

# Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards

Responsible Officer:	VP – Research and Innovations
Responsible Office:	Research and Innovations
Issuance Date:	6/17/2022
Effective Date:	6/17/2022
Last Review Date:	6/15/2022
Scope:	This policy for disclosure and management of conflicts of interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations),and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to PHS (NIH, CDC, FDA, etc.) and other non-federal sponsors that adopt the PHS policy for research.

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## I. POLICY SUMMARY

#### PURPOSE, SCOPE AND APPLICATION

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August 25, 2011, that effective no later than August 24, 2012, Public Health Service (PHS) - sponsored Investigators shall 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.

These regulations require the University to maintain a written policy on conflict of interest disclosure as a condition for receiving PHS awards. Therefore, the University is obligated to establish this policy consistent with these regulations to require disclosure, and identification and management of Financial Conflicts of Interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other non-federal sponsors that adopt the PHS policy, (for example, American Heart Association and the American Cancer Society). This policy is also used to implement the federal Department of Energy (DOE) Interim Conflict of Interest Policy for Financial Assistance, which applies to all DOE financial assistance applications and awards with the exception of those from the Office of Indian Energy and Phase I SBIR/STTR applications and financial assistance awards.

This policy applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

Consistent with PHS regulations, this policy will be made available via a publicly- accessible website. All University of California Investigators (that is, individuals who, regardless of position or title, are responsible for the design, conduct or reporting of PHS supported research, and Investigators seeking PHS research support) shall be informed where this policy and relevant reporting requirements may be accessed via the web.

# II. DEFINITIONS

#### **Designated Official(s)**

An official or officials designated by the campus Chancellor or National Laboratory Director, or designee, to solicit and review Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.

#### **Financial Conflict of Interest**

A Significant Financial Interest that is related to the PHS-funded research activity in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/or reporting of PHS-funded research activity.

#### Independent Substantive Review Committee (ISRC)

A Committee which may be appointed (in lieu of or in addition to a designated individual) by the

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Chancellor or National Laboratory Director (or designee) to review Investigators' Significant Financial Interests related to PHS funded research, and to serve as the Designated Official(s) who determines whether any of the Significant Financial Interests constitutes a Financial Conflict of Interest. At the campus' discretion, this review may by conducted by either an individual designated as a Designated Official or the ISRC.

#### Institutional Responsibilities

Teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California which are in the course and scope of the Investigator's University of California appointment/employment.

#### Investigator

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, and any other individual who has responsibility for designing, conducting, or reporting of research funded by PHS or proposed for such funding.

#### **Key Personnel**

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, grant, or contract.

#### **Principal Investigator**

An Investigator, (normally an academic appointee), who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

#### Research

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 Small Business Innovative Research (STTR) awards. Phase I Small Business Technology Transfer Research (STTR) awards.

#### 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<sup>1</sup> and dependent children for the following categories:

<sup>&</sup>lt;sup>1</sup> The inclusion of "registered domestic partner" is consistent with California State law (Family Code section 297 et seq.), but is not specifically required under PHS regulations

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- A. With regard to any *publicly-traded entity* (domestic or foreign), a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceptions below) 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 salary (other than salary described in the exceptions below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value;
- B. With regard to any *non-publicly-traded entity* (domestic or foreign), including a non-U.S. institution of higher education or a non-U.S. government agency, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in the exceptions below) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse, registered domestic partner, or dependent children) holds any equity interest;
- C. 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;
- D. Travel related to the Investigator's Institutional Responsibilities must also be disclosed when the travel is reimbursed or sponsored by an individual or entity other than a U.S. federal, state or local government agency, a U.S. institution of higher education, or a research institute, academic medical center, or hospital affiliated with a U.S. institution of higher education. Consistent with federal regulations and as described in <u>RPAC Operating Guidance Memo 13-03</u>, individual UC campuses/locations have the discretion to develop and implement local procedures that either (1) require disclosure of all such reimbursed or sponsored travel related to a PHS-funded Investigators' Institutional Responsibilities, regardless of the amount, or (2) require disclosure of such reimbursed or sponsored travel only if the aggregated total of such reimbursed or sponsored travel exceeds \$5,000 per entity during the twelve months preceding disclosure.

