy, consistent with the underlying federal regulations, are Phase I SBIR and Phase I STTR awards.</td>
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Significant Financial Interest (SFI) for Other Federal (Non-DOE) Sponsors

Significant Financial Interest (SFI) means a financial interest consisting of one or more of the following interests of the investigator or the investigator's spouse or registered domestic partner* and dependent children for the following categories, except in the case of travel:

- With regard to any income or compensation, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds $10,000. Included are consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measures of fair market value.
- With regard to equity, a financial interest exists if the value of any stock or stock options received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $10,000.
- Intellectual property rights and interests, upon receipt of income, exceeding $10,000 during the twelve months preceding disclosure from such rights and interests. However, SFIs do not include royalties received from the University of California Regents.

*The inclusion of "registered domestic partner" is consistent with California state law (Family Code, section 297 et seq.).

The term "financial interest" does not include the following types of financial interests:

- Salary, royalties, or other payments paid by the University of California Regents to a University or Laboratory investigator who is currently employed or otherwise appointed by the Laboratory or University.
- Income from investment vehicles, such as mutual funds and retirement funds, in which the investigator does not directly control investment decisions.

G. Recordkeeping Requirements

- Records of financial disclosures and the Laboratory's review of, or response to, such disclosures, must be maintained for at least three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.
- Records must be maintained whether or not a disclosure resulted in the Laboratory's determination of a financial conflict of interest.
- Records pertaining to pending litigation and audits, where real property and equipment purchased under the award are retained beyond three years, or as otherwise required under 45 CFR 74.53(b) and 92.42(b), must be retained beyond that time frame.
- Records relating to unfunded awards need not be retained.

H. Implementing Documents

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<tr>
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<tr>
<td>Form DFI-1</td>
<td>Principal Investigator's List of Participants Who Must File Disclosures of Financial Interest</td>
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<td>Form DFI-2</td>
<td>Disclosure of Financial Interests</td>
<td>Form</td>
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<tr>
<td>Form DFI-3</td>
<td>Positive Disclosure of Financial Interests</td>
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I. Contact Information

Research and Institutional Integrity Office
RIIO@lbl.gov

J. Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>By whom</th>
<th>Revision Description</th>
<th>Section(s) affected</th>
<th>Change Type</th>
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<td>Stoufer</td>
<td>Rewrite for wiki (brief)</td>
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**Source Requirements Documents**

- 42 CFR Part 50, *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*
- 45 CFR Part 94, *Responsible Prospective Contractors*
- University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects

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