Conflict of Interest in Research – Federal (NIH, PHS)

BRIEF

Policy Summary

This policy describes requirements for Berkeley Lab investigators who are responsible for the design, conduct, or reporting of research sponsored by the U.S. Public Health Service (PHS) and certain other sources. These investigators must disclose financial interests related to their institutional responsibilities periodically over the life cycle of the research project.

Who Should Read This Policy

This policy applies to all researchers who are responsible for the design, conduct, or reporting of research sponsored by PHS and certain other 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

A. Purpose

The U.S. Department of Health and Human Services (DHHS) requires that U.S. Public Health Service (PHS)-sponsored investigators be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from investigator financial conflicts of interest.

B. Persons Affected
This policy applies to all Lawrence Berkeley National Laboratory (Berkeley Lab) researchers who are responsible for the design, conduct, or reporting of research sponsored by PHS (National Institutes of Health).

C. Exceptions

Not applicable

D. Policy Statement

1. Disclosure of Significant Financial Interests (SFIs)
   a. Investigators seeking PHS research funding or seeking PHS-sponsored research funding are required to disclose significant financial interests (SFIs) related to their institutional responsibilities.
      i. These investigators must submit a disclosure of SFI in accordance with Berkeley Lab implementation procedures.
   b. The requirement that an investigator disclose an SFI under the terms of this policy does not in and of itself imply the existence of an actual or potential financial conflict of interest.
      i. The existence of a financial conflict of interest, based upon the relationship of the investigator's SFIs to the investigators' institutional responsibilities, is determined by a designated official(s) or an Independent Substantive Review Committee (ISRC) with input from the investigator.
      ii. If a financial conflict of interest is identified, the designated official(s) or the ISRC will recommend additional steps to manage or eliminate the conflict, to the Laboratory Deputy Director, the official who is authorized to act on that recommendation.
   c. Investigators, as defined by this policy, must disclose to Berkeley Lab all SFIs related to the investigator's institutional responsibilities, no later than at the time of application for PHS funding.
   d. This initial disclosure responsibility is separate from and in addition to an investigator's ongoing duty throughout the period of the PHS research award to disclose his or her SFIs, and those of his or her spouse or registered domestic partner and dependent children, related to the investigator's institutional responsibilities:
      i. Within 30 days of discovering or acquiring any new SFI and
      ii. At least annually throughout the period of the award
   e. Before joining an ongoing PHS-funded research project, new investigators must submit a disclosure of SFIs to the Laboratory.
   f. Under the terms of this policy, principal investigators must identify all investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose SFIs.
   g. Collaborators from other institutions who share responsibility for the design, conduct, or reporting of research results, and who will be conducting research under a subgrant or subcontract from the University of California, are expected to comply with the policies and procedures for disclosure and review of an SFI at the institution at which they are employed or, if their institution does not have a conflict-of-interest policy that complies with the DHHS regulations, they must comply with the University's policies and procedures for disclosure and review of an SFI related to PHS-sponsored awards.
      i. Subawards issued by the University will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict-of-interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its investigators and, if a financial conflict of interest is identified, for sending the University notification of the conflict and of the subrecipient institution's plan to manage, reduce, or eliminate the identified conflicts, in accordance with PHS reporting requirements.
   h. Collaborators who share responsibility for the design, conduct, or reporting of research results and who will participate in research under an independent consulting agreement issued by the Laboratory will be identified as investigators by the principal investigator and must complete the Laboratory disclosure forms.
      i. If, upon review, the Laboratory determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce, or manage the identified conflicts of interest.

2. Review of Disclosures and Management Plans
   a. With each PHS proposal, progress report, incremental funding, or extension, investigators' SFI disclosures will be reviewed by the reviewing official(s) to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the investigator is engaged. Investigators will have an opportunity to indicate whether or not they believe the SFI(s) they reported are related to their PHS-funded research activities.
   b. In the event that the reviewing official(s) conclude that an investigator's SFI reasonably appears to directly and significantly affect the design, conduct, or reporting of the PHS-funded research; or is in an entity whose financial interest could be affected by the research, the disclosure and appropriate documentation must be forwarded to the campus or national
laboratory ISRC or designated official for consideration. (At Berkeley Lab, this requirement can be delegated to the reviewing official working in concert with national laboratory management and ad hoc review committees, where appropriate).

i. When it is determined that there is a financial conflict of interest, the ISRC (or Laboratory equivalent) will make a final recommendation to the Chancellor or Laboratory Director (or designee) about whether any conditions or restrictions should be placed on the project to eliminate or manage the financial conflict of interest before the support can be accepted.

ii. The management plan is to be implemented prior to the Laboratory/University's expenditure of PHS funds awarded for the research project, and must specify the actions required to manage the financial conflict of interest, and must include:
   a. The role and principal duties of the conflicted investigator
   b. Conditions of the management plan
   c. How the plan will safeguard objectivity in the research activity
   d. Confirmation of the investigator's agreement to the plan and
   e. How the plan will be monitored

iii. The same review process takes place when an investigator reports a new SFI.