**Exceptions**: The term "Significant Financial Interest" does not include the following types of financial interests:

- Salary, royalties, or other payments made by the University of California Regents to a University of California Investigator who is currently employed or otherwise appointed by the University;
- Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a government agency of the United States (including federal, state, or local government), a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with a U.S. 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..

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# III. POLICY TEXT

#### A. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

Investigators seeking PHS research funding or receiving PHS research support are required to disclose Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests in accordance with campus implementation procedures.

The requirement that an Investigator disclose a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential Financial Conflict of Interest. The existence of a Financial Conflict of Interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigators' Institutional Responsibilities, is determined by a Designated Official(s) or an Independent Substantive Review Committee (ISRC) with input from the Investigator. If a Financial Conflict of Interest is identified, the Designated Official(s) or the ISRC shall recommend additional steps to manage or eliminate the conflict, to the Chancellor or Lab Director or designee who is authorized to act on that recommendation.

Investigators as defined by this policy, shall disclose to their campus all Significant Financial Interests related to their Institutional Responsibilities, no later than at the time of application for PHS funding.

This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose to the campus Designated Official the Investigator's Significant Financial Interests, and those of the Investigator's spouse or registered domestic partner,<sup>2</sup> and dependent children), related to the Investigator's Institutional Responsibilities:

- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
- At least annually throughout the period of the award.

Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to the campus.

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 Significant Financial Interests.

Sponsored or reimbursed travel may be disclosed:

A. Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip, as well as

<sup>&</sup>lt;sup>2</sup> The inclusion of "registered domestic partner" is consistent with California State law (Family Code section 297 et seq.

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any other information that may be required by the campus) for the twelve (12) month period following the filing of the Investigator's annual disclosure form; and/or

B. Within thirty (30) days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the University are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests 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 a Significant Financial Interests related to PHS sponsored awards. 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.

Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by the University should be identified as Investigators by the Principal Investigator and should complete the University disclosure forms. If, upon review, the University 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.

#### B. REVIEW OF DISCLOSURES; MANAGEMENT PLAN

With each PHS proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official(s) to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

In the event that the campus Designated Official(s) conclude that an Investigator's Significant Financial Interest 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 shall be forwarded to the campus or National Laboratory ISRC or Designated Official for consideration. (At the Lawrence Berkeley National Laboratory, this requirement can be delegated to the Reviewing Official working in concert with National Laboratory management and Ad Hoc Review Committees, where appropriate). When it is determined that there is a Financial Conflict of Interest, the ISRC (or Laboratory equivalent) shall make a final recommendation to the Chancellor or Laboratory Director (or designee) about whether any conditions or restrictions

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should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

The management plan is to be implemented prior to the University's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the Investigator's agreement to the plan; and
- How the plan will be monitored.

The same review process takes place when an Investigator reports a new Significant Financial Interest.

#### C. REPORTING TO PHS

Prior to the University's expenditure of any funds provided under a PHS award, the University 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 University is not required to submit a report to the PHS funding agency.

During the period of the award, the University shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency.

For any Financial Conflict of Interest that the University reports to a PHS awarding agency, the University shall 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. The annual report shall specify whether the Financial Conflict of Interest is still being managed or explain why it no longer exists. The University must provide annual reports to the PHS awarding agency for the duration of the project period ((including extensions with or without funds).

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.

In any case in which the Department of Health and Human Services (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 University shall 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.

# D. MONITORING

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

#### E. RETROSPECTIVE REVIEWS AND MITIGATION REPORTS

When during the course on ongoing PHS-funded research project, the University identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS- funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.

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 University did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, the University must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. The University will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

• Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the University will take to manage the identified Financial Conflict of Interest going forward.

If bias was found during the retrospective review, the University 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 University's plans to eliminate or mitigate the effect of the bias.

#### F. RECORD RETENTION

Records will be retained for as long as designated in the <u>UC Records Retention Schedule</u>. All records pertaining to pending, foreseeable or ongoing litigation; an investigation, an ongoing audit, or a request for records, cannot be destroyed until these actions have been completed or resolved. These records will be maintained according to the University's Records Management Program and instructions from legal counsel.

