Interim Guidance on Requirements of the Department of Energy (DOE) Interim Conflict of Interest Policy

As of August 3, 2022

The Department of Energy (DOE) issued an Interim Conflict of Interest Policy for Financial Assistance ("DOE Interim COI Policy") on December 20, 2021, effective June 18, 2022. See Financial Assistance Letter (FAL) 2022-02, Dec. 20, 2021. The DOE Interim COI Policy applies to all DOE-funded financial assistance awards (e.g., a grant, cooperative agreement, or technology investment agreement) issued on or after June 18, 2022, with the exception of those from the Office of Indian Energy and Phase I SBIR/STTR applications and financial assistance awards. The DOE Interim COI Policy is also applicable to all DOE formula financial assistance awards and financial assistance awards selected non-competitively on or after the effective date of this FAL. As a recipient of DOE-funded financial assistance awards, the University of California and its investigators must comply with this new policy.

Per DOE Financial Assistance Letter 2022-02, the DOE Interim COI Policy "largely align[s]" with the PHS COI Regulations. As such, the <u>UC</u>

Policy on Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards ("UC PHS COI Policy")

has been expanded to also apply 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. Therefore, UC locations and Investigators applying for or receiving

new DOE funding after June 18, 2022, will follow the UC PHS COI Policy for compliance with the DOE Interim COI Policy. This interim UC

guidance is subject to modification pending the DOE's release of its final policy. Each UC campus can design their implementation to produce the least burdensome administrative impact on their research community.

Note that the DOE Interim COI Policy may have additional or slightly different requirements from the PHS COI Regulations. UC locations and Investigators need to be aware of these differing areas for full compliance with the DOE Interim COI Policy. DOE may provide future clarifications as to how its DOE Interim COI Policy aligns with the PHS COI Regulations. These differences are identified below:

	Public Health Service	Department of Energy	Guidance
Certifying Disclosures of Significant Financial Interests	PHS does not require certification.	Under the DOE Interim COI Policy, the Investigator must certify that each disclosure and updated disclosure is true, complete, and accurate. The DOE Interim COI Policy provides the certification statement and requires its use.	Investigators must certify, either electronically or by paper, their disclosures according to the language provided by DOE. UC locations can add the DOE certification statement to their existing disclosure forms. If using the same disclosure form for PHS and DOE, the certification statement should indicate that it is only applicable to Investigators with DOE-funded financial assistance awards. Alternatively, Investigators may complete a separate certification document, either electronic or paper, that accompanies the disclosure form.
Definition of "Financial Conflict of Interest"	The PHS COI Regulations define a Financial Conflict of Interest (FCOI) as a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.	The DOE Interim COI Policy defines an FCOI as a situation in which a Significant Financial Interest or financial relationship that could directly and significantly affect the design, conduct, reporting, or funding of the project.	UC locations must review SFIs or financial relationships to determine whether they constitute FCOIs as defined by DOE. Per DOE's presentation to the Council on Government Relations (COGR) on June 9, 2022, DOE has clarified that the inclusion of the term "financial relationship" is intended to mean that an FCOI could result from either an SFI involving financial ownership or a financial relationship that covers other financial arrangements without transfer of control.

	Public Health Service	Department of Energy	Guidance
Definition of "Investigator"	The PHS COI Regulations define an investigator as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of a project funded by PHS.	The DOE Interim COI Policy defines an investigator as the Principal Investigator and any other person who is <i>responsible</i> for the purpose, design, conduct, or reporting of a project funded by DOE. The DOE Interim COI Policy also gives DOE program offices discretion to expand the definition to include any person who <i>participates</i> in the purpose, design, conduct, or reporting of such a project.	If a DOE program office expands the definition in the Funding Opportunity Announcement (FOA) or Terms and Conditions (T&C) of the award, disclosures should be collected from the Principal Investigator and any person who <i>participates</i> in the purpose, design, conduct, or reporting of a project. Per DOE's presentation, they have "No desire to expand the definition beyond the PHS definition at this point."
			In addition, per DOE's presentation to the Council on Government Relations (COGR) on June 9, 2022, DOE clarified "purpose" refers to an individual with the ability to change the scope of a project. The addition of "purpose" was not intended to apply to university settings, but rather to include commercial entities where corporate leadership could change the scope of a research project. Therefore, until further notice, UC locations may use the PHS definition of an Investigator for both PHS and DOE.
Retrospective Reviews	If bias is found after completing a retrospective review, the PHS COI Regulations require entities submit a mitigation report and annual FCOI reports.	Under the DOE Interim COI Policy, in addition to a mitigation report, a DOE program office may require subsequent FCOI reports be submitted more frequently than once a year as required by policy.	UC locations should check the language in the Funding Opportunity Announcement or the award terms and conditions to identify the frequency with which FCOI reports need to be submitted, and submit FCOI reports accordingly.

