

**Carnegie Mellon University**  
**Guidelines for the Research Community**  
**Compliance with Conflict of Interest in Research Requirements**

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## **INTRODUCTION**

As a research university, Carnegie Mellon University (CMU or University) must conduct itself in accordance with the highest ethical and scientific standards. CMU also must maintain policies and processes that facilitate compliance with federal regulation and sponsor policy governing financial and other conflicts of interest in research.

This document is intended to assist members of CMU’s research community with understanding their obligations and responsibilities regarding conflicts of interest in research. This guidance document focuses primarily on financial conflicts of interest in sponsored research, but broader conflict of interest requirements are referenced as appropriate.

This document is divided into four main sections:

- Introduction
- Conflicts Disclosure Requirements for Investigators
- Sponsor-Specific Requirements
- General

Additional information is available on the [Office of Research Integrity and Compliance \(ORIC\) website](#).

This Guidelines document is a companion to the separate [Guidelines for the Research Community on Disclosure of Outside Activities](#). Each Guidelines document outlines different disclosure requirements for financial interests or activities that Investigators (as defined later in this document) may have. Taken together, the documents explain the range of financial interests and activities that Investigators must disclose within CMU’s SPARCS disclosure system. Investigators may find it helpful to refer to the [quick reference chart of disclosure requirements](#) on ORIC’s COI website.

## **Purpose**

This document provides guidelines to promote objectivity in research; provides a framework for disclosure, review, and reporting of conflicts of interest in research consistent with the requirements of external sponsors; and assists CMU Investigators to understand and meet their obligations with respect to conflicts of interest.

CMU Investigators (as specifically defined later in this document) include any person – regardless of title or position – who is responsible for the design, conduct, or reporting of sponsored research. CMU considers Investigators to include all faculty, staff, and students specifically named in sponsored research funding applications, proposals, or budgets, including in any proposal or budget submitted in SPARCS, and all key personnel who are identified in a progress report or other report submitted by CMU to a funder.

Financial conflicts of interest in sponsored research occur when the financial interests of Investigators (or those of the Investigator's spouse/domestic partner and dependent children) could directly and significantly affect the design, conduct or reporting of CMU research, or present the appearance thereof. Conflicts of interest have the potential to inappropriately influence many aspects of research – from how a study is designed, how data is collected, analyzed and reported, to what individuals/suppliers are involved in the work. In a university setting, especially one that promotes technology transfer and entrepreneurial activity, conflicts of interest naturally arise and they must be addressed appropriately.

Federal regulations and guidance regarding financial conflicts of interest in research (e.g., PHS regulations entitled "Promoting Objectivity in Research," 42 CFR Part 50 and 45 CFR Part 94) also promote objectivity in research and require that the design, conduct, and reporting of research funded under federal grants, cooperative agreements, or contracts will be free from bias resulting from conflicts. Many non-governmental funding organizations also have conflict of interest requirements.

Conflicts may also arise in other University activities unrelated to sponsored research (e.g., unfunded research or educational or service activities) when a University member's personal/external interests may influence how they conduct their University activities. These guidelines do not directly address such situations, but ORIC can advise on best practices and in some cases may recommend completing a disclosure and review process described in this document.

## Overview

The University's principal missions are the education of students and the generation and dissemination of knowledge. In pursuit of these missions, or as a natural outgrowth of such activities, faculty, staff, and students often become involved in outside professional activities, such as consulting or business activities. Investigators also may have outside financial interests. In some circumstances such activities or interests give rise to conflicts of interest. The University must identify and manage situations in which financial or other personal interests could bias or compromise – or have the appearance of biasing or compromising – objectivity or judgment relative to scientific research.

Investigators have a professional obligation to act in the best interests of CMU and to ensure that the design, conduct, and reporting of research is free from bias resulting from Investigator financial conflicts of interest.

CMU has five broader policies that address conflicts of interest:

- [Conflict of Interest and Commitment](#)
- [Compliance with Financial Conflict of Interest Requirements](#)
- [Organizational Conflict of Interest in Research](#)
- [Consulting by Faculty](#)
- [Code of Business Ethics and Conduct](#)

Members of the research community should review these policies and the guidance in this document so they understand their responsibilities as they pertain to sponsor requirements and University policy. These policies set forth CMU's commitment to follow the law and promote the ethical conduct of research and other University business.

The Office of the Vice President for Research (OVPR) is designated as the institutional unit responsible for supporting compliance with regulations and policies related to research activities, including financial conflict of interest requirements.

