

COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

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July 8, 2016

Mr. Gilbert Tran
Ms. Rhea Hubbard
Ms. Bridget Miller

White House Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Subject: Conflict of Interest under Uniform of Guidance

Dear Gil, Rhea, and Bridget:

Thank you for meeting with us in May to hear our concerns regarding the open Uniform Guidance (UG) issues we shared. Through this collaborative effort, we've seen many positive changes, including the granting of the procurement grace period, clarification of cost sharing requirements, and improved flexibility in effort reporting, to name a few.

Over the past couple of months we had various conversations with our members. Although we've seen significant improvements in certain areas, we want to maintain the commitment to continue the open dialogue and express our ongoing concerns with regard to the interpretation and implementation of §200.112 in the UG.

We believe that the open-ended structure of §200.112, gives agencies the opportunity to develop conflict of interest policies outside of the procurement requirement. The absence of a single, broadly accepted interpretation of the subpart makes it difficult for institutions to develop a consistent policy. Further, it confuses institutions because it extends beyond procurement COIs to those commonly identified in research, which are different in focus. Traditionally, PHS and NSF have distinguished themselves in this area by adopting COI policies that are clear and functional. For example, under PHS, it is the institution's responsibility to report the managed conflict prior to the expenditure of funds. Under the FAR, however, the Contracting Officer identifies and evaluates potential organizational conflicts of interest early in the acquisition process, and aims to avoid, neutralize, or mitigate significant potential conflicts before contract and award; the requirements thus placed on universities and research organizations is to identify, review, and make determinations of how a potential COI may be avoided, neutralized, or mitigated prior to the submission of a proposal for funding.

A number of universities and other research organizations have contacted us citing examples where organizational COI requirements are being applied to financial assistance awards. These examples have created the following overall concerns:

- Premature and inconsistent timing of required disclosures and/or University review by agencies;
- Widely varying definitions of terms among federal departments, which are not always provided;
- Lack of clarity and inconsistency in who is supposed to disclose, including a discloser list that extends far beyond “investigator” as defined in the PHS FCOI regulation;
- Setting of standards for personal COIs and organizational COIs that are atypical for academic environments – e.g., evaluating the work of colleagues or work done elsewhere within the university and expecting disclosure and/or mitigation;
- Requirements for a written summary of COI review processes at the time of proposal;
- Lack of agency policies that provide context to requirements in solicitation guidelines;
- Lack of agency guidance or unreasonable expectations to avoid, neutralize or mitigate conflict of interests via a conflict of interest management plan;
- Unreasonable review or response time;
- Requirements for a separate compliance program to manage only a few awards or proposals.

Based on these observations, we have prepared a selected list of major federal grant making agencies and compared the varying COI requirements to illustrate the inconsistencies in implementation of 200.112. This is not meant to be an exhaustive list of requirements, but rather an indicative cross section of varying policies. See **Appendix A**.

In closing, we appreciate your willingness to continue the open dialogue on this issue. As agencies have and will continue to release their policies, we ask that the OMB maintain a culture of ensuring that federal regulations seek more affordable, less intrusive means to achieve policy goals, considering benefits and costs of the regulations. Specifically, we propose the following:

- 1) **Delay implementation of §200.112 to coincide with procurement sections.** As the COFAR FAQ 200.112.1 specifically references the General Procurement Standards set forth in 200.318 (and no other reference to COI exists in the UG outside of 200.112 and .318) and it states that the policy does not refer to scientific conflicts that might arise in the research community an implementation date that coincides with procurement implementation is appropriate and necessary;
- 2) **A further FAQ clarification that eliminates the reference to subrecipients** since a subrecipient means a non-Federal entity that receives a subaward. A subaward is not considered a procurement action as it does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program;
- 3) **Harmonized definitions** (e.g., individual, personal, organizational, institutional and conflicts of interest; immediate family, apparent vs. perceived vs. potential & actual vs. real vs. identified, etc.) that would be pertinent to institutions performing research under both financial assistance agreements and contracts;

4) **Disclosures should be obtained only from personnel who are responsible for the design, conduct and reporting of research;**

5) **Disclosures to be provided and reviews and management actions to occur at reasonable times** – e.g., after the grantee is notified by the funding agency that it intends to fund the award instead of at the time of proposal submission-- as the majority of proposals are not funded. Allowing COI reviews and determinations to occur at time of award would be more consistent with the policies and procedures institutions have already had to implement to comply with PHS's 42 CFR § 50, an implementation that cost an average of \$318,000 per institution according to the Association of American Medical Colleges COI Metrics Project

(<https://www.aamc.org/download/429214/data/april2015implementingtheregulationsonfinancialconflictsofintere.pdf>); and

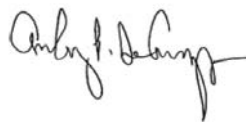
6) **Establish a standard that conflicts can be managed, reduced or eliminated.**

Recognize the experience, expertise, and infrastructure that institutions currently have in place in addressing conflicts of interest with their employees, and require recipient institutions to report identified conflicts with a mitigation plan to manage, reduce or eliminate them.

