

Carnegie Mellon University Guidelines

Compliance with Conflict of Interest Regulations and Policy

INTRODUCTION

As the recipient of external funds to support research activities, Carnegie Mellon University (CMU) is required to have policies and processes that are consistent with federal regulation and sponsor policy governing financial conflicts of interest in research. This document is intended to assist members of CMU's research community with understanding the regulations, policies, individual responsibilities and the university's responsibilities. This document is divided into four main sections:

- Introduction
- Sponsor (except Public Health Service Agencies) Requirements
- Public Health Service¹ Requirements
- General

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

Purpose

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 activities. While extramural activities benefit the university and are generally encouraged, in some circumstances such activities give rise to conflicts of interest. Conflicts of interest are situations that need to be disclosed and sometimes managed. They are not inherently bad and do not always lead to biased behavior. This document is intended to assist members of CMU's research community in understanding the framework of federal law and university policy that governs the handling of financial conflicts of interest in research.

Conflicts of interest in research occur when university members are in a position to influence research and their extramural activities are such that they or their family may receive a financial benefit or improper advantage from the research. 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 are inevitable.

US law-makers and funding agencies are concerned that researchers' financial interests not negatively impact the objectivity of research funded by the government. Federal regulations regarding financial conflict of interest in research are intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under federal grants, cooperatives agreements or contracts will be free from bias resulting from Investigator financial conflicts of interest. Many non-governmental funding organizations also have conflict of interest requirements.

Policy

Members of CMU's research community should make the fulfillment of their responsibilities to the university the focal point of their professional activities. University members should only become involved in extramural

professional activities insofar as they advance the mission or prestige of the university and the activities do not interfere with their responsibilities to the university.ⁱⁱ

CMU has three policies that address conflicts of interest in research:

- [Conflict of Interest and Commitment](#)
- [Compliance with Financial Conflict of Interest Requirements](#)
- [Organizational Conflict of Interest in Research](#)

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.

The Office of the Vice President for Research and the Office of Research Integrity and Compliance (ORIC) are responsible for compliance with research related conflict of interest regulations and policy.

Process

Federal regulations and many non-governmental sponsors require that Investigators disclose financial conflicts of interest or significant financial interests to CMU prior to submission of a proposal for funding. In the event it is determined that an actual financial conflict of interest exists, the conflict must be managed prior to spending on the award.

Information is available on the ORIC website to assist researchers in completing certifications and understanding COI.

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

Once received by ORIC, certifications will be reviewed to determine if a financial conflict of interest exists. If no COI is identified, the certification will be stored as required by law. If it appears that a COI may exist, further review is required. This review may be conducted by ORIC staff, CMU's Conflict of Interest committee, the relevant department head and CMU's Vice President for Research.

Certification forms and the information contained therein are used for the purpose of reviewing and managing conflicts of interest and as required by law. The information is treated as private and confidential. As discussed later in this document some information must be shared with funding agencies and the public.

The terms "certification" and "disclosure" are used frequently in this guidance document. "Certifications" are a set of questions relating to your responsibilities at CMU and possible conflicts of interest. "Disclosures" are a set of questions embedded into Certifications, relating to your Significant Financial Interests.

Please note that the Public Health Service (PHS) and some other sponsors have a different standard for certification and disclosure. Investigators seeking or receiving PHS funds need to complete the PHS specific certification. Some non-government sponsors follow the PHS standards. The list as of the date of this document includes:

- 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)
- 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 the Assistant Secretary for Planning and Evaluation
- Office of Public Health and Science (OPHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- 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)
- Susan G. Komen for the Cure

Details are provided below in this guidance document. Please make sure you choose the correct set of requirements based on the type of funding you seek and/or receive.

SPONSOR REQUIREMENTS (EXCEPT PHS)

Individuals Seeking or Receiving Funding from the National Science Foundation (NSF) and Other Sponsors, excluding the Public Health Service

The National Science Foundation (NSF) and many other sponsors require that each “Investigator” disclose to the university, “Significant Financial Interests”:

- that appear to be affected by the research or educational activities funded or proposed for funding; or
- in entities whose financial interests would appear to be affected by such research or educational activities.

Essentially, an Investigator is asked to determine if his or her funded research activities create, or may appear to create, a conflict of interest and if so, to disclose the relevant financial relationships. This includes certain remuneration received or ownership interests held by the Investigator, spouse/domestic partner (as defined by CMU for purposes of benefits) or dependent children.

