

Submitted electronically to: www.regulations.gov.

To: U.S. Department of Energy
Office of Acquisition Management
Contract and Financial Assistance Policy Division

From: Association of American Universities (AAU): Contact – Meredith Asbury, Meredith.Asbury@aau.edu
Association of Public & Land-Grant Universities (APLU): Contact – Deborah Altenburg, daltenburg@aplu.org
Council on Governmental Relations (COGR): Contact – Kristin West, kwest@cogr.edu

Date: August 16, 2024

RE: Financial Assistance Regulations-Conflict of Interest and Conflict of Commitment Policy Requirements (Agency/Docket Number -- DOE-HQ-2024-0029; RIN – 1991-AC18)

We write on behalf of our organizations in response to the Department of Energy's (DOE) notice of proposed rulemaking "[Financial Assistance Regulations-Conflict of Interest and Conflict of Commitment Policy Requirements](#)"¹ (NPRM).

We appreciate the opportunity to submit comments in response to the NPRM. Ensuring the conduct of scientific research is free from bias, including bias that may arise from financial conflicts of interest (COIs), is of primary importance to academic research institutions. Research universities fully embrace their obligation to be good stewards of federal research funds and ensure that research personnel do not have conflicts of commitment (COCs) that would impede the conduct and success of their research projects. However, our associations and our member institutions are also keenly aware that researchers' ability to participate in external activities is a critical driver of U.S. scientific and technological advances and innovation, and such participation is actively encouraged by our institutions. Thus, it is important that any regulations in this area recognize that researcher participation in external activities should not in and of itself be viewed as problematic, but rather requires objective review, and in some cases, management plans tailored to mitigate any associated risks. We also believe that harmonized disclosure obligations across federal agencies ensures that consistent behavioral norms are understood by all researchers, regardless of which specific agency is funding a particular project.

Primary Concerns about the NPRM:

We have two primary concerns with the NPRM, each of which is discussed below:

- (1) The NPRM calls for institutions to develop a stand-alone COC policy to respond to concerns that are already addressed by DOE's present implementation of the current and pending (other) support disclosure standards set forth in [National Security Presidential Memorandum 33](#) (NSPM-**

¹ 89 F.R. 51460.

33)² and the [Guidance for Implementing NSPM-33 on National Security Strategy for United States Government-Support Research and Development](#)³ (“NSPM-33 Implementation Guidance”) and by DOE’s anticipated implementation of the [Common Form for Current and Pending \(Other\) Support Information](#).⁴ Accordingly, the requirement for a stand-alone COC policy is duplicative, unnecessary, and unduly burdensome to institutions and should be eliminated.

DOE participated with other federal research funding agencies in developing the “Biographical Sketch” and “Current and Pending (Other) Support” disclosure requirements set forth in the NSPM-33 Implementation Guidance. DOE implemented these disclosure requirements through its publication of [Financial Assistance Letter \(FAL\) 2022-04](#).⁵ This FAL requires that the following (or substantially similar) provisions aimed at capturing information used to identify and evaluate COCs be included in each DOE Funding Opportunity Announcement (FOA):

Current 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.

As part of the application, the principal investigator and each senior/key person at the prime applicant and any proposed subaward level *must provide a list 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.*

For every activity, list the following items:

- The sponsor of the activity or the source of funding
- The award or other identifying number
- The title of the award or activity. If the title of the award or activity is not descriptive, add a brief description of the research being performed that would identify any overlaps or synergies with the proposed research.
- The total cost or value of the award or activity, including direct and indirect costs and cost share. For pending proposals, provide the total amount of requested funding.
- The award period (start date – end date).
- *The person-months of effort per year being dedicated to the award or activity.*

² (Jan. 14, 2021).

³ (Jan. 2022).

⁴ (Nov. 1, 2023).

⁵ (Jun. 1, 2022).

If required to identify overlap, duplication of effort, or synergistic efforts, append a description of the other award or activity to the current and pending support. [Emphasis added.]

DOE also serves as a co-chair of the National Science and Technology Council (NSTC) Joint Committee on the Research Environment's (JCORE) Research Security Subcommittee that developed the [Common Form for Biographical Sketch](#) and [Common Form for Current and Pending \(Other\) Support Information](#)⁶ ("Common Disclosure Forms") to drive consistent disclosure requirements across federal agencies. In February 2024, the Office of Science & Technology Policy (OSTP) required each agency to submit a plan for the Common Disclosure Forms' implementation, with any deviations requiring review and approval from the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB/OIRA).⁷ The [Current and Pending \(Other\) Support Common Form](#) clearly states that it collects information that "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."⁸

In short, since 2022, DOE's current and pending (other) support disclosure requirements under the FAL (and DOE's anticipated implementation of the Common Disclosure Forms) require the disclosure and review of possible COCs, and institutions have communicated these disclosure expectations to researchers.⁹ Moreover, these efforts align with the NSPM-33 Implementation Guidance's harmonization push to establish consistent norms of behavior and disclosure expectations for researchers across multiple federal research funding agencies. Our associations and our member institutions have applauded the Research Security Subcommittee's efforts to promote consistency because harmonized requirements reduce administrative burden and facilitate researcher compliance.