## CONFLICTS DISCLOSURE REQUIREMENTS FOR INVESTIGATORS

### Disclosure Process and Review

- a. **Initial Disclosure:** Each Investigator who is planning to participate in CMU sponsored research must disclose through CMU's electronic system (SPARCS) an up-to-date listing of the Investigator's significant financial interests (SFI) (as defined below) no later than the time of application for research funding. Before CMU submits a new funding proposal, Investigators listed on the proposal will receive an email reminding them of their current disclosures listed in SPARCS. It is the Investigator's responsibility to review this email and, if they find their information is out of date, to log in to SPARCS and submit an update prior to the proposal's submission. Each new Investigator who, subsequent to the submission of an application for funding, or during the course of a sponsored research project, plans to participate in the project, must similarly disclose SFIs through SPARCS prior to participating in the sponsored research project. On a case-by-case basis, ORIC may request disclosures through SPARCS for unfunded, gift funded, or internally-funded research.
- b. **Annual updates:** Each Investigator who is participating in CMU research must submit an updated disclosure of SFIs at least annually (even if only to acknowledge no change to previous disclosures) during the period of the research activity. Such disclosure must include any information that was not disclosed initially pursuant to paragraph (a) above or in a subsequent disclosure of SFIs, and must include updated information regarding any previously disclosed SFIs (e.g., the updated value of a previously disclosed interest).
- c. **Updates within 30 days:** Each Investigator who is participating in CMU research must submit an updated disclosure of SFIs within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI, or upon request by ORIC.

CMU uses an electronic system (SPARCS) to collect and store disclosures. Specific instructions on how to use SPARCS to meet disclosure requirements are available on the [SPARCS website](#).

Information is available on the ORIC website to assist Investigators in completing their SPARCS disclosures and training. At any time, and at CMU's discretion, information from disclosures may be shared with the relevant department head, dean, research, finance, or business staff, Office of the Vice President for Research, Office of General Counsel, and/or their designees. Beyond this, access to information in disclosures will be limited to those with a need to know and will be shared in accordance with applicable law, sponsor policy, or CMU policies.

ORIC will review disclosures to determine if a conflict exists, and ORIC may contact the Investigator for additional information. The objective of ORIC's review is to determine whether an Investigator's SFI is related to the Investigator's research activity, and if so, whether the SFI is a Financial Conflict of Interest (FCOI). An Investigator's SFI is related to the Investigator's research activity when ORIC reasonably

determines that the SFI could be affected by the Investigator's research activity or is in an entity whose financial interest could be affected by the Investigator's research activity.

A FCOI exists when ORIC reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Investigator's research activity. ORIC will consider the following factors in determining whether a conflict exists:

- The nature and extent of the research and an Investigator's role on a project;
- The nature of the Investigator's research activity, including whether it relates to basic or fundamental research directed at understanding basic scientific processes;
- Whether the research involves intellectual property linked to the SFI;
- Whether the research could affect the value of the SFI;
- The amount of the SFI; and
- Where the SFI is in another company, whether the Investigator's SFI could result in the Investigator influencing company decisions, or whether the research could have a significant impact on the company's business or financial outlook.

In conducting its review, ORIC may call upon subject-matter experts as needed with respect to any particular project, such as division management and others with relevant expertise.

If it appears that a FCOI may exist, further review is required. This review may be conducted by ORIC staff, the relevant department head, dean, OVPR, the Office of General Counsel, and/or their designees.

Where a FCOI is found to exist, ORIC in consultation with the Investigator will determine the means to appropriately address the FCOI, which may include conditions or restrictions (i.e., a management plan, described below) for the Investigator.

Staff members at the Software Engineering Institute (SEI) have their own SEI-specific conflict requirements discussed later in this document. Investigators who have signed Campus Collaborator Agreements with the SEI must comply with both sets of requirements.

## **Definitions and Guidance for Financial Disclosure**

To complete a disclosure in the SPARCS system, it is critical to understand the terms used in the regulations and CMU requirements. Below are definitions and examples.

*"Investigator"* means the Project Director (PD), Principal Investigator (PI), Co-Investigator or any other person, regardless of title or position, who is responsible for design, conduct or reporting of sponsored research, including research that is funded or proposed for funding. This includes all faculty, staff, and students specifically named in sponsored research funding applications, proposals, or budgets, including in any proposal or budget submitted in SPARCS, and all key personnel who are identified in a progress report or other report submitted by CMU to a funder. If an individual's role in the research is significant enough that they are specifically named in a proposal for funding or on a budget, CMU considers the individual to be an Investigator as defined above and the individual should complete a disclosure. If an individual's role changes during the course of a project or after a proposal has been submitted so that they would then be considered an Investigator, they are required to submit a disclosure update at that time.

A “Significant Financial Interest” (SFI) is a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse/domestic partner and dependent children) that reasonably appear to be related to the Investigator’s Institutional Responsibilities (defined further below):

- **With regard to any publicly traded entity**, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - For example, if publicly traded entity Acme paid Dr. Smith \$3,000 for consulting and she owns \$1,000 of Acme stock, she need not disclose this. However, if she were paid \$3,000 for consulting and owns \$2,500 of such stock, she should disclose this because the aggregated amount exceeds \$5,000. If an investigator is not sure whether an entity is public or private, they should contact ORIC for assistance.
- **With regard to any non-publicly traded entity**, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - An Investigator does not need to know the specific dollar value of an ownership interest because any equity interest in a non-publicly traded entity is a SFI even if the value is unknown.
- **With regard to intellectual property rights and interests (e.g., patents, copyrights)**, a SFI exists upon receipt of income of greater than \$5,000 related to such rights and interests.