# G. TRAINING

Each Investigator, including collaborators, consultants or subcontractors, must complete NIHcompliant training about this policy (Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards) and the PHS Conflict of Interest regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94) prior to engaging in research

related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by the University in accordance with DHHS regulations. For PHS-funded Investigators who are new to the campus or who are joining an ongoing PHS Research Activity, the campus should establish a reasonable, expeditious timeframe when Investigators must complete training.

#### H. PUBLIC ACCESS TO INFORMATION

The Designated Official at each University of California campus shall identify one campus email address and one office address as the recipient addresses for public requests for information under the PHS regulations and this policy, and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on the campus web site.

The campus must respond within 5 business days to any request for information about Significant Financial Interests held by Key Personnel when the University has determined that the disclosed Significant Financial Interests are related to the PHS- funded research, and constitute Financial Conflicts of Interest. Each campus should designate an address to which public requests for information should be sent. The 5-day response time shall 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 requestor.

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.

#### I. SANCTIONS

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 the University Policy on Faculty Conduct and the Administration of Discipline (Academic Personnel Manual, <u>APM-016</u>) and/or other applicable employee or student disciplinary policies.

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. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and University policy.

#### IV. **COMPLIANCE / RESPONSIBILITIES**

Function	Responsibilities
Investigators, as defined by this policy	Must disclose to their campus all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for PHS funding.
	• Throughout the period of the PHS research award, must disclose to the campus their SFIs, and those of their spouse or registered domestic partner and dependent children:
	<ul> <li>Within 30 days of discovering or acquiring any new SFI; and</li> </ul>
	<ul> <li>At least annually throughout the period of the award.</li> </ul>
	Before joining an ongoing PHS-funded research project new Investigators must submit a disclosure of Significant Financial Interests to the campus.
	• Principal Investigators must fully identify all Investigators on the award who are required to disclose SFIs under the terms of this Policy.
	• Investigators must complete NIH-compliant training about the University's PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding and at other times as may be required by the University under this Policy.
	• In cases where the University 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.
	• 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 University shall 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.

Function	Responsibilities
Non-UC collaborators, consultants or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the University	<ul> <li>Must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is compliant with the DHHS regulations, they must comply with this policy and campus procedures for disclosure and review of SFIs related to PHS-sponsored awards.</li> <li>Must comply with all requirements of their institution's (or this) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding</li> </ul>
Institutions that receive subawards issued by the University for PHS- funded research	<ul> <li>In cases where the agreement between the University and the subrecipient specifies that the subrecipient's conflict of interest policy shall apply:</li> <li>Must certify that the subrecipient's conflict of interest policy complies with the requirements of the DHHS regulations</li> <li>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.</li> <li>In cases where the agreement between the University and the subrecipient specifies that the University's conflict of interest policy shall apply, 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.</li> </ul>
Campus Designated Official	<ul> <li>Must solicit and review Investigators' 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.</li> <li>If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research activity, the Campus Designated Official shall forward the disclosure and appropriate documentation to the campus or Laboratory ISRC for consideration.</li> <li>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 Interest, how the plan will safeguard objectivity in the research activity, confirms the investigator's agreement to the plan, and specifies the way in which the Investigator's compliance with the management plan shall be monitored.</li> </ul>

Function	Responsibilities
	<ul> <li>Must respond within 5 business days to any request for information submitted in accordance with this policy about SFIs held by Key Personnel when the University has determined that the disclosed SFIs are related to the PHS-funded research, and constitute Financial Conflicts of Interest.</li> </ul>
	• Prior to the University'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.
	<ul> <li>During the period of the award shall, within 60 days of receipt of disclosure 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 should be reported to the PHS funding agency.</li> </ul>
	• 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 new Investigator who joins an ongoing PHS-funded research activity.
	• If UC is a subrecipient of a PHS award from another institution, must report to that institution any FCOIs that UC identifies for UC investigators.
Independent Substantive Review Committee (ISRC) or National Laboratory equivalent	<ul> <li>Must determine whether, based on documentation from designated Campus 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 should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>
Campus Contracts & Grants office	• If the PHS award is to be conducted thru a subaward, must incorporate as part of a written agreement with subrecipients terms that establish whether the UC PHS COI policy or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators.