Given the prominent role the DOE played in developing the Common Disclosure Forms, we are puzzled by the NPRM's requirement for a separate COC policy. These NPRM requirements disregard the NSPM-33 Implementation Guidance's directive that agencies "ensure that implementation of NSPM-33 is uniform across agencies, to the greatest extent practicable" and "avoid taking major NSPM-33 implementation actions, including but not limited to new regulations, requirements, and disclosure forms, unless coordinated through NSTC."¹⁰ Notably, no other federal research funding agency requires a separate COC policy; they instead address COCs through current and pending (other) support disclosure mechanisms.¹¹

⁶ [OSTP, 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 \(Feb. 24, 2024\)](#). The OSTP Policy designates NSF as the forms' custodian. See, [NSTC Research Security Subcommittee NSPM-33 Implementation Guidance Disclosure Requirements and Standardization](#), [Common Form for Biographical Sketch](#), [Common Form for Current and Pending \(Other Support\) Information](#), and [Definitions](#).

⁷ [OSTP, 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 \(Feb. 24, 2024\)](#).

⁸ (Nov. 1, 2023) at p. 1.

⁹ See, e.g., MIT, Office of the Vice President for Research, Research Admin. Services, [DOE/Office of Science Disclosure Guidance](#) (updated Nov. 6, 2023); Stanford University, Office of Research Administration, [DOE Current and Pending Support Disclosures](#) (accessed Jul. 23, 2024); University of California Riverside, Research and Economic Development, [DOE Funded Research](#) (accessed Jul. 23, 2024).

¹⁰ [NSMP-33 Implementation Guidance](#) at p. 1.

¹¹ See, e.g., NASA, [Proposer's Guide](#), Section 2.16 (ver. eff. Feb. 28, 2023); NIH, Grants & Funding, [Other Support](#) (last updated Mar. 12, 2021); NSF, [Documents Required for Senior/Key Personnel](#) (last accessed Jul. 23, 2021).

Finally, the requirement for a separate COC policy imposes additional burdens on institutions without corresponding benefits. The NPRM cites Executive Orders 12866, 13563, and 14094's requirements for agencies to propose a regulation "only upon a reasoned determination that its benefits justify its costs" and to tailor regulations to be less burdensome, "taking into account, among other things, and to the extent practicable, the costs of cumulative regulations."¹² Mandating that institutions develop a distinct DOE COC policy with separate disclosure, review, reporting, and training requirements would place a tremendous and unnecessary administrative and financial burden on institutions (particularly smaller institutions with more limited resources) without any corresponding benefit. Further, the NPRM provides no justification as to how a separate COC policy will confer any benefits over and above those gained from DOE's current process for reviewing information on COCs obtained through the existing current and pending (other) support review process.

(2) Unlike DOE's Interim Conflict of Interest Policy,¹³ ("Interim Policy") which was purposely aligned with the PHS COI regulations ("PHS Regulations") to reduce implementation burden, the NPRM differs from the PHS Regulations in several substantive ways. Abandoning the Interim Policy in favor of implementing a policy that differs in many key respects from the PHS Regulations will impose significant, unnecessary administrative burden on many institutions by requiring them to develop new COI policies, processes, and training specific to DOE-funded research. To reduce this institutional burden and to promote cross-agency consistency that facilitates researcher compliance, we urge DOE to retain the DOE Interim COI Policy and adopt the suggested changes to that policy specified below, or alternatively, align the provisions of the NPRM more closely with the PHS Regulations.

In the NPRM's preamble, DOE states that to "minimize the implementation burden on non-Federal entities," it drafted its Interim Policy so that it was "largely aligned with the long-standing COI regulations established by the Public Health Service at 42 CFR Part 50, subpart F"¹⁴ ("PHS Regulations").¹⁵ A vast number of institutions receive PHS funding, and these institutions greatly appreciated DOE's approach which enabled them to leverage well-established COI processes that were developed to comply with the PHS Regulations to quickly address the new DOE requirements.