ORIC may on a case-by-case basis request disclosure of additional types of financial interests to comply with requirements of specific sponsors. Specific sponsors may define “Significant Financial Interest” more broadly; see the appendices of this document for sponsor-specific requirements.

SFI *does not* include (Investigators need not disclose) the following types of financial interests:

- Salary, royalties, or other payments from CMU to an Investigator who is currently employed or otherwise appointed by CMU, **including** intellectual property rights assigned to CMU and agreements to share in royalties related to such rights.
- Income from investment vehicles such as mutual funds or retirement accounts where the Investigator does not directly control investment decisions made in these vehicles.
- Income from seminars, lectures, teaching engagements, or service on an advisory committee or review panel, if these engagements were sponsored by a U.S. government agency, U.S. institution of higher education, U.S. academic teaching hospital, U.S. medical center, or U.S. research institute affiliated with a U.S. institution of higher education. **Investigators must disclose these**

***types of income if they come from non-U.S. governments, non-U.S. universities, or other non-U.S. entities and meet the dollar thresholds described above.***

- Grants, gifts, discretionary funds, travel expenses or reimbursement, or other funding received through CMU.

CMU also defines a SFI to include any reimbursed or sponsored travel (i.e., that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse/domestic partner or dependent children), related to the Investigator's Institutional responsibilities, in the preceding twelve (12) months. Disclosure of reimbursed or sponsored travel should be made by submitting a disclosure profile update within SPARCS within 30 days of the travel.

- Investigators do not need to disclose reimbursed or sponsored travel if it was sponsored or reimbursed by any of the following:
  - CMU or a CMU sponsored award
  - A U.S. federal, state or local government entity,
  - A U.S. institution of higher education,<sup>1</sup>
  - A U.S. academic teaching hospital,
  - A U.S. medical center, or
  - A U.S. research institute affiliated with an U.S. institution of higher education.

***Investigators must disclose these types of reimbursed or sponsored travel if they come from non-U.S. governments, non-U.S. universities, or other non-U.S. entities.***

"*Institutional Responsibilities*" include professional activities on behalf of CMU or associated with an Investigator's CMU appointment or position, such as teaching, research, scholarship, professional practice, service (e.g., on CMU committees) and administrative activities or responsibilities for CMU.

Examples of Institutional Responsibilities:

- Teaching – teaching CMU graduate and undergraduate courses, advising CMU students;
- Service – participating in a CMU committee;
- Research – conducting CMU research related to one's professional expertise;
- Performance – engaging in artistic performance on behalf of CMU;
- Practice – engaging in professional practice of one's craft or art on behalf of CMU.

Examples of activities that may be related to Institutional Responsibilities and must be disclosed if they meet the definition of SFI:

- Consulting – providing professional expertise to a start-up company, non-governmental organization or other university; any such engagement that involves research conducted at or for the outside entity;

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<sup>1</sup> 20 USC § 1001(a) The term "institution of higher education" means an educational institution in any State that— (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of section 1091(d) of this title; (2) is legally authorized within such State to provide a program of education beyond secondary education; (3) provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary; (4) is a public or other nonprofit institution; and (5) is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the Secretary for the granting of pre-accreditation status, and the Secretary has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

- Expert testimony – using professional expertise to provide testimony on behalf of a client or as part of a government proceeding;
- Appointment at another institution – teaching or conducting research at another institution in an area related to professional expertise;
- Participation in a Foreign Talent Program – affiliation with a Foreign Talent Program in an area related to professional expertise;
- Service – serving on an advisory board or committee in a topical area where the investigator has professional expertise; serving on a committee of a professional organization;
- Other paid work – writing a textbook in the Investigator’s area of expertise.

Examples of activities likely *NOT related to* Institutional Responsibilities:

- Teaching – teaching ski lessons;
- Service – participating on a committee as a parent for a child’s school;
- Consulting – activity outside of the Investigator’s CMU expertise, for example, a member of the science faculty receiving payment to sing in a musical; to be considered “not related” to the Investigator’s Institutional Responsibilities, the consulting must not involve research in any capacity.
- Other paid work – jury duty.

### **Training Requirements**

Training on conflict of interest is required when first disclosing in SPARCS, and at least every two years thereafter. SEI staff members, and other faculty/staff/students who collaborate with the SEI on research, will complete training annually to comply with the SEI’s contractual requirements.

In the event it is determined that an Investigator has failed to comply with CMU's conflict disclosure requirements, additional training may be required.

### **Reporting to Research Sponsors**

CMU is required to notify certain research sponsors about FCOIs and management plans to address the FCOI. Investigators will cooperate with CMU to fulfill all reporting requirements to research sponsors, including those relating to organizational conflicts of interest and other conflicts.

### **SPONSOR-SPECIFIC REQUIREMENTS**

OVPR is authorized to prepare, administer, and modify supplemental sponsor-specific appendices to these Guidelines in order to comply with all applicable sponsor requirements. Investigators should consult these appendices for additional guidance on conflicts of interest in research, including sponsor-specific supplementation and modification to these Guidelines.

