



March 8, 2023

Via Email to christopher.e.murguia@nasa.gov

Christopher Murguia, Senior Analyst
National Aeronautics and Space Administration (NASA)
Headquarters, 300 E Street, S.W., Room 5L32
Washington, D.C. 20546

RE: *New Conflict of Interest and Conflict of Commitment Policy for Recipients of NASA Financial Assistance Awards* ([88 FR 5930](#)) (Jan. 30, 2023)

Dear Mr. Murguia:

On behalf of our organizations representing the higher education and research university community, we submit these comments in response to the request for public comment on NASA's proposed new Conflict of Interest and Conflict of Commitment Policy ("Proposed Policy") to be implemented through a revision to the [NASA Grant and Cooperative Agreement Manual](#) (GCAM).

Our member institutions conduct innovative research that is crucial to the advancement of scientific knowledge and development of significant technological advances, and they are deeply committed to safeguarding the integrity of that research from bias of any type, including that resulting from undue foreign influence. Academic research institutions have long had rigorous policies and processes to identify and manage investigator financial conflicts of interest (COIs) and to ensure that researchers appropriately balance their research and institutional responsibilities to avoid any conflicts of commitment (COCs). We commend NASA's efforts in developing this Proposed Policy and soliciting public input on its provisions, and we trust that our comments here will help to improve the Proposed Policy and facilitate the conduct of vital federally funded research in a conscientious and diligent manner.

Before providing comments regarding specific provisions of the Proposed Policy, we note the following two key general concerns: (a) the lack of consistency between the Proposed Policy's COI requirements and the COI requirements of other federal research funding agencies; and (b) the conflation of COC and COI in the Proposed Policy's provisions, along with the fact that the

COC provisions unnecessarily duplicate current and upcoming research security disclosure requirements. Each of these concerns is detailed below, and we believe that they warrant NASA's consideration of fundamental modifications to the structure and content of the Proposed Policy.

Lack of Consistency

The efforts by the Office of Science and Technology Policy (OSTP) to promote consistency across federal research funding agencies' implementation of COI and COC disclosures have been critical in enhancing institutional compliance, while reducing associated administrative burden. Section 4.b. of the [Presidential Memorandum on National Security – United States Government-Supported Research and Development National Security Policy](#)¹ (“NSPM-33”) mandates consistency in “disclosure of information related to potential conflicts of interest and commitment from participants in the Federally funded R&D enterprise” by directing agencies to standardize disclosure forms and minimize associated administrative burden.² The National Science and Technology Council (NSTC) and OSTP drove home this directive for consistency with the issuance of the [Guidance for Implementing National Security Presidential Memorandum 33 \(NSPM-33\) on National Security Strategy for United States Government Supported Research and Development](#) (“NSPM-33 Implementation Guidance”) and its requirement that agencies “should coordinate together [through the NSTC] to ensure that implementation of NSPM-33 is uniform across agencies, to the greatest extent possible,”³ as well as the development of standardized disclosure forms for research support and biographical information.⁴

Our associations have consistently applauded and supported OSTP, NSTC, and federal agencies' efforts to harmonize COI and COC research security disclosure and review requirements. Accordingly, we were surprised to see that NASA's development of this Proposed Policy failed to follow a similar trajectory. Rather, as detailed below, there are numerous substantive differences between the Proposed Policy and other agencies' existing COI policies. We appreciate that differences in agency missions may call for distinct award criteria, but, as the NSTC efforts to standardize disclosure form prove, the information that is required to identify and evaluate COIs and COCs is homogeneous, and thus lends itself to cross-agency consistency. Further, the advantages that consistency brings to promoting broad compliance across the awardee community, outweighs any marginal gains to individual agencies from imposing separate requirements. In short, when awardees are forced to develop unique processes, tools, and training to address idiosyncrasies in agency requirements across the same subject area, compliance efforts become more complicated, more expensive, and less effective.

¹ (January 14, 2021)

² *Id.* at §4.b(vi).

³ NSPM-33 Implementation Guidance at p. 1.