We were disappointed that this approach was not carried over to DOE's newly proposed rule, and, as we note in our comments, several provisions of the NPRM differ substantively from the Interim Policy and the PHS regulations. The current approach undercuts the federal government's efforts (via OSTP) to bring cross-agency harmonization to regulations concerning COI and COC as outlined in the NSPM-33 Implementation Guidance. Further, it adds significant burdens to awardee institutions that will need to develop DOE-specific policies and

¹² 89 F.R. 51460 at p. 51461.

¹³ (Dec. 20, 2021).

¹⁴ 89 F.R. at p. 51461.

¹⁵ See, generally, [University of California, Office of the President, Research Policy Analysis and Coordination, Interim Guidance on Requirements of the Department of Energy \(DOE\) Interim Conflict of Interest Policy \(Aug. 3, 2022\)](#) (comparing DOE Interim COI Policy with requirements under the PHS Regulations). Notably, NASA followed a similar standardization approach when it issued its final Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards. [88 F.R. 60243 (Aug. 31, 2023)]("The revised policy is designed to standardize NASA's conflict to (*sic*) interest disclosure requirements with those of other Federal research funding agencies.").

processes, as well as creating confusion and added burden for researchers who receive funding from multiple federal agencies. To avoid these issues and facilitate researcher compliance, we urge DOE to retain and make permanent the Interim Policy that institutions have been using since December 2021 with some suggested modifications, as noted below, to promote consistency and reduce administrative burden. Alternatively, DOE should more fully align the proposed rule with the PHS Regulations, as described in our specific comments.

Comments Regarding Specific Provisions of the NPRM:

If DOE continues with implementation of the NPRM as currently structured, we offer the following comments on specific NPRM provisions.

SECTION 910.200, DEFINITIONS

General Comments: The work of the NSTC Research Security Subcommittee, which DOE co-chairs, is aimed at promoting cross-agency consistency in areas that touch on research security to the greatest extent practicable. Such consistency establishes common behavioral standards for researchers and promotes compliance by reducing confusion arising from individual agency idiosyncrasies. One important product of the Subcommittee's efforts is the definition appendix for the Common Disclosure Forms ("[Appendix](#)"),¹⁶ which contains definitions for many terms used in the NPRM. If DOE declines to implement the Interim Policy as a final rule, we urge DOE to instead adopt the Appendix definitions, rather than develop different meanings for terms that should be standardized across agencies.

Specific Comments:

Provisions of the of the NPRM shown in ***bold, italicized*** text followed by our comments.

Conflict of commitment (COC) means a situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities. This may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments. Other types of conflicting obligations, including but not limited to, obligations to improperly share information with, or to withhold information from, an employer or DOE, can also threaten research, technology or economic security and integrity. Examples of situations that may give rise to conflicts of commitment include, but are not limited to, current or pending employment; positions, appointments, or affiliations such as titled academic, professional, or institutional appointments, whether remuneration is received and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary positions); and participation in or applications to foreign government-sponsored talent recruitment or similar programs.

Comments: As previously noted, we urge DOE to remove from the NPRM all provisions concerning COCs because they are already addressed by DOE's current and pending (other) support disclosure and review mechanisms and the upcoming Common Disclosure Forms. If the definition of COC is retained, then for the reasons previously discussed DOE should adopt the pertinent provisions of the COC definition that appear in the [Appendix](#):

¹⁶ [NSPM-33 Implementation Guidance, Appendix: Definitions \(Nov. 1, 2023\)](#).

Situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities. Many organizational policies define conflicts of commitment as conflicting commitments of time and effort, including obligations to dedicate time in excess of organizational or research agency policies or commitments.

The Appendix's definition of COC includes the following final sentence:

Other types of conflicting obligations, including obligations to improperly share information with, or to withhold information from, an employer or research agency, can also threaten research security and integrity, and are an element of a broader concept of conflicts of commitment used in this document.

This provision is unnecessary in a regulation designed to outline the requirements for a COC policy and should be deleted.¹⁷ Similarly, we strongly suggest that DOE remove examples from definitions in the NPRM and reserve them for guidance or FAQs. Finally, concerning the definition's example of "pending employment" as a situation that may give rise to COCs, we note that it is practically impossible for institutions to identify or mitigate COCs in this area, as researchers do not typically share plans to seek other employment with their current employers.