### **GENERAL**

#### **Examples**

Examples of SFIs that must be disclosed to CMU by Investigators:

1. Dr. Karl is a founder of a non-publicly traded company that utilizes technology developed in her lab at CMU. She has an equity interest in the company. This must be disclosed as a SFI because, (i) with regard to any non-publicly traded entity, a SFI exists when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in the non-publicly traded entity; and (ii) the SFI is related to Dr. Karl's Institutional Responsibility because it involves technology developed in her lab at CMU. The SFI may or may not constitute a FCOI.
2. Dr. Smart is an economist at CMU. Dr. Smart consults for a bank, assisting with economic forecasting. Dr. Smart received \$8,000 in payment for his consulting services last year. This must be disclosed as a SFI because (i) the remuneration exceeds \$5,000; and (ii) the SFI is related to Dr. Smart's Institutional Responsibilities because it involves Dr. Smart's CMU expertise. The SFI may or may not constitute a FCOI.
3. Dr. Singh patented technology he developed at Great Eastern University. Dr. Singh is currently on faculty at CMU doing similar work. Dr. Singh has received royalties from Great Eastern University exceeding \$5,000. This must be disclosed as a SFI because, with regard to intellectual property rights and interests (e.g., *patents*, *copyrights*), a SFI exists upon receipt of income of greater than \$5,000 related to such rights and interests; and (ii) the SFI is related to his Institutional Responsibilities because the patented technology relates to his CMU expertise. The SFI may or may not constitute a FCOI.
4. Dr. Bing is a founder of a non-publicly-traded company that utilizes technology developed in her lab at CMU. Dr. Bing receives federal funding at CMU for further development of the technology. Dr. Bing would like to issue a subcontract to the company for a portion of the work to be done. This must be disclosed as a SFI since (i) with regard to any non-publicly traded entity, a SFI exists when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in the non-publicly traded entity; and (ii) the SFI is related to Dr. Bing's Institutional Responsibility because a subcontract will be issued from Dr. Bing's CMU award. The SFI may constitute an FCOI and a management plan may be required.

### Organizational Conflicts of Interest

The Defense Advanced Research Projects Agency (DARPA), the Intelligence Advanced Research Projects Activity (IARPA), the Department of Energy (DOE), and other sponsors may have requirements regarding a particular type of conflict of interest called Organizational Conflict of Interest (OCOI). The Organizational Conflict of Interest Policy linked earlier in this document describes OCOIs in more detail. When these requirements apply, ORIC may need to ask Investigators to complete an additional COI statement to fulfill this requirement. This is typically handled via email. ORIC will work with Investigators and their department to satisfy the specific requirements.

### Management of Financial Conflicts of Interest

In some instances it is necessary to manage, mitigate, reduce or eliminate FCOIs. CMU works with Investigators to explore whether there are structures that would allow research to continue when there is an appropriately-avoided or managed FCOI. Examples of mechanisms that are used to avoid or manage conflicts include:



- Public disclosure of SFIs (e.g., when presenting or publishing research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Change of personnel or personnel responsibilities;
- Divestment of the financial interest;
- Severance of relationships that create the conflict (e.g., consulting);
- For research projects involving human subjects research, disclosure of FCOIs directly to human participants; or
- Written disclosure of the conflict to all individuals working on the research project.

ORIC will communicate its determination regarding a management plan to the Investigator in writing.

The Investigator may not commence or participate in the research until the Investigator agrees to and complies with a management plan imposed to manage a FCOI. Once agreed to, ORIC works with departments to monitor compliance with the management plan. Management plans are sometimes updated to reflect changes in research personnel, financial interests or other factors.

### **Software Engineering Institute Employees and Campus Collaborators**

The Software Engineering Institute has its own conflict of interest policy that applies to everyone whose primary department is the SEI. The policy requires an annual disclosure process, typically completed in August. The policy requires disclosure of all financial interests, not only those related to Institutional Responsibilities. Details of SEI's policy can be obtained from the SEI Ethics and Compliance Office.

Faculty and staff who have other primary departments but who have signed a Campus Collaboration Agreement to engage in SEI research are required to abide by both CMU's general conflict of interest requirements and SEI's. Any such faculty and staff should review the SPARCS questions and instructions carefully to ensure they have disclosed any additional financial interests that might be necessary.

For example: A researcher who was not previously a Campus Collaborator may have a disclosure that discloses her SFIs related to her Institutional Responsibilities. However, she may not have disclosed other financial interests unrelated to her work, such as equity held in a non-public company that is not related to her CMU work, or payment for a freelance job unrelated to her CMU responsibilities. Once she becomes a Campus Collaborator, she must update her SPARCS disclosure profile to include these additional financial interests.

### **Compliance**

In the event there is a violation of the compliance procedures and disclosure requirements set out in this document, an Investigator may be subject to sanctions set forth in the relevant disciplinary policy. The relevant disciplinary policies include the Appointment and Tenure Policy (for a faculty member); the Disciplinary Guidelines in the staff handbook (for a staff member); and the applicable provisions of the student handbook - The Word (for a student).

