UCLA Interim Policy 927: Conflicts of Interest in Department of Energy Funded Projects

Issuing Officer: Vice Chancellor for Research and Creative Activities Responsible Department: Research Policy and Compliance Effective Date: June 22, 2022 Supersedes: New

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I. PURPOSE & SCOPE

This Policy implements the 2022, U.S. Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance. The DOE Interim Policy establishes standards that provide a reasonable expectation that the purpose, design, conduct, or reporting of projects funded under DOE financial assistance awards (e.g. grants, cooperative agreements or technology investment agreements) will be free from bias resulting from financial conflicts of interest or organizational conflicts of interest.

This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the purpose, design, conduct or reporting of a project funded under a DOE Financial Assistance Award (FOA). DOE Program Offices have the discretion of requesting that others who are participating on the project are also covered by this Policy.

This Policy applies to all DOE funding opportunity announcements issued after June 18, 2022, and to all new and renewal awards selected from those FOAs. This Policy does not apply to awards made by the Office of Indian Energy, and Phase 1 SBIR/STTR awards.

UCLA Policy 927 complements UCLA Policies 925 and 926.

II. DEFINITIONS

For the purposes of this Policy:

<u>Conflict of Interest Review Committee (CIRC)</u> means a UCLA faculty committee charged with determining if Significant Financial Interests that are related to the proposed research constitute Financial Conflicts of Interest and developing plans to eliminate, reduce or manage Financial Conflicts of Interest. The CIRC acts as the Designated Official under DOE regulations. CIRC is appointed by the Chancellor and is advisory to the Vice Chancellor for Research & Creative Activities.

Designated Official(s) means campus official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator to determine whether an Investigator's Significant Financial Interest is related to the Investigator's DOE research activity and if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.

<u>Financial Assistance Awards(FOAs)</u> means grants, cooperative agreements or technology investment agreements.

Financial Conflict(s) of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the purpose, design, conduct, reporting or funding of a DOE financial assistance award.

<u>Institutional Responsibilities</u> means the 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 UC appointment/employment.

Investigator means the Principal Investigator or project director and any other person regardless of title or position who is responsible for the purpose, design, conduct or reporting of research proposed for funding or funded by DOE. This includes, but is not limited to, Key Personnel named on a proposal budget.

Key Personnel means the Principal Investigator or any other person who significantly influences the purpose, design, conduct, or reporting of a project funded under a DOE award; and any other person identified as senior/key personnel by the non-Federal entity in the application for financial assistance, approved budget, progress report, or any other report submitted to the DOE by the non-Federal entity under this Policy.

Principal Investigator (PI) is defined in UCLA Policy 900.

Significant Financial Interest (SFI): means anything of monetary value that:

• meets the thresholds (see Section III.C below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse or registered domestic partner and dependent children for the following categories; and

• reasonably appears to be related to the Investigator's Institutional Responsibilities.

Examples of SFIs include:

- <u>Income or honoraria</u> received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside of the University of California.
- <u>Any equity interest</u> in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
- <u>Receipt of income</u> from any organization other than the University of California for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers and other universities.
- <u>The occurrence of travel</u> by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, *excluding* a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

III. POLICY STATEMENT

Each institution applying for or receiving financial assistance awards from DOE must comply with the regulations by putting in place a policy to ensure that:

A. Investigators complete a training/education program:

- 1. Before engaging in a project related to a DOE financial assistance award and at least every four years thereafter while receiving DOE funding, and
- 2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

B. Investigators disclose SFIs at the following times:

- 1. Initial disclosures must be made by all Investigators planning to participate on a project to be funded under a DOE financial assistance award, before the application for funding is submitted.
- 2. UCLA Investigators who are engaged in DOE have an ongoing responsibility to update their disclosures throughout the period of DOE support:
 - Within 30 days of acquiring or discovering any new SFI; and
 - At least annually
- 3. New Investigators must complete an initial disclosure of SFIs before joining an ongoing DOE supported activity.
- C. Investigators disclose to UCLA SFIs that meet the following thresholds:
- For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

Note: Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles.

2. For a non-publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months, which when aggregated, exceeds \$5,000, or equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.

Note: Investigators are not required to disclose (a) payments made by The UC Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of California; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.

- 3. *Intellectual property rights and interests:* Income received during the previous 12 months. **Note:** *SFIs do not include royalties received from The UC Regents related to patents or copyrights.*
- 4. *Travel:* The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:
 - a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
 - b. Within 30 days of the occurrence if the trip wasn't reported prospectively.

Note: Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education.

D. Investigators submit a certification statement with each disclosure and disclosure update:

Each disclosure and updated disclosure must be signed and dated by the Investigator and include a certification statement that reads:

I understand that this Disclosure is required to obtain funding from the U.S. Government. I, [Full Name and Title], certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. §§ 1001 and 287, and 31 U.S.C. 3729 -3730 and 3801-3812). I further understand and agree that (1) the statements and representations made herein are material to U.S. Government's funding decision, and (2) I have a responsibility to update the disclosures during the period of performance of the award should circumstances change which impact the responses provided above."