Conflict of interest (COI) means a situation in which a covered individual or the spouse or a child of the covered individual has a significant financial interest or financial relationship, whether with a domestic or foreign entity, that could directly and significantly affect the design, conduct, reporting or funding of a project or other Federal financial assistance award-related activities. Examples of situations that may give rise to a COI include, but are not limited to, holding an executive position, director position, or equity over a certain dollar amount in a company that stands to benefit from Federal financial assistance award-related activities, receiving financial compensation in the form of consulting payments or payment for services from a company that stands to benefit from Federal financial assistance award-related activities, or intellectual property rights or royalties from such rights whose value may be affected by the outcome of Federal financial assistance award-related activities.

Comments: As previously discussed, if DOE does not retain the Interim Policy as a final rule, it should modify this definition to conform with the definition for COI that appears in the Appendix. The use of examples should be reserved for guidance documents or FAQs. Finally, we note that this definition of COI is much broader than the definition of "significant financial interest" (SFI) and does not align with other federal agencies' COI definitions, which define COIs based solely on the existence and nature of an SFI.¹⁸

Covered individual means any individual, regardless of title or position, who:

(1) Contributes in a substantive, meaningful way to the development or execution (e.g., purpose, design, conduct, or reporting) of a project funded by DOE or proposed for funding by DOE; and,

¹⁷ Of note, Congress has already made determinations on unacceptable outside engagements that may pose a threat to national security in the CHIPS and Science Act of 2022, and institutions have implemented prohibitions on participation in "malign foreign talent programs" as required by current laws and regulations. Given the clear definitions of, and prohibition against, such relationships in law, this provision of the NPRM is superfluous.

¹⁸ See, e.g., 42 C.F.R. §50.604(f)(PHS Regulations); NASA, Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards, 88 F.R. 60243, 60244 (Aug. 31, 2023); NSF, Proposal & Award Policies & Procedures Guide, NSF 24-1, (eff. May 20, 2024), Chapt. IX.A.4.

(2) Is designated as a covered individual by DOE. DOE designates as covered individuals any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co- project director (Co-PD), or project manager; and any individual (including an individual at the masters or baccalaureate level) that contributes in a substantive, meaningful way to the development or execution of a subject project that is listed by the non-Federal entity in the application for Federal financial assistance, approved budget, progress report, or any other report submitted to DOE by the non-Federal entity regarding the subject project.

This list of designated covered individuals may be expanded if specified in the applicable funding opportunity announcement and/or terms and conditions of the Federal financial assistance award, to include individuals on the project team as covered individuals, including up to any person who participates in the purpose, design, conduct, or reporting of a project funded by DOE or proposed for funding by DOE, including, for example, collaborators, consultants, graduate (master's or Ph.D.) students, and postdoctoral associates.

Comments: As previously discussed, if DOE does not adopt the Interim Policy as a final rule, it should modify this definition to conform with the definition for “Covered individual or senior/key person” that appears in the Appendix, provided, that the last sentence of this definition should be modified as follows to appropriately reflect the NPRM’s scope:

~~Consistent with NSPM-33, This means principal investigators (PIs) and other senior/key person seeking or receiving Federal research and development funding (i.e., extramural funding) and researchers at Federal agency laboratories and facilities (i.e., intramural researchers, whether or not federally employed), including Government-owned, contractor-operated laboratories and facilities.~~

Additionally, instead of listing positions that DOE designates as “covered individuals,” we suggest that DOE retain the Interim’s Policy’s definition of “Senior/key personnel” (reabeled as “Senior/key person”):

~~Senior/key personnel means the PI; any other person who significantly influences the 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.~~

We also note that the current list of designated covered individuals is unnecessarily broad, as it is extremely unlikely that any student at the masters, let alone the baccalaureate level, would be in a position to contribute “in a substantive, meaningful way to the development or execution of subject project.”

Finally, we urge DOE to delete the provision in the last paragraph of this definition that permits DOE to expand “covered individuals” to include “up to any person who participates in the purpose, design, conduct, or reporting of a project funded by DOE or proposed for funding by DOE, including, for example, collaborators, consultants, graduate (master’s or Ph.D.) students and postdoctoral associates.” First, the mere fact of *any participation* in a project (e.g., individual who assists in setting up lab equipment, individual who checks citations in a paper) does not mean that the participant could exert bias on the research through COIs or lack capacity to complete the project because of COCs. Second, if participants meet the definition of “in-kind contribution” under the Common Disclosure Forms (e.g., student or employee resources), then covered individuals must report them as current and pending (other) support. Finally, the practical difficulties of

implementing this requirement cannot be underestimated. Requiring institutions to identify, receive disclosures from, and train “every person” who may participate in a project’s “purpose, design, conduct or reporting” over the course of a project that can take years to complete and that involves multiple individuals who constantly change over time, sets an unachievable bar for compliance. Given that these individuals’ participation would not, by definition, “significantly influence the design, conduct, or reporting” of the project, requiring their participation in COI and COC processes yields few benefits in terms of mitigating potential bias, particularly when balanced against the institutional and individual time and resources required to implement this provision.