⁴ NSF, *Request for Comment Regarding Common Disclosure Forms for the Biographical Sketch and Current and Pending (Other) Support*, ([87 FR 53505](#)) (Aug. 31, 2022).

The need for cross-agency consistency is particularly imperative in the COI and COC arena because institutions must train investigators (who frequently receive support from multiple agencies) on necessary disclosures and develop processes for the collection and vetting of this information. Even slight differences in agency requirements can result in confusion and inadvertent errors. Other federal research funding agencies such as the Public Health Service (PHS) and NSF have long-standing requirements governing financial COIs⁵ (respectively the “PHS COI Policy” and the “NSF COI Policy”) with similar fundamental precepts, and other agencies have modeled their COI policies on these predecessors.⁶ As shown in the table below, and as more fully discussed in our specific comments on the Proposed Policy, there are substantive differences between current NSF and NIH COI Policies and the Proposed Policy.

COI Policy Requirement	NIH & NSF COI Policies	NASA Proposed Policy Provisions re. COIs
What must be reported?	Investigators must report “Significant Financial Interests” (SFIs) to institutions.	Investigators report “COIs” to institutions.
How is it defined?	The definitions of SFIs incorporate dollar thresholds and relationships to funded activities or institutional responsibilities, and there are well-defined exclusions.	The definition of COI refers to a “significant financial interest or financial relationship,” but neither of these terms are defined, nor are there any defined exclusions.
What does the institution review and when?	Institutions review investigators’ SFI disclosures to determine if a “financial COI” (NIH) or “COI” (NSF) exists. The terms “financial COI” and “COI” are defined. Review occurs before awarded funds are expended.	Institutions review investigators’ “COI disclosures” to determine if an “actual, apparent, or potential COI” exists. “COIs” are required to be both disclosed by investigators and determined via institutional review, and the terms “actual, apparent, or potential” are undefined, creating ambiguity. Disclosure and review occur at the proposal stage.

⁵ See, PHS, *Promoting Objectivity in Research*, [42 CFR Part 50, Subpart F](#) (“PHS COI Policy”) and NSF, Proposal and Award Policies and Procedures Guide (PAPPG) ([NSF 23-1](#)) (Jan. 30, 2023) at Chapt. IX.A., *Conflict of Interest Policies* (“NSF COI Policy”).

⁶ Compare PHS COI Policy and Department of Energy (DOE), *Interim Conflict of Interest Policy Requirements for Financial Assistance* ([FAL 2022-02](#)) (Dec. 20, 2021) (“DOE Interim COI Policy”). Although the DOE COI Policy and PHS COI Policy have some notable differences, both policies share a similar structure and have many common defined terms.

Most research institutions have already developed robust policies and tools (e.g., forms, databases, data collection tools, and applications) to comply with established NSF and/or PHS COI Policy requirements. If NASA were to model its COI requirements after either of these agencies' policies, institutions would be able to leverage existing processes to comply, thus reducing burden on institutions and researchers and facilitating compliance.

Conflation of COI and COC

Financial COIs and COCs affect research in very distinct ways, and thus the actions taken in response to a COI are very different from those taken in response to a COC. Financial COIs may bias the design, conduct, or reporting of the research, and they have long been subject to robust agency and institutional disclosure and review requirements to identify and manage the financial COI and any associated potential for bias. COIs are first identified by institutions and the existence of a financial COI need not impact agency funding decisions if institutions have processes in place to effectively manage the conflict. COCs, on the other hand, may impact a researcher's capacity to conduct the research, and institutions have processes for evaluating/managing researchers' effort across multiple projects/responsibilities. Accordingly, COCs are best addressed through biographical and research support disclosures made by an investigator to both institutions and funding agencies at the time of proposal because they may affect institutional funding decisions.

The NSPM-33 Implementation Guidance recognizes these distinctions between COIs and COCs by separately addressing the collection of information necessary to identify/evaluate COIs and information (i.e., research support and biographical information) required to identify COCs and potential research security threats.⁷ By conflating COC and COI concepts, the Proposed Policy fails to establish requirements that are tailored to address the markedly different impacts of these separate areas of conflict. Further, this approach is unnecessarily duplicative of the NSPM-33 Implementation Guidance's disclosure requirements (and the upcoming standardized disclosure forms), which already address COC capacity concerns and research security concerns associated with COCs and a small subset of COIs.