3. Reporting to PHS

a. Prior to the Laboratory's expenditure of any funds provided under a PHS award, the Laboratory must provide to the PHS funding agency an initial report regarding investigator financial conflict of interest. If financial conflicts of interest are eliminated before research funds are expended, the Laboratory is not required to submit a report to the PHS funding agency.

b. During the period of the award, the University will, within 60 days of receipt of disclosure of a new or newly discovered SFI:
   i. Review the disclosure
   ii. Determine whether it is related to PHS-funded research
   iii. Determine whether it constitutes a financial conflict of interest, and if so
   iv. Implement a management plan and report the Financial Conflict of Interest to the PHS funding agency

c. For any financial conflict of interest that the Laboratory reports to a PHS awarding agency, the Laboratory will provide to the PHS awarding agency an annual financial conflict of interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project.
   i. The annual report must specify whether the financial conflict is still being managed or explain why it no longer exists.
   ii. The Laboratory must provide annual reports to the PHS awarding agency for the duration of the project period (including extensions with or without funds).

d. Within 60 days of determining that a financial conflict of interest exists for a new investigator who joins an ongoing PHS-funded research activity, the University must implement a management plan and submit a report to the PHS funding agency.

e. In any case in which DHHS determines that a PHS-sponsored 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 financial conflict of interest that was not managed or reported by the Laboratory as required by this policy and federal regulation, the Laboratory will require the investigator to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

4. Monitoring. The management plan put in place by the campus will specify the way in which the investigator's compliance with the management plan will be monitored on an ongoing basis until completion of the PHS-funded research project.

5. Retrospective Reviews and Mitigation Reports

a. When during the course of an ongoing PHS-funded research project, the University identifies an SFI that was not disclosed in a timely manner by an investigator or that was not previously reviewed, the designated official will, within 60 days, review the SFI to determine whether it is related to a PHS-funded research activity, determine whether a financial conflict of interest exists, and if so, implement a management plan on at least an interim basis.

b. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, regardless of whether the investigator did not disclose an SFI that was later determined to be a financial conflict of interest, or the Laboratory failed to review or manage the financial conflict of interest, or the investigator failed to comply with a previously implemented management plan, the Laboratory must within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research.

c. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct, or reporting.

d. The University will document the retrospective review; such documentation will include the project number, the project title, the name of investigator with the financial conflict of interest, the name of the entity with which the investigator has a financial conflict of interest, the reasons for the retrospective review, the detailed methodology used for the retrospective review, findings, and conclusions.

i. Based on the results of the retrospective review, if appropriate, the previously submitted financial conflict of interest report must be updated to specify the actions that the University will take to manage the identified financial conflict of interest going forward.
e. If bias was found during the retrospective review, the Laboratory will promptly notify the PHS funding agency and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the Laboratory’s plans to eliminate or mitigate the effect of the bias.

6. Training
a. Each investigator, including collaborators, consultants, or subcontractors, must complete NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every four years thereafter, while receiving PHS research funding, and at other times as may be required by the University in accordance with DHHS regulations.
b. For PHS-funded investigators who are new to the Laboratory or who are joining an ongoing PHS research activity, the Laboratory will establish a reasonable, expeditious time frame when investigators must complete training.

7. Public Access to Information
a. The Laboratory must respond within five business days to any request for information about SFIs held by key personnel when the Laboratory has determined that the disclosed SFIs are related to the PHS-funded research, and constitute financial conflicts of interest.
   i. Each campus or location will designate an address to which public requests for information should be sent.
   ii. The five-day response time will be measured from the date that the request for information is received at the campus-designated address until the date a response is sent to the requester.
b. Disclosure forms, disclosure update forms, and management plans, including determinations of financial conflicts of interest, under this policy are public records open to public inspection, under federal and state law.

8. Sanctions
a. Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed award-monitoring bodies, will be grounds for discipline pursuant to Human Resources policy and/or other applicable employee or student disciplinary policies.
   i. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause.
b. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and Laboratory policy.