We note that a similar expansion provision also appears in the last two sentences of definition of “Investigator” in the Interim Policy. If DOE retains the Interim Policy, we urge deletion of these sentences.

Other support means all resources made available to a covered individual in support of and/or related to all of their professional research (including basic and fundamental research), development, demonstration, and/or deployment efforts, including resources provided directly to the covered individual rather than through the research organization, and regardless of whether or not they have monetary value (e.g., even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers and visiting scholars supported by other sources of funding.

Comments: The definition of “other support” is not relevant to the concepts of COIs. COIs are of concern because they involve significant financial interest that may bias researchers in the purpose, design, conduct, or reporting of research. As noted, information on “other support” that relates to COCs (e.g., effort required to perform other projects for which a researcher received support) is already collected through DOE’s current and pending (other) support disclosure mechanisms and the upcoming Common Disclosure Forms. Both current DOE disclosure mechanisms and the Common Disclosure Forms provide a definition of current and pending (other) support, and thus including the definition in the NPRM is unnecessary.

SECTION 910.210 APPLICABILITY

(a) This subpart applies to any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award on or after [Date 30 days after date of publication of final rule], including any covered individual who plans to participate in or is participating in the project funded wholly or in part under the DOE Federal financial assistance award, and each non-Federal entity subrecipient under the Federal financial assistance award, subject to the following exceptions:

(1) This subpart does not apply to DOE Office of Indian Energy applications and Federal financial assistance awards.

Comments: We strongly recommend that DOE extend the effective date for the application of the new policy to one year from the publication of the final rule, particularly if DOE retains the NPRM’s requirements for a stand-alone COC policy. As previously noted, no other federal research funding agency currently requires a stand-alone COC disclosure/review policy and process, and institutions will be required to develop these items from scratch. The development and implementation process for a new COI and/or COC policies/processes will

take much longer than the 30-day period currently specified in the NPRM. With regard to subsection (a)(1), we recommend that DOE retain the Interim Policy's exemption for "Phase I Small Business Innovation Research (SBIR/Small Business Technology Transfer (STTR) applications and awards,"¹⁹ which also aligns with the scope of the PHS Regulations.²⁰

SECTION 910.230 REQUIRED CONFLICT OF INTEREST (COI) AND CONFLICT OF COMMITMENT (COC) POLICIES

General Comments: As previously discussed, we urge DOE to remove from this and the other sections of the NPRM all provisions concerning COC policies. However, in the event COC provisions are retained, we offer the following comments regarding these and other provisions of the NPRM.

(b)(2) Require review by the designated official(s) of all covered individuals' disclosures to determine whether an actual, apparent, or potential COI or COC exists; and, if so, require the designated official(s) determine the actions that have been and shall be taken to eliminate or, where appropriate, manage or reduce the conflict. Examples of conditions or restrictions that a recipient or subrecipient might impose to manage, reduce, or eliminate a conflict include, but are not limited to:

Comments: The term "apparent" is redundant as used in this subsection and elsewhere throughout the NPRM and should be deleted. If a review determines that there is either an "actual" or "potential" COI or COC, then such a COI or COC would also be "apparent."²¹ If DOE retains the term "apparent," it should be defined and distinguished from "actual" and "potential." We note that there is ample precedent within institutions and among their researchers for understanding what the terms "actual" and "potential" mean in the context of applying PHS COI regulations. Once again, we urge DOE to follow the path it initially charted in the Interim Policy and harmonize with the PHS Regulations to enable institutions to leverage these existing and accepted understandings and norms.

(b)(4) Require each covered individual who is participating in the DOE Federal financial assistance award update those disclosures on an annual basis and as soon as any new actual, apparent, or potential COI or COC arises.

Comments: It is unduly burdensome and impractical to require institutions and covered individuals to update disclosures "***as soon as*** any new, actual, apparent, or potential COI or COC arises" [***Emphasis added.***] We suggest that DOE retain the approach used in the Interim Policy (which aligns with the PHS Regulations) and continue to afford individuals thirty days to submit an updated disclosure of significant financial interests after discovering or acquiring the new interest.²² The thirty-day rule is objective, measurable, allows appropriate mitigation measures to be taken in a timely manner, and is far more understandable to researchers.