In light of these fundamental concerns regarding the Proposed Policy's structure and the difficulties that institutions will encounter in its implementation, we strongly urge NASA to reconsider the Proposed Policy as a whole, and take the following actions instead:

- Adopt a financial COI policy that is modeled after, uses the same defined terms, and contains the same requirements as those set forth in either the PHS or NSF COI Policy,

⁷ Compare NSPM-33 Implementation Guidance, Disclosure Requirements and Standardization, Paragraph 6, *Collection of information related to financial conflicts of interest within R&D application* and Table 2.a., *Guidance for disclosure of personal and professional information within R&D award application processes*.

including review of disclosures and reporting of identified financial COIs prior to expenditure of awarded funds; and

- Address COCs through the biographical and research support disclosure requirements set forth in the NSPM-33 Implementation Guidance and the upcoming associated disclosure forms, instead of incorporating into the COI Policy a duplicative, potentially conflicting, and unnecessary process for the disclosure and review of COCs that will create additional confusion among investigators and potentially increase the risk of inadvertent noncompliance.

Comments on Specific Provisions of the Proposed Policy

In the event NASA is unwilling to reconsider replacing the Proposed Policy with a policy that is substantively the same as the NSF or PHS COI Policy, the remainder of this letter provides comments on specific Proposed Policy provisions in the order in which they appear.

1.a. Definition of COI: The Proposed Policy defines a COI as follows:

[A] situation in which an individual, or the individual's spouse or dependent children, 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 research or other award-related activities. Examples of potential 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 award-related activities, receiving financial compensation in the form of consulting payments or payment for services from a company that stands to benefit from award-related activities, or intellectual property rights or royalties from such rights whose value may be affected by the outcome of award-related activities.

This definition will be extremely difficult for institutions to implement because it contains circular reporting/review requirements and multiple vague, undefined terms that result in an infinite scope of reporting. First, the Proposed Policy requires covered individuals to disclose COIs and COCs, while also requiring the institution to appoint designated individuals to review these disclosures to “determine whether an actual, apparent, or potential COI or COC exists.” Accordingly, it is unclear whether the covered individual or the institution is charged with deciding what constitutes a COI and COC, or alternatively, whether the institution must simply eliminate, reduce, or manage everything a covered individual reports. Second, unlike other agencies’ COI policies,⁸ the Proposed Policy provides no definition of “significant financial interest” (SFI), nor is any dollar threshold ascribed to what should/should not be considered an SFI. Failure to define SFI leaves covered individuals and/or institutions with the responsibility to determine “significance,” leading

⁸ See, PHS COI Policy at §50.603; NSF COI Policy at Chapt. IX.A.2; and DOE Interim COI Policy at App. 1, § III.

to inconsistent application of the Proposed Policy. Further, the absence of a dollar threshold is particularly confusing considering the definition's reference to examples of COIs including "holding an executive position, director position, or equity *over a certain dollar amount.*" [*Emphasis added.*] Additionally, unlike other agencies' COI policies, the Proposed Policy encompasses undefined "financial relationships," and examines the impact that SFIs or "financial relationships" have on "the design, conduct, reporting" of research/other award-related activities *and* on the "funding" of those activities. Yet, funding decisions are in the hands of agencies and cannot be evaluated by institutions. Accordingly, if this definition is retained, we strongly recommend that it require covered individuals to report SFIs, as opposed to COIs; that the term "funding" be deleted; and, that clear definitions be provided for the terms "SFI," "financial relationship," and "from award-related activities."

1.b. Definition of COC: As previously noted, we recommend that COC issues be addressed separately from COIs through the disclosures collected using OSTP's forthcoming standardized disclosure forms. If this approach is not followed, then, as noted, the definition of COC is circular and requires substantial clarification. The Proposed Policy broadly defines COC as a "non-financial conflict of interest in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities." The definition goes on to provide examples that encompass two distinct concerns: (a) capacity issues arising from an overcommitment of time and effort; and (b) inappropriate foreign influence issues resulting from "other conflicting obligations that threaten research security and integrity."

