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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200

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August 16, 2024

U.S. Department of Energy
Office of Acquisition Management
Contract and Financial Assistance Policy Division, MA-611
1000 Independence Avenue SW
Washington, DC 20585

RE: Comments on proposed DOE "Financial Assistance Regulations-Conflict of Interest and Conflict of Commitment Policy Requirements"

To Whom It May Concern:

I am writing on behalf of the University of California (UC) system to provide comments on the Department of Energy's (DOE) "Financial Assistance Regulations-Conflict of Interest and Conflict of Commitment Policy Requirements" ("DOE Policy") published in the June 18, 2024, Federal Register ("NPRM").[1]

The UC system, comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories, receives more than $4.4 billion from more than thirty Federal agency sponsors. More than $135 million is attributable to DOE awards. UC is committed to following all Federal agency policies to protect that research investment.

UC appreciates DOE's efforts to enhance the integrity of research by refining its conflict of interest (COI) policies. However, it is crucial to ensure that these revisions align with existing federal COI policies, such as those from PHS and other funding agencies, to promote consistency and reduce administrative complexities for institutions managing multiple federal awards.

UC also acknowledges the need for DOE and every Federal agency "to strengthen protections of U.S. Government-supported [Research & Development] against foreign government interference and misappropriation, while maintaining an open environment to foster research discoveries and

[1] 89 Fed. Reg. 51460 (Jun. 18, 2024) [hereinafter *NPRM*].

innovation."[2] The federal government has taken other regulatory actions to strengthen its protections of federally funded research against foreign interference and exploitation. UC respectfully asks DOE to keep those efforts in mind and avoid new requirements that are duplicative, unnecessary, or counterproductive. To that end, COI should not be conflated with other types of reviews, such as those for research security, conflict of commitment, and current and pending support.

Endorsement of AAU/APLU/COGR Comment Letter

UC endorses the AAU/APLU/COGR Comment Letter.[3] UC emphasizes their recommendation of removing conflict of commitment (COC) from this policy. In addition, UC supports their recommendation adopting the Interim Conflict of Interest Policy for Financial Assistance ("Interim Policy")[4] as a final policy, but also recommends some additional changes to the Interim Policy to align it with the U.S. Public Health Service "Objectivity in Research" Regulations[5] ("PHS COI Regulations") when possible.

Implement the Interim Policy with Changes Aligned with the PHS COI Regulations

On December 20, 2021, DOE issued the Interim Policy that "largely aligned with the long-standing COI regulations established by the Public Health Service."[6] Institutions were able to utilize long-standing, understood definitions and processes to effectively implement the Interim Policy. At the time, UC provided guidance to its campuses that identified differences between the Interim DOE Policy and the PHS COI Regulations so that they could modify their PHS conflict of interest processes to comply with the Interim Policy.[7]

Aligning the DOE Policy with the PHS COI Regulations would be beneficial for several reasons. First, with respect to conflict of interest and conflict of commitment, Presidential Memorandum on United States Government-Supported Research and Development National Security Policy ("NSPM-33") directs agencies to standardize their disclosure "processes, definitions, and forms . . .

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[2] National Science and Technology Council, Guidance for Implementing National Security Presidential Memorandum (NSPM-33) on National Security Strategy for United States Government-Supported Research and Development ix (Jan. 2022).
[3] Letter from AAU, APLU, and COGR to DOE (Aug. 16, 2024).
[4] Dept. of Energy, Financial Assistance Letter, FAL 2022-02 app. 1 (Dec. 20, 2021).
[5] 42 C.F.R. § 50.601-.607 (Jan. 20, 2016).
[6] *FAL 2022-02* at 2.
[7] See University of California, Interim Guidance on Requirements of the Department of Energy (DOE) Interim Conflict of Interest Policy (Aug. 3, 2022) (identifying differences between Interim DOE Policy and PHS COI Regulations).

to the extent practicable."[8] In addition, the GAO Report, Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence, notes that stakeholders from universities and agencies would benefit from harmonized disclosure requirements.[9] The Office of Science and Technology Policy (OSTP) provided additional reasons as to why agency standardization furthers the goal of research security while decreasing administrative burden:

- Increases "clarity, transparency, and equity" in disclosures
- Decreases "burden to the research community"
- Facilitates "compliance and accuracy in reporting"
- Provides "better information fidelity among agencies"
- Enables institutions and agencies to "identify potential conflicts of interest and commitment more rapidly and accurately"[10]

Unfortunately, the proposed DOE Policy deviates further from the PHS COI Regulations rather than remaining aligned with it. These further differences, such as incorporating conflict of commitment, using "covered individual" instead of "investigator," etc., undermine the aim of standardizing conflict of interest disclosures and processes across agencies.