E. Roles and Responsibilities

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td>Investigators, as Defined by This Policy</td>
<td>• Must disclose to the Laboratory all significant financial interests (SFIs) related to the investigator’s institutional responsibilities, no later than the time of application for PHS funding</td>
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<td>• Throughout the period of the PHS research award, must disclose to the Laboratory their SFIs, and those of their spouse or registered domestic partner and dependent:</td>
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<td>• Within 30 days of discovering or acquiring any new SFI and</td>
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<td>• At least annually throughout the period of the award</td>
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<td>• Before joining an ongoing PHS-funded research project, new investigators must submit a disclosure of SFIs to the Laboratory.</td>
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<td>• Principal investigators must fully identify all investigators on the award who are required to disclose SFIs under the terms of this policy.</td>
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<td>• Investigators must complete NIH-compliant training about the Laboratory’s PHS financial conflict-of-interest policy prior to engaging in research related to any PHS-funded project and at least every four years thereafter, while receiving PHS research funding and at other times as may be required by the University under this policy.</td>
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<td>• In cases where the Laboratory has identified a financial conflict of interest held by the investigator and has implemented a management plan to eliminate, reduce, or manage the conflict, must adhere to the terms of the management plan</td>
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<td>• Where DHHS determines that a PHS-sponsored 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 financial conflict of interest that was not managed or reported by the University as required by this policy and federal regulation, the Laboratory will require the investigator to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.</td>
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In cases where the agreement between the University and the subrecipient specifies that the subrecipient's conflict-of-interest policy applies, must submit to the University, within the time period specified in its subrecipient agreement with the University, all disclosures by subrecipient investigators of significant financial interests, for the University's review

- Must certify that the subrecipient's conflict-of-interest policy complies with the requirements of the DHHS regulations
- Must review financial disclosures made by investigators at the subrecipient institution and, if any financial conflicts of interest are identified, send the University notification of the conflict and of the subrecipient institution's plan to manage, reduce, or eliminate the identified conflicts, in accordance with PHS reporting requirements
- In cases where the agreement between the University and the subrecipient specifies that the University's conflict-of-interest policy applies, must submit to the University, within the time period specified in its subrecipient agreement with the University, all disclosures by subrecipient investigators of significant financial interests, for the University's review

### Responsible Official

- Must solicit and review investigators' significant financial interest (SFI) disclosures for each PHS proposal, progress report, incremental funding or extension, to determine whether there are any SFIs that reasonably appear to be related to the PHS-funded research activity in which the investigator is engaged
- If an SFI reasonably appears to directly and significantly affect the design, conduct, or reporting of the PHS-funded research activity, must forward the disclosure and appropriate documentation to the Laboratory ISRC for consideration
- Upon the ISRC's determination of a financial conflict of interest (see below), must develop a management plan specifying actions required to manage the financial conflict of and safeguard objectivity in the research activity, confirm the investigator's agreement to the plan, and specify the way in which the investigator's compliance with the management plan will be monitored
- Must respond within five business days to any request for information submitted in accordance with this policy about SFIs held by key personnel when the Laboratory has determined that the disclosed SFIs are related to the PHS-funded research, and constitute financial conflicts of interest
- Prior to the Laboratory's expenditure of any funds provided under a PHS award (and within 60 days of any subsequently identified financial conflict of interest), must provide to the PHS funding agency an initial report regarding investigator financial conflict of interest, including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will follow the University of California's financial conflict-of-interest policy
- During the period of the award, within 60 days of receipt of a disclosure of a new or newly discovered SFI, must review the disclosure, determine whether it constitutes a financial conflict of interest, and if so, report the financial conflict of interest to the PHS-funding agency. If a financial conflict of interest ceases to exist during the course of the award, updated information about the status of that financial conflict of interest must be reported to the PHS funding agency.
- Must provide an annual financial conflict-of-interest report to the PHS awarding agency addressing the status of the conflict and any changes to the management plan, for the duration of the project period, including extensions with or without funds
- Must submit a report to the PHS-funding agency within 60 days of determining that a financial conflict of interest exists for a new investigator who joins an ongoing PHS-funded research activity
- If the Laboratory is a subrecipient of a PHS award from another institution, must report to that institution any financial conflict of interests that the Laboratory identifies for Laboratory investigators

### Independent Substantive Review Committee (ISRC) or National Laboratory Equivalent

Must determine whether, based on documentation from the responsible official, there is a financial conflict of interest, and makes a final recommendation to the Chancellor or Laboratory Director (or designee) about whether any conditions or restrictions will be placed on the project to eliminate or manage the financial conflict of interest