## **Record Keeping**

Records related to research, disclosures of SFIs and CMU’s reviews of and responses to such disclosures, and financial conflicts of interest and related management plans will be maintained for a period of at least three years after the date a project’s final expenditure report is submitted to the sponsor, or for such other time required by applicable law.

## **Current and Pending/Other Support**

Current and Pending/Other Support disclosure requirements are distinct from conflicts of interest in research requirements. However, some information disclosed for Current and Pending/Other Support may overlap with information disclosed for conflicts of interest in research requirements.

Many federal research sponsors have requirements for disclosing sources of support during the proposal or award process, such as National Institutes of Health’s (NIH) “Other Support” form and National Science Foundation’s (NSF) “Current and Pending Support” and Biographical Sketch requirements. These forms are separate from conflicts of interest in research requirements and require separate and distinct submissions. Researchers should refer to relevant sponsor guidance or any CMU guidance documents on current and pending/other support for more information.

## **References**

[CMU ORIC COI website](#)

[CMU COI FAQs](#)

## Appendix A – Specific Requirements for PHS<sup>2</sup> Research Funding

### SPECIFIC REQUIREMENTS FOR PHS RESEARCH FUNDING

CMU complies with Public Health Service (PHS) regulations at 42 CFR Part 50 and 45 CFR Part 94.

### Training Requirements

Investigators receiving PHS funds must participate in training about CMU's Guidelines for the Research Community on Compliance with Conflict of Interest in Research Requirements (Guidelines), this Appendix, and the PHS regulations before engaging in research related to any PHS-funded activity and at least every four years thereafter, and immediately when any of the following circumstances apply:

1. CMU revises this Appendix in any manner that affects the requirements of Investigator (training will be completed in the manner and within the time frame specified in communications announcing such changes);
2. An Investigator is new to CMU; or
3. An Investigator is not in compliance with the Guidelines, this Appendix, or a FCOI management plan, as determined by CMU.

The University will track training for all PHS-funded researchers.

### Subcontractor/Consultant Disclosures

For any PHS award to CMU that CMU carries out through a subrecipient under a subaward to another institution, the written agreement between CMU and the subrecipient will establish whether the conflict guidelines of CMU or that of the subrecipient will apply to the subrecipient's Investigator(s). Where the conflict policy of the subrecipient will apply to the subrecipient's Investigator(s), the subrecipient will certify that its policy complies with the PHS regulations. In all cases, the subrecipient agreement will include time periods to meet CMU's disclosure and/or FCOI reporting requirements to PHS.

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<sup>2</sup> The following agencies are a part of PHS: Agency for Health Care Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

The following U.S. Department of Health and Human Services units typically follow PHS regulations on financial conflicts of interest in research: Office of Global Affairs (OG), Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Planning and Evaluation (OASPE), Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of Public Health and Science (OPHS).

The following nongovernmental research sponsors often follow PHS regulations on financial conflicts of interest in research: Alliance for Lupus Research (ALR), American Asthma Foundation, American Cancer Society (ACS), American Heart Association (AHA), American Lung Association (ALA), Arthritis Foundation (AF), CurePSP, Juvenile Diabetes Research Foundation (JDRF), Lupus Foundation of America (LFA), Patient-Centered Outcomes Research Institute (PCORI), and Susan G. Komen for the Cure.

If a subrecipient does not have PHS-compliant policies, CMU's conflict guidelines will apply to the subrecipient. ORIC and the Office of Sponsored Programs (OSP) will work with Investigators during the proposal, new award, and ongoing reporting stages of such awards to ensure collaborators complete the necessary requirements and disclosures.

## Reporting to PHS Components

Prior to CMU's expenditure of any funds under a PHS-funded project, CMU will provide to the appropriate prime or PHS awarding component a FCOI report (containing all elements that PHS regulations require) regarding any Investigator's SFI that CMU finds to be a FCOI and ensure that CMU has implemented a management plan.

For any SFI that CMU identifies as a FCOI subsequent to CMU's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), CMU will provide, within sixty (60) days, a FCOI report (containing all elements that the PHS regulations require) regarding the Investigator's SFI found by CMU to be a FCOI, and ensure that CMU has implemented a management plan in accordance with this Appendix. ORIC staff will make these reports to the appropriate prime or PHS awarding component and include the following:

- Project number;
  - PI/PD name;
  - Name of the Investigator with the conflict;
  - Name of the entity related to the conflict;
  - Nature of the financial interest, e.g., equity, consulting income, travel reimbursement, etc.;
  - Value of the financial interest in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 by increments of \$50,000), or if the interest is one whose value cannot be readily determined through reference to public information, a statement to that effect;
  - A description of the financial interest related to the funded research and why CMU determined there is a conflict;
  - A description of the key elements of CMU's management plan.
- Annual report. For every FCOI previously reported by CMU to PHS with regard to an ongoing PHS-funded research project, CMU will submit an annual report to PHS that addresses the status of the FCOI and any changes to the management plan. Annual FCOI reports are due at the same time as when CMU is required to submit the award's annual progress report, multi-year funded progress reports, or at the time of an extension.
  - Late certification or review. Whenever CMU identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by CMU during an ongoing PHS-funded research project, CMU will, within sixty (60) days, review the SFI, determine whether it is related to PHS-funded research, and determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI going forward.