UC recommends that DOE adopt the Interim Policy as a final policy with changes outlined below to maximize its consistency with the PHS COI Regulations. As mentioned above, UC has identified several areas where there are differences between the PHS COI Regulations and Interim Policy.[11] The differences that UC thinks are most important to address in the final policy are discussed below:

1. Adopt the PHS definition for "Financial conflict of interest" and remove the term "financial relationship"

Instead of "Conflict of Interest," UC recommends adopting the PHS definition of "Financial conflict of interest": "Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research." Specifically, UC recommends removing "financial relationship" from the definition as it is vague and not defined. If DOE decides to retain the term, UC recommends that it be defined.

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[8] Presidential Memorandum on United States Government-Supported Research and Development National Security Policy, NSPM-33, § 4(b)(vi) (Jan. 14, 2021).
[9] Government Accountability Office, Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence, GAO-21-130 (Dec. 17, 2020).
[10] Office of Science and Technology Policy, An Update on Research Security: Streamlining Disclosure Standards to Enhance Clarity, Transparency, and Equity (Aug. 31, 2022).
[11] *University of California, Interim Guidance*.

2. Adopt the PHS definition for "Investigator"

UC recommends adopting the PHS definition of "Investigator":

> "Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants."

The Interim Policy definition adds the term "purpose." It is unclear as to what it means to be responsible for the purpose of a project or how it might be different from being responsible for the "design" of the project.

In addition, UC recommends removing the provision that allows DOE program offices to expand the definition to include any person who participates in the purpose, design, conduct, or reporting of the project. As noted in the AAU/APLU/COGR Letter, there are many individuals that may "participate" on a project but lack the influence or capacity to result in bias in the research.[12] Furthermore, an expanded definition of "investigator" on an ad hoc basis introduces difficulties for institutions having to use different rules for different projects.

3. Allow institutions to have a $5,000 threshold for disclosure of reimbursed or sponsored travel

UC recommends DOE, like PHS, allow institutions to have a $5,000 threshold for disclosure of reimbursed or sponsored travel. PHS has provided in its Frequently Asked Questions to the PHS COI Regulations that "[I]nstitutions may . . . impose the $5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies."[13] UC understands the concern that excessive travel payments may lead to bias in the design, conduct, or reporting of the research. But many institutions have found that rather than requiring disclosure of all travel regardless of the amount, their resources are best used to focus on reviewing those travel reimbursements that present the highest risk of creating perceived or actual bias. We think it would be beneficial for DOE to give institutions the flexibility to adopt policies that establish such a de minimis threshold, as PHS has done via the FAQs it issued in connection with its COI policy.

4. Allow institutions to have a $5,000 threshold for disclosure of intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests

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[12] *AAU/APLU/COGR Comment Letter* 7.

[13] National Institutes of Health, Frequently Asked Questions (FAQs): Responsibility of Applicants for Promoting Objectivity in Research (2011 Revised Regulations) E.9.

UC recommends DOE, like PHS, allow institutions to have a $5,000 threshold for disclosure of intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. When asked what an investigator must disclose related to intellectual property rights and interests, PHS has provided in its Frequently Asked Questions to the PHS COI Regulations that "[u]pon the receipt of income, the Investigator is required to disclose the aggregated value of income received in excess of $5,000 from the entity in the twelve months preceding the disclosure."[14] Like with disclosure of travel payments, UC understands that intellectual property rights and interests may bias the design, conduct, or reporting of research. Again, giving institutions the flexibility to adopt a de minimis disclosure threshold would be beneficial, in that it would allow institutions to decide how best to focus their resources on reviewing those rights and interests more likely to raise potential concerns.

Other Comments on the proposed DOE Policy

Again, UC's strong recommendation is that DOE adopt as final the Interim Policy that it previously issued, with the minor changes suggested above. However, should DOE choose instead to move ahead with the version of its COI policy that was proposed in the current NPRM, UC recommends the following changes:

1. Remove conflict of commitment from the DOE conflict of interest policy and collect conflict of commitment information through other disclosure requirements (e.g., Biographical Sketch, Current and Pending Support).

The concepts of conflicts of interest and conflicts of commitment are different and should not be conflated. Similarly review processes for the two are different. Institutions review and manage conflicts of interest to protect the research from bias in the design, conduct, or reporting of the research. In contrast, institutions evaluate potential conflicts of commitment to determine whether obligations to outside organizations would adversely impact a faculty member's ability to perform their primary institutional duties, including teaching and research.

Academic institutions already have in place policies that address conflicts of commitment that are separate and distinct from policies that address conflicts of interest. Expanding the meaning of "conflict of commitment" to include "obligations to improperly share information with, or to withhold information from, an employer or DOE, [that] can also threaten research, technology or economic security and integrity" and including it in a conflict of interest policy would likely create confusion between these separate policies.