### Procurement and Property Management Department

If the PHS award is to be conducted through a subaward, the Laboratory's Procurement and Property Management Department must incorporate, as part of a written agreement with subrecipients, terms that establish whether the University of California PHS conflict-of-interest policy or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators
Chancellor or National Laboratory Director (or Designee) | Must determine, based on final recommendation of the Independent Substantive Review Committee, the conditions or restrictions that should be placed on the project to eliminate or manage the financial conflict of interest

F. Definitions/Acronyms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Responsible Official(s)</td>
<td>An official or officials (typically the campus academic conflict-of-interest administrator) designated by the Laboratory Director or designee to solicit and review investigators’ completed Disclosure of Financial Interest forms and assess whether any reported significant financial interest could reasonably appear to be related to the sponsored project.</td>
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<tr>
<td>Financial Conflict of Interest</td>
<td>A significant financial interest related to the Public Health Service (PHS)-funded research activity in which the investigator is engaged, and that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research activity.</td>
</tr>
<tr>
<td>Independent Substantive Review Committee (ISRC)</td>
<td>A committee appointed by the Laboratory Director (or designee) to review investigators’ interests related to Public Health Service-funded research, and to determine whether the significant financial interests constitute a financial conflict of interest. At Berkeley Lab, this role is filled by the Conflict of Interest Advisory Committee.</td>
</tr>
<tr>
<td>Institutional Responsibilities</td>
<td>Teaching/education, research, outreach, clinical service, and Laboratory/University or public service carried out on behalf of the Laboratory and/or University of California, and that is within the course and scope of the investigator’s Laboratory/University of California appointment/employment.</td>
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<tr>
<td>Investigator</td>
<td>Any individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the PHS-sponsored project. This includes the principal investigator, co-investigators, collaborators, consultants, and any other individual who is responsible for designing, conducting, or reporting of research funded by PHS or proposed for such funding.</td>
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<tr>
<td>Principal Investigator</td>
<td>An investigator who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.</td>
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<td>Key Personnel</td>
<td>A PHS 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>
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<tr>
<td>Research</td>
<td>As used in this policy, any activity for which research funding is available from a PHS-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, and 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)

Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), Significant Financial Interest 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:

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 disclosure, when aggregated, exceeds $5,000. 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.
2. 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 holds any equity interest.
3. Intellectual property rights and interests, upon receipt of income, exceeding $5,000 during the twelve months preceding disclosure from such rights and interests. However, significant financial interests do not include royalties received from the University of California Regents
4. In the case of travel, sponsored travel or reimbursements made to or on behalf of the investigator that exceed $5,000 by a for-profit or non-profit entity related to the investigator’s institutional responsibilities. However, significant financial interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center, or hospital affiliated with an institution of higher education.

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

The term “significant 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 seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government; an agency; a U.S. institution of higher education; or a research institute, academic medical center, or hospital affiliated with an institution of higher education
- 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

<table>
<thead>
<tr>
<th>Document number</th>
<th>Title</th>
<th>Type</th>
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<tr>
<td>Form DFI-1 PHS</td>
<td>LBNL Declaration – Principal Investigator’s List of Participants Who Must File Disclosures of Financial Interest (for PHS/NIH proposals submitted on or after August 24, 2012)</td>
<td>Form</td>
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Form DFI-2 PHS | LBNL Disclosure of Financial Interests in PHS-Funded Research | Form
Form DFI-3 PHS | LBNL Positive Disclosure of Financial Interests in PHS-Funded Research | Form

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>
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<td>8/21/2012</td>
<td>0</td>
<td>M. Stoufer</td>
<td>Re-write for wiki</td>
<td>All</td>
<td>Major</td>
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<td>3/25/2013</td>
<td>0.1</td>
<td>M. Stoufer</td>
<td>Update definition of SFI</td>
<td>F. Definitions</td>
<td>Minor</td>
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<td>3/10/2015</td>
<td>N/A</td>
<td>M. Stoufer</td>
<td>Periodic three-year review (no changes)</td>
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Document Information

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<td>05.02.006.000</td>
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<td>3/25/2013</td>
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<td>Effective date:</td>
<td>3/25/2013</td>
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<td>Next review date:</td>
<td>3/10/2018</td>
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<td>COI in Research</td>
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<td>Conflict of Interest</td>
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<td>Functional Division</td>
<td>Operations</td>
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<td>Prior reference information (optional)</td>
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Source Requirements Documents

- 42 CFR Part 50 Subpart F, Public Health Service Regulation on Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought
- 45 CFR Part 94, Department of Health and Human Services Regulation on Responsible Prospective Contractors
- University of California Policy on Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards

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