FDP has already showed interest in creating a model policy for Organizational COIs, as they did for Investigator COIs in research (under the standards set by PHS), with the hope that agencies will then better understand the definitions and enact these policies or build upon them.

COGR will continue to monitor agency policies as they are released and notify you as issues arise that pertain to our membership. We look forward to continuing our partnership with OMB as we seek to establish harmonization to the greatest extent possible. We look forward to hearing from you.

Sincerely,



Anthony DeCrappeo
President

APPENDIX A

Requirements	PHS NSF	UG 200.112	UG 318c1, c2	EPA	DOI	CMS	DOD	DOJ	AHRQ	NOAA	DOE	DOEd
Timing of Disclosure	COI (Personal) Proposal	Unclear	C1: COI No disclosure Required C2: OCI No disclosure required	COI and OCI for Contracts at Proposal; COI and OCI for Grants at Award	COI and OCI at Proposal and Award	OCI Proposal; COI Award	OCI and COI Proposal	COI and OCI Proposal	OCI Proposal and Award (states both in solicitation)	OCI Award	Varies by solicitation COI and/or OCI Proposal or Award	Varies by solicitation COI and/or OCI Proposal or Award
Timing of Review	Award	Unclear	Award	Contracts, Proposal; Grants, Award	Proposal and Award	OCI Proposal; COI Award	Proposal	Proposal	Proposal and Award	Award (within 24-48 hrs)	Proposal and Award	Proposal and Award
Persons required to disclose vary across the agencies for personal (COI)	Individual regardless of title responsible for design, conduct or report of research	Unclear	Coverage: C1: employees engaged in the selection, award and administration of contracts	All individuals involved in contract or award (PLUS extended immediate family)	Childhood friend, positions of trust, etc.	Board, Directors, Trustees, Governing Body; study personnel	Investigators	Staff, consultant or subs responsible for research and evaluation	n/a	n/a	Applicant, team members, named senior/key personnel	PI and Key Personnel
Provides COI definition	Yes	No	Yes	Yes >PHS	Yes >PHS or UG	Yes >PHS or UG	No	Yes>PHS or UG	n/a	n/a	No	No
Incorporates FAR OCI or own OCI definition	n/a	Unclear	Own OCI definition “impartial in procurement”	Own OCI definition	Own OCI definitions	Starts with FAR OCI and expands significantly	FAR OCI	Own OCI definition	Own OCI definition	FAR OCI	No definition	Own OCI
Requires Apparent, Potential or Perceived (in additional to actual, real, or identified)	Actual	Unclear	C1: Actual C2: Perceived	Actual and potential	Actual, potential, and perceived	Actual, potential or perceived	Actual and potential	Actual, potential or perceived	Actual and potential	Actual and potential	Actual, potential and perceived	Actual
Which entity makes OCI or COI Determination	University	Unclear	University	University	Agency (Grants officer and Ethics Counselor)	Agency (University conducts first review but agency also reviews)	University	University but must describe process at proposal	University but must describe process at proposal	University	Agency approves University management plan	University
Requires COI to be resolved (instead of mitigate, neutralize, etc.)	Managed.	Unclear	C1: prohibition C2: Unclear.	Mitigation is OK with agency approval	Mitigation is OK with agency approval	Mitigation is OK with agency approval	Yes, resolved prior to award	Mitigation is OK with agency approval	Mitigation is OK with agency approval	Mitigation is OK with agency approval	Mitigation is OK with agency approval	Mitigation is OK with agency approval

§ 200.112 Conflict of interest.

The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.

§ 200.112 COFAR FAQ.

.112-1 Conflict of Interest Section 200.112 states “The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.” Does this policy refer to scientific conflicts of interest that might arise in the research community? No, however Federal agencies may have special policies or regulations specific to scientific conflicts of interest, such as HHS's policy at 42 CFR Part 50. The conflict of interest policy in 2 CFR 200.112 refers to conflicts that might arise around how a non-Federal entity expends funds under a Federal award. These types of decisions include, for example, selection of a subrecipient or procurements as described in section 200.318.

§ 200.318 General procurement standards.

(c)(1) The non-Federal entity must maintain written standards of conduct covering conflicts of interest and governing the performance of its employees engaged in the selection, award and administration of contracts.

No employee, officer, or agent must participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the non-Federal entity must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the non-Federal entity.

(2) If the non-Federal entity has a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian tribe, the non-Federal entity must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.