- Retrospective review. In the event CMU determines that a FCOI is not identified or managed in a timely manner, including, for example, failure by an Investigator to comply with the disclosure requirements; failure by CMU to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, CMU will, within one-hundred and twenty (120) days of CMU's determination of noncompliance, complete a retrospective review of the Investigator's research activities to determine whether any PHS-funded research was biased in the design, conduct or reporting of the research. CMU will document the retrospective review consistent with elements required by the PHS regulations. If bias is found during the review, CMU will notify PHS promptly and submit a mitigation report to the PHS. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and CMU's plan of action taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done, analysis of whether the research project is salvageable). Thereafter, CMU will submit FCOI reports annually as prescribed by PHS regulation.

If a management plan is established for a PHS-funded project, CMU will report details of the management plan to the PHS. The following key elements of the management plan must be included in the report:

- Role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the management is designed to safeguard objectivity of the research;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

No expenditure of funds under any PHS-funded research project will be permitted until the Investigator has complied with the obligations of the Guidelines and this Appendix and agrees to comply with any management plan.

## **Public Disclosure of COIs**

Prior to the expenditure of any funds under a PHS-funded research project, CMU will ensure public accessibility by written response to any requestor within five (5) business days of a request, of information concerning any SFI disclosed to CMU that meets the following three criteria:

- (i) The SFI was disclosed and is still held by the Investigator;
- (ii) CMU has determined that the SFI is related to the PHS-funded research; and
- (iii) CMU has determined that the SFI is a FCOI.

The information that CMU will release includes:

- Investigator's name;
- Investigators' title, and role with respect to the research;
- Name of the entity in which the SFI is held;
- Nature of the SFI (stock, income, etc.);
- The approximate dollar value of the SFI in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above

\$100,000 by increments of \$50,000), or if the interest is one whose value cannot be readily determined through reference to public information, a statement to that effect.

CMU will confirm with the Investigator that the information provided is current as of the date of the correspondence and note the same in its written response to the requestor, and CMU will also note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of CMU's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI will remain available, for responses to written requests, for at least three years from the date that the information was most recently updated.

## References

[HHS COI regulation](#)

[HHS COI website](#)

[HHS FAQs](#)

## Appendix B – Specific Requirements for DOE<sup>3</sup> Research Funding

### SPECIFIC REQUIREMENTS FOR DOE RESEARCH FUNDING

CMU complies with the U.S. Department of Energy’s (DOE) Interim Conflict of Interest Policy Requirements for Financial Assistance.

### Supplementation to Guidelines: Disclosure Process and Review

For purposes of DOE-funded research, an Investigator’s SFI is related to the Investigator’s research activity when ORIC reasonably determines that the SFI could be affected by the Investigator’s research activity, could affect the research activity, is in an entity whose financial interest could affect the research activity, or is in an entity whose financial interest could be affected by the Investigator’s research activity. A FCOI exists for DOE-funded research when ORIC reasonably determines that the SFI could directly and significantly affect the purpose, design, conduct, or reporting of the Investigator’s research activity.

### Supplementation to Guidelines: Definitions and Guidance for Financial Disclosure

#### Definitions

For purposes of DOE-funded research:

- “*Investigator*” includes any person – regardless of title or position – who is responsible for the purpose, design, conduct, or reporting of sponsored research or research proposed for funding. In the funding opportunity announcement and/or terms and conditions of award, DOE Program offices can expand the definition of “Investigator” to include any person who **participates in** the purpose design, conduct, or reporting of research. “Investigator” includes all key personnel and any other person who significantly influences the design, conduct, or reporting of sponsored research or who are specifically named in sponsored research funding applications, proposals, or budgets, including in any proposal or budget submitted in SPARCS, and all key personnel who are identified in a progress report or other report submitted by CMU to a funder.
- “*Financial Conflicts of Interest*” occur when the significant financial interests or financial relationships of Investigators (or those of the Investigator’s spouse/domestic partner and dependent children) could directly and significantly affect the design, conduct, reporting, or funding of a DOE-funded project, or present the appearance thereof.

#### Disclosures

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<sup>3</sup> Department of Energy means the U.S. Department of Energy, the National Nuclear Security Administration, and any components of the DOE.

With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration not otherwise disclosed as current, pending, or other support, received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

For purposes of DOE-funded research, SFI includes any reimbursed or sponsored travel regardless of value (i.e., that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse/domestic partner or dependent children) related to the Investigator's Institutional responsibilities that is not otherwise disclosed in current and pending or other support disclosures. Disclosure of reimbursed or sponsored travel should be made by submitting a disclosure profile update within SPARCS within 30 days of the travel.

For purposes of DOE-funded research, with regard to intellectual property rights and interests (e.g., *patents, copyrights*), a SFI exists upon receipt of income, regardless of value, related to such rights and interests.

DOE-funded researchers must submit a Certification statement regarding the truthfulness of their SFI disclosures and acknowledgement of their responsibility to update disclosures during the award period performance should circumstances change which affect previous responses. This Certification is completed as part of the SPARCS disclosure profile.