(5) Require each disclosure be signed and dated by the covered individual and include the certification statement in appendix A of this subpart;

¹⁹ Interim Policy, Appendix 1, Section II.

²⁰ 42 C.F.R. §50.602.

²¹ Additionally, we note that 2 C.F.R. §200.112 refers only to "potential" COIs and makes no mention of "apparent" COIs.

²² 42 C.F.R. §50.604(e)(3).

Comments: As previously noted, we urge DOE to remove from the NPRM all provisions concerning COCs. However, if these provisions are retained, we note that both the FAL and the Common Disclosure forms contain an individual certification statement that each senior/key person must complete regarding current and pending (other) support. Accordingly, the requirement for another certification statement on any COC disclosure statement required under the NPRM is redundant and should be deleted.

(6) Require each covered individual to complete COI and COC training prior to engaging in projects funded under a DOE Federal financial assistance award and complete refresher training at least every two years. The training must cover the non-Federal entity's COI and COC policy and the covered individual's responsibilities regarding disclosures. The non-Federal entity must require covered individual to complete COI and COC training within 30 days of any of the following circumstances:

Comments: To reduce administrative burden on institutions and facilitate implementation, we urge DOE to change the required training interval from two to four years to harmonize the training cycle with that established under the PHS Regulations.²³ We note that the Interim Policy currently has a four-year training period.

(7) With regard to reimbursed or sponsored travel, the non-Federal entity's COI and COC policy must require, at a minimum, reporting the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the non-Federal entity's policy, the non-Federal entity official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a COI or COC with the project funded under the DOE Federal financial assistance award; and

Comments: For policy consistency and to reduce implementation burden, we suggest that DOE consider following the approach that NIH has taken with regard to disclosure requirements for reimbursed and sponsored travel and clarify the institutions have the discretion to impose the \$5,000 de minimis threshold to reimbursed or sponsored travel through their institutional policies.²⁴

SECTION 910.240 REPORTING CONFLICTS OF INTEREST (COI) AND CONFLICTS OF COMMITMENT (COC)

(a)(1)(i) (a) Consistent with title 2 of the Code of Federal Regulation (CFR) 200.112, Conflict of interest, a non-Federal entity that is an applicant to or recipient of DOE financial assistance 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, if such conflict cannot be eliminated or appropriately managed or reduced in accordance with the entity's policy. 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,

²³ 42 C.F.R. §50.604(b).

²⁴ [NIH Provides Policy Clarification Concerning Disclosure Requirements for Reimbursed and Sponsored Travel – 42 CFR Part 50 Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought,” NOT-OD-13-004 \(Oct. 18, 2012\).](#)

or any other entities owned, funded, or otherwise controlled by a foreign government, as well as any measures the entity has taken to eliminate or, where appropriate, manage or reduce the COI or COC.

(1) For all conflicts that require disclosure to DOE:

(i) A non-Federal entity applying for DOE funding must clearly and explicitly disclose such conflict(s) in the application.

This provision of the NPRM requires institutions to report to DOE “any actual, apparent, or potential COI or COC, including any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, if such conflict cannot be eliminated or appropriately managed or reduced in accordance with the entity’s policy” in the application for funding. For the following reasons, we urge DOE to revise this provision to instead call for required reports to be made “prior to the expenditure of funds,” the approach currently used in the Interim Policy. First, DOE already receives information on current and pending (other) support at the time of application, so it has the information that it needs to evaluate COCs, and, thus, as previously discussed, the requirement for a separate COC policy is redundant and unnecessary. Second, the majority of applications for DOE research funding are unsuccessful.²⁵ Therefore, requiring institutions to collect, review, and, if necessary, develop management plans for COIs for an application that will more than likely never be funded is a waste of agency and institutional resources. Third, personnel on grants and their SFIs frequently change between the time of application and the time of award, so any analysis performed at the application stage will likely need to be redone, if and when, an award is made. Finally, requiring reporting prior to expenditure of funds is consistent with approaches taken by other federal research agencies²⁶ and promotes cross-agency consistency that facilitates compliance.

(a)(2) If specified in the applicable funding opportunity announcement and/or terms and conditions of the Federal financial assistance award, a DOE program office may require the non-Federal entity disclose to DOE in writing all covered individuals’ COIs and COCs, including those COIs and COCs determined by the non-Federal entity to be appropriately managed or reduced.