Although the provided examples relating to capacity are relatively clear, the examples related to inappropriate foreign influence are overly broad and muddled. For example, the definition states that "COC also includes obligations to improperly share information with, or to withhold information from, an employer or NASA . . ." First, the word "improperly" modifies only the phrase "share information," and not the phrase "or to withhold information." We recommend that the provision be modified so that "improperly" modifies both phrases. Otherwise, the current definition prohibits all situations in which information is withheld, both proper and improper, as well as activities that do not involve foreign entities and do not pose research security concerns. Further, as written, it may even include activities that serve to promote research integrity, such as a faculty member signing an agreement that they will not disclose data viewed in their capacity as a paid consultant to a data safety monitoring board for a federally supported clinical trial to test the safety and effectiveness of an U.S. pharmaceutical company's investigational new drug. Overall, the COC examples provided in this definition pull virtually any form of outside activity into their orbit and fail to provide any context for when an external activity actually poses a COC. Indeed, just as in the COI context, not every external obligation rises to the conflict level, particularly in the case of faculty with nine-month terms who are expected to, and do, pursue many of the listed example activities during the summer months. Yet the Proposed Policy's definitions of COI and COC will have the effect of imposing an obligation on institutions to eliminate, reduce,

or manage almost every outside activity of a covered individual regardless of whether the activity poses any risk.

1.c. Definition of Covered Individual: The Proposed Policy’s definition of “Covered Individual” includes individuals who contribute “in a substantive, meaningful way to the scientific development or execution” of a proposed project, as well as the following individuals designated by NASA: (i) principal/co-principal investigators; (ii) project/co-project directors; and (iii) any “other person listed as a team member in Section VI, Team Members.” The term “Team Members” potentially include “post-doctoral associates and graduate students who are not substantively responsible for the project.”⁹ The provision thus overburdens institution by requiring them to collect and review disclosures from persons who, by definition, aren’t responsible for the funded activities. We recommend that the term “Covered Individual” be replaced with the term “Investigator” and defined as the principal investigator, project director or other person who is “responsible for the design, conduct, or reporting” of the funded research/activity.

Section 2: Unlike the PHS and NSF COI Policies which call for disclosure of defined SFIs that are reviewed to determine if a COI exists, the Proposed Policy calls for solicitation and review of “COI and COC disclosures from each Covered Individual” without reference to SFIs. Further, the PHS and NSF COI Policies require the institution to review disclosures prior to the expenditure of awarded funds, while the Proposed Policy requires *both disclosure and review at the time of proposal*. Equally concerning, the Proposed Policy calls for the disclosure and identification of COIs and COCs that are “actual, apparent, or potential,” without further explanation or definition of these terms. Further, it requires Covered Individuals to provide COI and COC updates on an annual basis or “*as soon as any new actual, apparent, or potential*” COI or COC arises, a similarly undefined phrase. Overall, when read in conjunction with the broad definition of Covered Individual, the disclosure/review obligations described in Section 2 will significantly overburden both institutional processes and NASA Grant and Technical Officers. Moreover, many of these disclosures will pose little or no risk because they are not actual, but “potential” or “apparent,” are from individuals with no substantive responsibility for the project, and/or involve a project that may never be funded. Further, the information collected via COC disclosures is duplicative of that which will be obtained through the forthcoming NSPM-33 standardized disclosure forms, which provide agencies with the information they need to determine if a proposal should be funded. We urge NASA to require reviews prior to expenditure of awarded funds instead of at proposal, and to ideally delete, or at a minimum explicitly define, “actual, apparent, or potential” COI or COC.