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Function	Responsibilities
Chancellor or National Laboratory Director (or designee)	<ul> <li>Must determine, based on final recommendation of the ISRC, the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest.</li> </ul>

# V. PROCEDURES

Campuses and the Lawrence Berkeley National Laboratory shall develop procedures to implement this systemwide policy.

# VI. RELATED INFORMATION

*For related forms, templates and guidance*, please access the UCOP <u>Research Policy</u> <u>Analysis and Coordination website</u>.

<u>RPAC Guidance Memo 13-03</u>: Travel Disclosure Options under University of California Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards Policy.

For the University Conflict of Interest Policy Related to (non-PHS) NSF-Sponsored Research, please see: University Policy on Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards.

For the University Policy Related to Disclosure by Academic Appointees of Financial Conflicts of Interest in Private Sponsors of Research (pursuant to the State Political Reform Act), please see: <u>University Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research</u> and <u>Academic Personnel Manual APM-028</u>.

For the University Conflict of Interest Policy Related to State Public Records Act Conflict of Interest Requirements, please see: <u>University of California's Conflict of Interest Code</u>.

For the University Policy on Conflict of Commitment and Outside Activities of Faculty Members (APM 025), please see: <u>Academic Personnel Manual APM-025</u>.

For the University Policy on Conflict of Commitment and Outside Activities of Health Sciences Compensation Plan Participants (APM 671), please see: <u>Academic Personnel Manual APM-671</u>.

For information regarding disclosure of foreign interests or activities, please see the <u>Foreign</u> <u>Influence webpage (Ethics, Compliance and Audit Services)</u> – see FAQs below.

For the federal Department of Health and Human Services (HHS) regulations on conflict of interest, please see <u>42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, as revised on August</u> <u>25, 2011</u>. More information can be found on the <u>NIH website on Financial Conflict of Interest</u>.

For the federal Department of Energy (DOE) Interim Conflict of Interest Policy for Financial

Assistance see <u>Financial Assistance Letter No. FAL 2022-02 issued December 20, 2021</u>. See the <u>UC Office of the President Research Policy Analysis & Coordination (RPAC) website</u> for further information.

# VII. FREQUENTLY ASKED QUESTIONS

- Q. What is the difference between disclosures required under this policy and disclosures to PHS agencies regarding resources or financial support made available to an individual in support of or related to all of their research efforts (e.g., Other Support reporting, Foreign Components reporting, etc.)?
- A: Principal Investigators and senior/Key Personnel will need to disclose to PHS agencies financial and nonfinancial resources made available to them (from both foreign and domestic sources) in support of and/or related to all of their research efforts, in compliance with other PHS disclosure requirements associated with grant proposals or awards. Not all such support will meet the definition of a reportable Significant Financial Interest (SFI) under this policy. As such, those that do not meet the definition of an SFI do not need to be disclosed to UC as part of the PHS conflict of interest process. Additional information on other reporting for PHS and other federal agencies may be found on the Foreign Influence webpage (Ethics, Compliance and Audit Services)

See also <u>NIH website: Frequently Asked Questions</u> - *Responsibility of Applicants for Promoting Objectivity in Research* (2011 Revised Regulations)

# VIII. REVISION HISTORY

**June 17, 2022**: Technical edits to indicate that this policy also applies to Department of Energy financial assistance applications and awards.

**December 21, 2021**: Technical edits: fix broken links, clarify that campuses have the option of using a \$5,000 de minimis for required travel payment disclosures, clarify disclosure of income and travel payments from foreign governments and foreign institutions of higher education, and add an FAQ and resource link regarding disclosure.

**November 23, 2020:** Technical edits: updated Responsible Office name, contact info and Related Information links.

This Policy was also reformatted to meet Web Content Accessibility Guidelines (WCAG) 2.0. **August 24, 2012**: this new policy replaces the <u>University Policy on Disclosure of Financial</u> <u>Interests and Management of Conflicts of Interest Related to Sponsored Projects</u>, as that policy applies to PHS-funded research.