	Public Health Service	Department of Energy	Guidance
Reporting FCOIs to the Sponsor	The PHS COI Regulations require that when an FCOI is identified, the Institution must submit an FCOI report to the sponsor prior to expenditure of any funds, unless the FCOI is eliminated prior to expenditure of PHS-awarded funds. The report should outline the way in which the conflict will be managed. After an initial FCOI has been reported, the institution must submit an annual report.	The DOE Interim COI Policy only requires that institutions report unmanaged or unmanageable financial conflicts of interest to a DOE program office prior to expenditure of any funds, but also gives the DOE program offices discretion to also require (through language in FOAs or award terms and conditions) reporting of managed FCOIs. After an initial FCOI has been reported, the institution must submit an annual report. In addition to the annual FCOI report, DOE may require reports on other occasions, as outlined in their policy.	A UC location need only report FCOIs to the DOE program office if it finds the FCOI to be unmanaged or unmanageable, unless the DOE program office specifies otherwise. UC locations should check the language in the Funding Opportunity Announcements or the award terms and conditions to confirm specific reporting requirements.
Organizational Conflict of Interest	"Organizational Conflict of Interest" is not mentioned in the PHS COI Regulations.	The DOE Interim COI Policy defines an organizational conflict of interest (OCOI) as a situation where because of relationships with a parent company, affiliate, or subsidiary organization, the institution is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. The DOE Interim COI Policy requires institutions that have a parent, affiliate, or subsidiary that is not a state, local government, or Indian tribe to disclose potential or actual OCOIs to the DOE program office.	Per DOE's presentation to the Council on Government Relations (COGR) on June 9, 2022, DOE clarified that the OCOI portion of the DOE policy was meant to apply principally to commercial/business entities to prevent "self-dealing" under applicable federal procurement standards under 2 CFR 200.318. UC locations should follow the <u>UC Policy on Purchases of Goods and Services: Supply Chain Management (BFB-BUS-43)</u> .

	Public Health Service	Department of Energy	Guidance
Sponsored or Reimbursed Travel	Under the PHS COI Regulations, Investigators must disclose reimbursed or sponsored travel that is related to their institutional responsibilities. As indicated in the NIH COI FAQs, institutions have the discretion to use a \$5,000 <i>de minimis</i> reporting threshold within their implementing policies.	The DOE Interim COI Policy indicates that Investigators must disclose the occurrence of reimbursed or sponsored travel related to their institutional responsibilities that is not otherwise disclosed in current and pending or other support disclosures.	Unless DOE provides subsequent clarification, DOE Investigators must disclose reimbursed or sponsored travel related to their institutional responsibilities regardless of dollar amount.
Intellectual Property Rights and Interests	Under the PHS COI Regulations, an Investigator must disclose intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests. Additional clarification from PHS indicates that this requirement is subject to the \$5,000 threshold for disclosure of income.	DOE Interim COI Policy indicates that intellectual property rights and interests (e.g., patents, copyrights) must be disclosed upon receipt of income related to such rights and interests. No additional clarification has been provided to allow for the \$5,000 <i>de minimis</i> threshold for intellectual property rights and interests.	Unless DOE provides subsequent clarification, DOE Investigators must disclose all intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests, regardless of the dollar amount of income received.