Section 3: This section suffers from the same lack of defined terms and over-breadth that has been noted with respect to other provisions of the Proposed Policy. First, we note that this section appears to prefer that COIs and COCs be eliminated, given that the “manage” and “reduce” options

⁹ See, NASA, [Guidebook for Proposers Responding to a NASA Notice of Funding Opportunity](#) (eff. Feb. 18, 2022) at p. 35.

are to be used only “where appropriate,” while “eliminate” has no such modifier. This provision should be modified to make clear that elimination, reduction, or other management strategies are equally appropriate solutions. Second, we note the different disclosure requirements for “foreign COIs/COCs” per which institutions must disclose to NASA “any actual, apparent, or potential COI or COC involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government,” whether or not the institution has eliminated, reduced, or managed the COI and COC. Yet, the phrase “involving any foreign governments, their instrumentalities, or any other entities, owned, funded, or otherwise controlled by a foreign government,” is neither defined nor explained. Further, it is written so broadly that it could potentially include a U.S. university that received a subaward to conduct collaborative work in the U.S. under a grant to a foreign university made by a public funding agency of a country that adheres to the same research transparency and integrity standards followed in the U.S. We strongly recommend that this provision be tailored to address only activities that present actual risk of inappropriate foreign influence. Finally, as previously noted, information concerning foreign and domestic research support and affiliations is already collected via the NSPM-33 Implementation Guidance’s disclosure mechanisms, and this section unnecessarily duplicates those disclosures

Section 4: We note that under Section 4.a., the Grant Officer will assess “whether the circumstances disqualify an entity or individual from holding the award,” a delegation of responsibility that may result in inconsistency across awards and entities and will undoubtedly burden the Grant Officers as institutions struggle with the ambiguity around the definitions that define their reporting obligations. We also note that in some provisions of this section, it is not clear whether the described enforcement actions will be taken only with respect to active grants for which an uneliminated/unmanageable COI and COC or a “foreign government” COI or COC has been reported, as opposed to grants that merely report an “apparent” or “potential” COI or COC, domestic or foreign. Section 4 should be revised to make clear that in all cases in which a grant has not yet been awarded and in all cases in which a “potential” or “apparent” foreign or domestic COI or COC that cannot be eliminated/managed is reported, the recipient shall be offered the opportunity to address the COC or COI before any enforcement or other action is taken against the institution or investigator that is involved.

Conclusion

The NSF and PHS COI Policies are well-established COI policies with which the vast majority of research institutions are familiar and have the processes, structures, tools, and training in place to ensure compliance. Modeling the NASA Proposed Policy on these policies reduces administrative burden for both agencies and potential awardees, is a well-established and proven way to address COI, and carries out NSPM-33’s mandate for cross-agency consistency. With respect to COCs, the NSPM-33 Implementation Guidance and the upcoming standardized disclosure forms provide the information necessary for institutions and agencies to evaluate COC and inappropriate foreign

influence risks. Although the GAO report to which NASA is responding referenced adjusting COI policies to address COCs, it is important to note that this report was issued prior to the publication of the NSPM-33 Implementation Guidance, which clearly and appropriately differentiates between COIs and COCs. Creating a separate path for collection and review of disclosures of foreign and domestic COC information unnecessarily duplicates the NSPM-33 Implementation Guidance's requirements and will result in researcher confusion and increase the potential for inadvertent errors.

In short, the old adage "there's no need to reinvent the wheel" is an apt one for these circumstances. By using the existing NIH or NSF COI policy and NSPM-33 Implementation Guidance "wheels," instead of drafting an entirely new policy, NASA can enable institutions to leverage current COI and disclosure processes, thus reducing administrative burden, making compliance easier and more robust, and addressing GAO's recommendations.

We once again express our appreciation to NASA for allowing us to submit these comments on behalf of our associations and our member institutions. In the event that you have any questions regarding this letter, please feel free to contact any of the association representatives listed below:

Kris West, Director, Research Ethics & Compliance, COGR (Council on Governmental Relations) – kwest@cogr.edu

Julia Jester, Associate Vice President for Federal Relations, Association of American Universities (AAU) – Julia.Jester@aau.edu

Deborah Altenburg, Associate Vice President, Research Policy & Governmental Affairs, Association of Public & Land Grant Universities – daltenburg@aplu.org