Comments: Research institutions have well-established COI programs that collect and review disclosures and make required reports regarding COIs in accordance with stated regulatory requirements established by funding agencies. Requiring institutions to adjust and manage these requirements on an award-by-award basis creates a tremendous amount of institutional burden, causes confusion among the researchers who must comply with the disclosure requirements, complicates training of researchers, and provides multiple opportunities for errors and inadvertent noncompliance. Accordingly, we urge DOE to delete this provision which would permit alteration of COI disclosure requirements on an award-by-award basis. Further, as previously discussed, DOE already receives full disclosure of current and pending (other) support information at the time of application, and thus additional disclosure COC information is unnecessary.

²⁵ See, e.g., [Frequently Asked Questions, FY DOE Office of Science Early Career Research Program, Ver. 1.0 \(Sept. 8, 2021\)](#) (charts at p. 19-20 showing number of applications and awards under Early Career Research Program indicate success rate of <10% for university awards during FY10 – FY 21).

²⁶ See, e.g., NASA, Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards, 88 F.R. 60243 (Aug. 31, 2023) at p. 60244; PHS Regulations, 42 C.F.R. §50.605(a)(1).

We note that Sections V(a)(3)(iii) and V(b)(1), (b)(2)(ii), (b)(3)(viii) of the Interim Policy contain provisions that permit program offices to establish different disclosure and reporting requirements per the FOA or award terms. For the reasons discussed above, if DOE retains the Interim Policy, we suggest that these provisions be removed. Alternatively, if DOE retains the NPRM's approach, institutions should be afforded the opportunity to negotiate award requirements with the program office.

(b) DOE may require the non-Federal entity to provide associated disclosures, supporting documentation to demonstrate how the COI or COC was managed or reduced; and sufficient information to enable DOE to understand the nature and extent of the COI or COC, and to assess whether the actions are sufficient to ensure the integrity of the DOE-supported project and to protect the government's interests.

Comments: As noted, requiring institutions to adhere to requirements that may differ from award- to-award or individual-to-individual makes it extremely difficult for institutions to establish solid, workable processes to identify, manage, and report COIs. Accordingly, we strongly recommend that DOE replace this provision with specific requirements for COI reports that apply in all cases. In this respect, we suggest that DOE adopt the listed elements for COI Reports set forth in Section 50.605(b)(3)(i)-(viii) of the PHS Regulations. Finally, as previously noted COC information is already provided at the time of application via existing DOE mechanisms for reporting of current and pending (other) support and the upcoming Common Disclosure Forms.

As previously discussed, Sections V(a)(3)(iii) and V(b)(1), (2)(ii), (3)(viii) of the Interim Policy also contain provisions that permit program offices to establish different disclosure and reporting requirements per the FOA or award terms. For the reasons discussed above, if DOE retains the Interim Policy, we suggest that these provisions be removed.

(d) In addition to the annual COI/COC report, DOE may require a non-Federal entity to routinely, or upon request, submit all or some covered individuals' disclosures. Circumstances when DOE may require a non-Federal entity to submit all or some of such covered individual disclosures include but are not limited to:

Comments: We understand and respect the fact that DOE may need an institution to provide a covered individual's COI related disclosures upon request in specific cases, such as those outlined in (d)(1)-(5). However, mandating that institutions provide these disclosures "routinely" makes it extremely difficult for institutions to establish and maintain efficient processes for collecting and reviewing disclosures and making required reports. Accordingly, we strongly recommend that DOE delete "to routinely, or" from this section, as well as from Interim Policy Section V.(b)(5), if the Interim Policy is retained. Finally, as previously noted, COC information is already provided at the time of application via existing DOE mechanisms for reporting of current and pending (other) support and the upcoming Common Disclosure Forms.

(e) If a non-Federal entity becomes aware that a covered individual failed to comply with the non-Federal entity's COI and COC policy or a management plan, the non-Federal entity must promptly notify DOE in writing of the failure to comply and of the corrective action taken or to be taken. DOE will evaluate the situation and, as necessary, take appropriate action, which may include referring the matter to the non-Federal entity for further corrective action consistent with non-Federal entity's established COI and COC

policies, DOE directing the non-Federal entity to take specific mitigation measures, or termination of the Federal financial assistance award.

Comments: To provide institutions with sufficient time to evaluate and take any necessary corrective action (including the conduct of any required retrospective review) with respect to a covered individual's failure to comply, we suggest that DOE modify this provision to read as follows: "within 60 days of becoming aware, notify DOE in writing of the failure to comply . . ." This approach aligns with that taken by NASA and PHS agencies²⁷ and is currently used in the Interim Policy.