[14] *Id.* at E.28.

On June 1, 2022, DOE issued its Current and Pending Support Disclosure Requirements for Financial Assistance.[15] DOE notes that "[c]urrent and pending support is intended to allow the identification of potential duplication, overcommitment, potential conflicts of interest or commitment, and all other sources of support."[16] For its Current and Pending Support Disclosure, DOE requires the disclosure of:

> "all sponsored activities, awards, and appointments, whether paid or unpaid; provided as a gift with terms or conditions or provided as a gift without terms or conditions; full-time, part-time, or voluntary; faculty, visiting, adjunct, or honorary; cash or in-kind; foreign or domestic; governmental or private-sector; directly supporting the individual's research or indirectly supporting the individual by supporting students, research staff, space, equipment, or other research expenses. All involvement in foreign government-sponsored talent recruitment programs must be identified in current and pending support."[17]

The DOE Current and Pending Support Disclosure Requirements already capture the information related to a situation where an investigator may incur "conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities."[18] OSTP reemphasizes the purpose of Current and Pending Support disclosures to address conflicts of commitment when it issued its policy on Common Disclosure forms, noting: "The Current and Pending (Other) Support Common Form is used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed."[19]

Disclosures of conflicts of commitment should be removed from DOE's conflict of interest policy and should be addressed in the proposal disclosure requirements. Requiring conflict of commitment disclosures as part of the conflict of interest process will cause confusion and create a duplicative process that will not provide DOE with more valuable information, but it will certainly increase administrative burden.

2. <u>Change the reporting from the time of application to prior to expenditure of funds [Section 910.240(a)]</u>

UC recommends that conflicts of interest should be disclosed to DOE prior to expenditure of any funds under the project rather than in research proposals. This would be consistent with PHS and other federal agencies that have issued COI policies. As currently worded, the DOE Policy would

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[15] Dept. of Energy, Financial Assistance Letter, FAL 2022-04 (June 1, 2022).
[16] *Id.* at 5.
[17] *Id.*
[18] *NPRM*, § 910.200, Definitions (defining "Conflict of commitment (COC)").
[19] OSTP, Memorandum, Policy Regarding Use of Common Disclosure Forms for the "Biographical Sketch" and the "Current and Pending (Other) Support" Sections of Applications by Federal Research Funding Agencies (Feb. 14, 2024).

require disclosure of financial interests, review of those disclosures, and a determination on those disclosures, all prior to proposal submission. Reviews prior to submission would require institutions complete reviews, identify potential conflicts of interest, and design and implement management plans even for projects that may not be funded. This is not feasible as there is not sufficient time between receipt of completed proposals from investigators, and submission deadlines. This creates an impossible administrative goal to meet that does not seem justified.

Requiring disclosure prior to expenditure of funds would align with the other existing federal conflict of interest policies, reduce administrative burden by permitting institutions to focus their resources on awarded projects, and support the NSPM-33's directive to standardize processes.

3. <u>Provide additional definitions, clarity, and thresholds for disclosure [Section 910.200]</u>

The provision of clear definitions and thresholds will assist institutions in collecting correct and complete disclosures and facilitate compliance with the DOE Policy. The absence of definitions or thresholds and unclear requirements may create inconsistencies in implementation of the Policy among institutions. The fact that failure to disclose may result in one or more of several enforcement actions, including referring the failure to Federal law enforcement authorities, only underscores the need for clarity.

As discussed above, by adopting the Interim Policy with definitions aligned with the PHS COI Regulations, institutions would have long-standing and understood definitions.

However, If DOE decides not to adopt definitions found in the PHS COI Regulations, UC recommends the following:

First, UC provided suggested definition changes to the Interim Policy. As the proposed DOE Policy use some of the same definitions as the Interim Policy, UC reiterates the same suggestions here:

- Adopt the PHS definition of "Financial conflict of interest" and remove "financial relationship" from the definition
- Adopt the PHS definition of "Investigator"
- Allow institutions to apply the $5,000 threshold to travel payments and intellectual property rights and interests.