IV. DISCLOSURES BY COLLABORATORS AT OTHER INSTITUTIONS

Collaborators from other institutions who significantly influence the purpose, design, conduct, or reporting of a project funded under a DOE subaward from UCLA are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by UCLA will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending UCLA notification of their ability to manage the identified conflicts, in accordance with DOE reporting requirements.

Collaborators who significantly influence the purpose, design, conduct, or reporting of a project funded under a DOE subaward from UCLA, and who will participate in research under an independent consulting agreement issued by UCLA must be identified as Investigators by the UCLA PI and must complete UCLA disclosures. If, upon review, UCLA determines that an SFI could directly and significantly affect the purpose, design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to manage the identified conflicts of interest.

V. REVIEWS AND REPORTING

- A. Disclosed SFIs will be reviewed prior to acceptance of new and renewal awards, and before submission of progress reports, proposals for supplemental funding, or requests for no-cost time extensions. Investigators may be asked to provide additional information about the SFIs that they previously disclosed. This information will be used by UCLA to conduct a preliminary review in order to reasonably determine whether any of an Investigator's SFIs:
 - Could be affected by the DOE activity; or
 - Are in an entity whose financial interest could be affected by the research.

If after review it is determined that an SFI is related to the proposed DOE activity, a second review will be conducted by the CIRC or a Designated Official to determine whether the SFI(s) reasonably appears to directly and significantly affect the purpose, design, conduct, or reporting of the DOE activity and thereby constitute an FCOI that may need to be managed.

In accordance with the DOE Interim Policy, plans put into place to manage an identified FCOI will be monitored for compliance until the completion of the DOE activity. Each management plan will specify the way in which that will be accomplished.

B. Initial reports of FCOI must be made to DOE prior to UCLA's expenditure of any funds provided under a DOE activity. UCLA is required to report to DOE only if FCOIs are unmanaged or unmanageable.

Additional FCOI reports must be submitted to DOE under the following circumstances:

- 1. Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (either through extension notification or a DOE prior approval request). When during the course of an ongoing DOE activity an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
- 2. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing DOE activity.
- 3. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing DOE activity.
- C. When during the course of an ongoing DOE activity, UCLA identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within 60 days to determine whether it is related to DOE activities and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI 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 an FCOI, or UCLA did not review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, UCLA must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the DOE activities. The purpose of this retrospective review is to determine if the ongoing DOE research activity was biased in its purpose, design, conduct, or reporting.

- Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that UCLA will take to manage the identified FCOI.
- If bias was found during the retrospective review, UCLA will promptly notify DOE 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 UCLA's plans to eliminate or mitigate the effect of the bias.

VI. RECORDS ACCESS AND RETENTION

- A. DOE regulations require that UCLA respond within 5 business days to any request for information about SFIs held by Key Personnel when UCLA has determined that the disclosed SFIs are related to DOE research activities and constitute FCOIs.
- B. The information provided in the disclosure forms may be released or transmitted to DOE upon request. Completed disclosure forms also may be released in response to a public records request, pursuant to the terms of the California Public Records Act.
- **C.** Records of financial disclosures, Designated Official's determinations, CIRC recommendations, and University actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by DOE involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

VII. SANCTIONS

Failure by 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 project monitoring bodies, will be grounds for discipline pursuant to the University Policy on Faculty Conduct and the Administration of Discipline (Academic Personnel Manual, APM-016) 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. Similarly, an agreement with a subrecipient organization may be terminated for cause if that organization fails to comply with its obligations under the DOE regulations. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and University policy.

VIII. REFERENCES & RELATED POLICIES

- 1. UCLA Policy 925, Financial Conflicts of Interest in Research;
- 2. UCLA Policy 926, Public Health Service Regulation on Objectivity in Research;
- 3. University of California Policy on Disclosure of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards, June 2022;
- 4. California Public Records Act (Government Code § 6250 et seq.);
- 5. 18 U.S.C. §§ 1001 and 287;
- 6. 31 U.S.C. 3729 3730 and 3801-3812;
- 7. UC Business & Finance Bulletin, RMP-1, University Records Management Program;
- 8. UC Business & Finance Bulletin, RMP-2, Records Retention and Disposition;
- 9. UCOP Memo on Administrative Records Relating to Research: Retention Disposition and Requirements, September 26, 2006;
- 10. DOE Interim Conflict of Interest Policy for Financial Assistance;
- 11. FAQs DOE Interim COI Policy for Financial Assistance;
- 12. Academic Personnel Manual, APM-016.

Issuing Officer

/s/ Roger Wakimoto

Vice Chancellor for Research & Creative Activities

Questions concerning this policy or procedure should be referred to the Responsible Department listed at the top of this document.