§ 920.270 REMEDIES, PENALTIES, AND ENFORCEMENT

(a)(1) If a non-Federal entity fails to disclose a conflict of interest (COI) or conflict of commitment (COC) as required under this subpart, or fails to sufficiently manage or mitigate a COI or COC to ensure the integrity of the DOE-supported project or to protect the government's interests, DOE may:

and

(2) DOE may inquire, at any time before, during, or after a Federal financial assistance award, into any covered individual's disclosures and the non-Federal entity's review (including any retrospective review) of and response to such disclosure, regardless of whether the disclosure resulted in the non-Federal entity's determination of a COI or COC. A non-Federal entity is required to submit or permit on-site review of all records pertinent to compliance with this subpart. To the extent permitted by law, DOE will maintain the confidentiality of all records of financial interests. Based on its review of records or other information that may be available, DOE may determine that a particular COI or COC will bias the objectivity of or adversely impact the project funded under the DOE Federal financial assistance award to such an extent that further corrective action is needed or that the non-Federal entity has not managed the COI or COC in accordance with this subpart. DOE may determine that the imposition of specific award conditions under [2 CFR 200.208](#) is necessary. DOE may also take one or more the actions specified under [2 CFR 200.339](#), as appropriate in such circumstances.

Comments: Enforcement standards should be clearly drafted to inform institutions of their compliance obligations. Subsection (a)(1) states that a non-Federal entity may be considered non-compliant if it "fails to sufficiently manage or mitigate a COI or COC to ensure the integrity of the DOE-supported project or to protect the government's interests." This standard is incredibly vague given that the terms "integrity" and "protect the government's interests" are undefined, exceedingly broad, and in the case of identifying the "government's interests," apart from the interest in avoiding or mitigation bias in research, are unknowable to institutions.

As previously noted, we recommend that COCs be removed from consideration under the NPRM, as they are addressed under mechanisms (including enforcement mechanisms) governing current and pending (other) support. We also strongly recommend that this provision be modified to provide institutions with notice of what the term "fails to sufficiently manage or mitigate" means. In this respect, we suggest that DOE retain the

²⁷ *Id.*

approach used in the Interim Policy that calls for corrective action if noncompliance “appears to have biased the purpose, design, conduct, or reporting of” the funded research project. This approach is also very similar to that taken by the PHS Regulations.²⁸

Similarly, subsection (2) includes the vague standard that “DOE may determine that a particular COI or COC will bias the objectivity of or *adversely impact* the project” (*emphasis added*) without providing any notice to institutions about what “adversely impact” entails. Section VII(b) of the Interim Policy also uses the phrase “adversely impact.” We recommend that DOE either eliminate or define the phrase “adversely impact” in the NPRM, or in the Interim Policy, if it is retained. Finally, for reasons previously discussed, we recommend removing all references to COCs.

(b) If a non-Federal entity fails to disclose an OCI to DOE prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the costs of such procurement or transaction may be disallowed. If a non-Federal entity fails to disclose an OCI to DOE that is not avoided, eliminated, or mitigated or fails to avoid, eliminate, or mitigate a disclosed OCI, prior to engaging in a procurement or transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, DOE may determine that imposition of specific award conditions under [2 CFR 200.208](#) is necessary. DOE may also take one or more actions specified under [2 CFR 200.339](#), as appropriate in the circumstances.

Comments: The use of the term “procurement or transaction” in this provision is unclear. Title 2 C.F.R. Section 200.318, *General procurement standards* clearly states that it is concerned with “procurement standards” and therefore this section should be limited to “procurement transactions” so that it comports with the underlying regulations. As this language is also used in Section VI of the Interim Policy, the same modification should be made to that policy, if it is retained.

Conclusion:

The best and easiest path forward for DOE and institutions is to maintain the Interim Policy and include the suggestions for improvement listed in the above comments. Institutions have already implemented and socialized the Interim Policy with their researchers. The Interim Policy’s requirements are also much more closely aligned with those of the PHS Regulations, than those of the NPRM. As noted, such inter-agency consistency greatly facilitates institutional and researcher compliance. Further, as discussed, no other federal research funding agency requires a separate COC policy, but, instead, address COCs through current and pending (other) support disclosure mechanisms. In sum, when the comprehensive COI protections provided by the Interim Policy are considered in connection with COC-related protections that are in place under DOE’s current and pending (other) support disclosure and review mechanisms (as well as in the upcoming Common Disclosure Forms), there is little, if any, justification for requiring institutions to undertake the burden of implementing the new requirements detailed in the NPRM. We urge DOE to stay the course, withdraw the NPRM, modify the Interim Policy as suggested, and then issue the Interim Policy as a final rule.

²⁸ 42 C.F.R. §50.606(a).

Please do not hesitate to contact any of the points of contact listed above if you have any questions regarding this transmittal.