In addition, while the definition of "covered individual" in the DOE Policy is similar to definition of "investigator" used in the PHS COI Regulations and would likely capture many of the same of individuals, using a different term and different language introduces confusion among researchers. UC recommends using the term "investigator" instead of "covered individual," and adopting the definition of investigator incorporated into the PHS COI Regulations:

> "the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded

> by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants."[20]

4. Extend date for implementation of the Policy to 1 year after the publication of the Final Rule [Section 910.210]

UC recommends the DOE Policy make clear that institutions have 1 year after the publication of the Final Rule to comply with the Policy. Currently, the DOE Policy states that it applies to an applicant or recipient 30 days after the publication of the final rule. This is not sufficient time to implement new policies, update processes and training, and outreach to investigators. When PHS implemented its revised PHS COI Regulations, they published the final rule on August 25, 2011, and gave institutions until August 24, 2012, to be in full compliance.[21]

UC notes that if the final DOE Policy remains more closely aligned with the Interim Policy, the final DOE Policy will be implemented more quickly and smoothly. Institutions have already implemented the Interim Policy over the past two years, and minimizing the changes from the Interim Policy would minimize the time needed to update processes to implement. Wholesale changes will take a longer time to implement as it would require consultation with institutional stakeholders.

5. Clarify that covered individuals update disclosures with significant financial interests [Section 910.230(b)(4)]

The proposed DOE Policy requires covered individuals to update disclosures "as soon as any new actual, apparent, or potential COI or COC arises." The current wording suggests that the covered individual is responsible not only for disclosing new significant financial interests, but also for determining whether a conflict of interest or conflict of commitment exists.

However, covered individuals only know when they obtain new significant financial interests. The institution has the responsibility for conducting reviews of these disclosed significant financial interests to determine whether a financial conflict of interest exists.

UC recommends amending this section as follows to be consistent with the PHS COI Regulations:

> Require each Investigator who is participating in the DOE-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (3) of this section, or in a subsequent disclosure

[20] 42 C.F.R. § 50.603.
[21] 76 Fed. Reg. 53256 (Aug. 15, 2011).

of significant financial interests (e.g., any financial conflict of interest identified on a DOE-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Require each Investigator who is participating in the DOE-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

6. Remove reference to 2 C.F.R. Section 200.112 [Section 910.240(a)]

Because the focus of this DOE Policy is on individual conflict of interest in research, UC recommends removing the reference to the Code of Federal Regulations, Title 2, Section 200.112. This section of the Uniform Guidance on conflicts of interest addresses conflicts that might arise when a non-Federal entity expends funds under a Federal award, such as decisions about subrecipient selection or procurement.[22] In contrast, the focus of the proposed DOE Policy is on individual conflicts of interest in the context of research.

UC additionally notes that when NASA initially published its proposed conflict of interest policy as a Notice in the Federal Register, it also included a reference to 2 C.F.R. 200.112.[23] This reference was removed when it issued its final conflict of policy.[24]

7. Add "if known" to disclosing any COI or COC involving a foreign government; remove phrase "actual, apparent, or potential" and modifier "where appropriate" [Section 910.240(a)]

UC understands the need for disclosing conflicts of interest when there are concerns about possible undue foreign influence. However, determining if an entity (foreign or domestic) is connected to a foreign government can be complicated as the information may not be publicly available or accessible. Thus, the requirement should be more flexible. Additionally, UC recommends removing the modifier "where appropriate" and instead inserting the phrase "manage, reduce, or eliminate." Finally, UC recommends removing the phrase "actual, apparent, or potential," as none of these modifiers are defined and makes the defined term "COI" unclear.

UC recommends revising Section 910.240(a) as follows:

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[22] U.S. Chief Financial Officers Council, 2 CFR Frequently Asked Questions, Q-18 (May 3, 2021).
[23] 88 Fed. Reg. 5930 (Jan. 30, 2023).
[24] 88 Fed. Reg. 60243 (Aug. 31, 2023).

> In addition, such entity must disclose to DOE in writing any ~~actual, apparent, or potential~~ COI~~ or COC~~, including any ~~actual, apparent, or potential~~ COI~~ or COC~~ reported to the recipient by a subrecipient, involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, if known, as well as any measures the entity has taken to ~~eliminate or, where appropriate, manage or reduce~~ manage, reduce, or eliminate the COI~~ or COC~~.

Conclusion

UC urges DOE to reconsider its proposed DOE Policy. UC strongly recommends DOE align the DOE Policy with the long-standing PHS COI Regulations by implementing its Interim Policy with some changes rather than introducing a policy that is substantively different from the conflict of interest policies of other federal agency sponsors. By so doing, DOE will harmonize its Policy with other federal agency conflict of interest policies as prescribed by NSPM-33.

UC reiterates the recommendation that DOE remove conflicts of commitment from its proposed DOE Policy. DOE should collect COC information through its Biographical Sketch and Current and Pending Support disclosure requirements.

Finally, if DOE decides to issue a DOE Policy that deviates from the PHS COI Regulations, UC recommends that DOE address the other concerns raised within this comment letter.

Thank you for the opportunity to comment. Please contact Timothy Miller, Research Policy Manager, at Timothy.Miller@ucop.edu, if you have any questions about these comments.

Sincerely,

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the President