## **Training Requirements**

Investigators receiving DOE funds must participate in training about the Guidelines, this Appendix, and DOE policies and guidelines before engaging in research related to any DOE-funded activity and at least every four years thereafter, and immediately when any of the following circumstances apply:

1. CMU revises this Appendix in any manner that affects the requirements of Investigator (training will be completed in the manner and within the time frame specified in communications announcing such changes);
2. An Investigator is new to CMU; or
3. An Investigator is not in compliance with the Guidelines, this Appendix, or a FCOI management plan, as determined by CMU.

The University will track training for all DOE-funded researchers.

## **Subcontractor/Consultant Disclosures**

For any DOE award to CMU that CMU carries out through or with the assistance of one or more subrecipients under subawards to another institution, the written agreement between CMU and the subrecipient will establish whether the conflict guidelines of CMU or that of the subrecipient will apply to the subrecipient's Investigator(s). Where the conflict policy of the subrecipient will apply to the subrecipient's Investigator(s), the subrecipient will certify that its policy complies with the relevant sponsor regulations and policies, and the subrecipient shall make such policy available via a publicly accessible website. If the subrecipient does not have any current presence on a publicly accessible website, the subrecipient shall make its written policy available to any requestor within five business days



of a request. In all cases, the subrecipient agreement will include time periods to meet CMU's disclosure and/or FCOI reporting requirements to DOE.

If a subrecipient does not have DOE-compliant policies, CMU's conflict guidelines will apply to the subrecipient. ORIC and the Office of Sponsored Programs (OSP) will work with Investigators during the proposal, new award, and ongoing reporting stages of such awards to ensure collaborators complete the necessary requirements and disclosures.

## **Reporting to DOE Program Offices**

Prior to CMU's expenditure of any funds under a DOE-funded project, CMU will provide to the appropriate prime or DOE program office a FCOI report (containing all elements that DOE guidelines and policies require) regarding any Investigator's unmanaged or unmanageable SFI that CMU finds to be a FCOI. If required by a DOE program office through language in a funding opportunity announcement or term and condition of award, CMU will provide to the DOE program office a list of any Investigator's SFI found by CMU to be conflicting and addressed by a management plan. CMU shall, upon DOE's request, provide to DOE FCOI reports and supporting documentation about any SFI that CMU finds to be conflicting, regardless of whether the conflict has been managed, mitigated, or eliminated.

For any SFI that CMU identifies as a FCOI subsequent to CMU's initial FCOI report during an ongoing DOE-funded research project (e.g., upon the participation of an Investigator who is new to the research project), CMU will provide, within sixty (60) days, a FCOI report (containing all elements that the relevant regulations and policies require) regarding the Investigator's SFI found by CMU to be a FCOI. Where the DOE program office requires CMU to include only unmanaged or unmanageable FCOIs in the FCOI report, the FCOI report must include only those FCOIs that CMU determines to be unmanageable. Where the DOE program office requires CMU to include all Investigator FCOIs, including managed and unmanaged FCOIs, in the FCOI report, CMU must ensure that it has implemented a management plan in accordance with this Appendix and DOE guidelines and policies. ORIC staff will make these reports to the appropriate prime or DOE program office and include the following:

- Project number;
- PI/PD name;
- Name of the Investigator with the conflict;
- Name of the entity related to the conflict;
- Nature of the financial interest, e.g., equity, consulting income, travel reimbursement, etc. and/or applicable external relationships or activities;
- Value of the financial interest in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 by increments of \$50,000), or if the interest is one whose value cannot be readily determined through reference to public information, a statement to that effect;
- A description of the financial interest related to the funded research and why CMU determined there is a conflict;
- A description of the key elements of CMU's management plan (to be included in FCOI reports submitted to DOE only where the DOE program office requires CMU to include all Investigator FCOIs, including managed and unmanaged FCOIs).

- Annual report. For every FCOI previously reported by CMU to DOE with regard to an ongoing DOE-funded research project, CMU will submit an annual report to DOE that addresses the status of the FCOI and any changes to the management plan. Annual FCOI reports are due at the same time as when CMU is required to submit the award’s annual progress report, multi-year funded progress reports, or at the time of an extension.
- Routine FCOI submissions to DOE. In addition to the annual FCOI report, CMU will routinely submit all or some Investigator disclosures of financial interests as required by DOE. Circumstances when DOE may require CMU to submit all or some Investigator disclosures include:
  - As part of monitoring CMU’s compliance with DOE conflict of interest policies;
  - Bankruptcy;
  - Other legal winding down;
  - Acquisition of CMU by a foreign entity, where “acquisition” includes a foreign entity obtaining a controlling interest in CMU; or
  - As required by 2 CFR 200.
- Late certification or review. Whenever CMU identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by CMU during an ongoing DOE- funded research project, CMU will, within sixty (60) days, review the SFI, determine whether it is related to DOE-funded research, and determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI going forward.
  - Retrospective review. In the event CMU determines that a FCOI is not identified or managed in a timely manner, including, for example, failure by an Investigator to comply with the disclosure requirements; failure by CMU to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, CMU will, within one-hundred and twenty (120) days of CMU’s determination of noncompliance, complete a retrospective review of the Investigator’s research activities to determine whether any DOE-funded research was biased in the **purpose**, design, conduct or reporting of the research. CMU will document the retrospective review consistent with elements required by the relevant regulations. If bias is found during the review, CMU will notify the sponsor promptly and submit a mitigation report to the sponsor. The mitigation report will include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and CMU’s plan of action taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done, analysis of whether the research project is salvageable). Thereafter, CMU will submit FCOI reports annually as prescribed by applicable DOE guidelines and policy, and more frequently as required by DOE program offices through language in funding opportunity announcements or term and conditions of award.

If a management plan is established for a DOE-funded project, CMU will report details of the management plan to the DOE. The following key elements of the management plan must be included in the report:

- Role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the management is designed to safeguard objectivity of the research;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

No expenditure of funds under any DOE-funded research project will be permitted until the Investigator has complied with the obligations of the Guidelines and this Appendix and agrees to comply with any management plan.

### **Public Disclosure of COIs**

Prior to the expenditure of any funds under a DOE-funded research project, CMU will ensure public accessibility by written response to any requestor within five (5) business days of a request, of information concerning any SFI disclosed to CMU that meets the following three criteria:

- (iv) The SFI was disclosed and is still held by the Investigator;
- (v) CMU has determined that the SFI is related to the DOE-funded research; and
- (vi) CMU has determined that the SFI is a FCOI.

The information that CMU will release includes:

- Investigator's name;
- Investigators' title, and role with respect to the research;
- Name of the entity in which the SFI is held;
- Nature of the SFI (stock, income, etc.);
- The approximate dollar value of the SFI in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$20,000 - \$100,000 by increments of \$20,000, amounts above \$100,000 by increments of \$50,000), or if the interest is one whose value cannot be readily determined through reference to public information, a statement to that effect.

CMU will confirm with the Investigator that the information provided is current as of the date of the correspondence and note the same in its written response to the requestor, and CMU will also note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of CMU's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI will remain available, for responses to written requests, for at least three years from the date that the information was most recently updated.

### **Supplementation to Guidelines: Record Keeping Requirements**

Records related to research, disclosures of SFIs and CMU's reviews of and responses to such disclosures, and financial conflicts of interest and related management plans will be maintained for three years, dates specified in the individual award terms and conditions, or such other date as is required by law.

## References

[DOE Interim COI policy](#)

## Appendix C – Specific Requirements for NSF Research Funding

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### **SPECIFIC REQUIREMENTS FOR NATIONAL SCIENCE FOUNDATION (NSF) RESEARCH FUNDING**

#### **Supplementation to Guidelines: Definitions and Guidance for Financial Disclosure**

SFI includes “anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, private equity, or other ownership interests); venture or other capital financing, and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).”

#### **References**

[NSF COI policy](#)

## Appendix D – Specific Requirements for NASA<sup>4</sup> Research Funding

### **SPECIFIC REQUIREMENTS FOR NASA RESEARCH FUNDING**

CMU complies with the National Aeronautics and Space Administration (NASA) Grant and Cooperative Agreement Manual and its Conflicts of Interest Policy.

### **Supplementation to Guidelines: Definitions and Guidance for Financial Disclosure**

#### Disclosures

SFI includes “anything of monetary value, including, but not limited to, salary or other payments for services not otherwise identified as salary (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, private equity, or other ownership interests); venture or other capital financing, and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).”

### **Subcontractor/Consultant Disclosures**

For any NASA grants and cooperative agreements to CMU that CMU carries out through a subrecipient under a subaward to another institution, CMU will ensure (1) subaward recipients have their own policies in place that meet the requirements of NASA’s conflict of interest policy, or (2) Investigators working for subaward recipients follow CMU’s conflict guidelines.

### **Reporting to NASA Program Offices**

Prior to CMU’s expenditure of any funds under a NASA-funded grant or cooperative agreement, CMU will provide to the appropriate NASA office a FCOI report (containing all elements that NASA guidelines and policies require, such as award number, name of Investigator, nature of the SFI, etc.) regarding any Investigator’s SFI that CMU finds to be a FCOI and that CMU cannot satisfactorily manage, reduce, or eliminate.

For any SFI that CMU identifies as a FCOI subsequent to CMU’s initial FCOI report during an ongoing NASA-funded grant or cooperative agreement (e.g., upon the participation of an Investigator who is new to the research project), if CMU cannot manage, reduce, or eliminate the conflict, CMU will provide, within sixty (60) days, a FCOI report to the appropriate NASA office containing all elements that the relevant regulations and policies require, such as award number, name of Investigator, nature of the SFI, etc.

No expenditure of funds under any NASA-funded grant or cooperative agreement will be permitted until the Investigator has complied with the obligations of the Guidelines and this Appendix and agrees to comply with any management plan.

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<sup>4</sup> NASA means the U.S. National Aeronautics and Space Administration, and any components of NASA.

## References

[NASA Grant Information Circular 23-07](#)

[NASA Grant and Cooperative Agreement Manual](#)