To certify and disclose appropriately it is critical to understand the terms used in the regulations. Below are definitions and examples.

“*Investigator*” means the Project Director, Principal Investigator or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded or proposed for funding.

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

SFI includes

- An ownership interest that exceeds \$10,000 in fair market value and represents more than 5% ownership in a single entity.
- Salaries, consulting fees, royalties, and other payments that when aggregated over the next twelve month period are expected to exceed \$10,000.

SFI does not include:

- Income from investments such as mutual funds or retirement accounts where you do not directly control investment decisions;

- Salary, compensation, royalties or other payments from CMU;
- Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees, or review panels for public or non-profit entities.

A “*Conflict of Interest*” (COI) exists when it is determined that a significant financial interest could directly and significantly affect the design, conduct or reporting of the funded research or educational activities.

For example, if you own 10% of Acme’s stock (whether publicly or privately held) and the stock is worth \$15,000, you have a SFI. If Acme is involved in research at CMU, you should disclose this as a potential conflict of interest. However, if you own \$15,000 in Microsoft stock, this constitutes less than 5% ownership in

Microsoft. Even if you receive funding from Microsoft for research, you do not have a SFI and do not need to disclose a conflict of interest.

So that researchers do not have to disclose the value of privately held entities to CMU, we ask that researchers consider any ownership interest in a privately held entity to be a SFI and to disclose such interest. For example if you own stock in a start-up company and that company is somehow involved in research with CMU, you should disclose this as a potential conflict of interest.

Reporting to NSF

CMU is required to notify NSF’s Office of General Counsel in the event a financial conflict of interest is identified and CMU finds that it is unable to appropriately manage the conflict.

PUBLIC HEALTH SERVICE REQUIREMENTS

Individuals Seeking or Receiving Public Health Service (PHS) Agency Funds (includes NIH and CDC)

Although the PHS and NSF terminology is the same, the standards are different. Please make sure you select the certification standard that aligns with the funding you seek and/or receive.

“Investigators” seeking or receiving funds from a PHS agency are required to disclose “Significant Financial Interests” (SFI) that are related to their “Institutional Interests”. This includes certain remuneration received or ownership interests held by the Investigator, spouse/domestic partner (as defined by CMU for purposes of benefits) or dependent children.

Investigators are responsible for ensuring their information in SPARCS is up to date prior to submitting a proposal for funding. Certifications must be updated annually and

within thirty (30) days of discovering or acquiring (through marriage, purchase, gift, inheritance, etc.) a new Significant Financial Interest, as well as at other times if requested by ORIC.

To complete a certification it is critical to understand the terms used in the regulations. Below are PHS definitions and examples.

“*Investigator*” means the Project Director, Principal Investigator, Co-Investigator or any other person, regardless of title or position, who is responsible for design, conduct or reporting of research funded or proposed for funding. This includes all key personnel identified in the grant application, progress report or other report submitted to the funding agency by the Institution.

To be considered an Investigator for the purpose of COI, an individual has a level of responsibility such that they can have a

meaningful impact on the results of the research. This could include recording study data without quality control mechanisms, independently analyzing data, and serving as an author on publications. If an individual's role in the research is significant enough that they are specifically listed in a proposal for funding, they are considered to be an Investigator and should complete a certification.

"Institutional Responsibilities" involve a variety of scholarly and professional obligations carried out on behalf of the university such as teaching, research, scholarship, professional practice and service (on university, association, advisory or technical committees, editorial boards). Activities related to an individual's field of professional expertise are usually either Institutional Responsibilities or related to their Institutional Responsibilities.

Examples of Institutional Responsibilities:

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

Examples of activities related to Institutional Responsibilities:

- Consulting - providing your professional expertise to a start-up company, non-governmental organization or other university;
- Expert testimony – using your professional expertise to provide testimony on behalf of a client or as part of a government proceeding;
- Service – serving on an advisory board or committee in a topical area where you have professional expertise; serving

on a committee of a professional organization;

- Other paid work – writing a textbook in your area of expertise.

Examples of activities NOT related to Institutional Responsibilities:

- Teaching - Teaching ski lessons;
- Service - participating on a committee as a parent for your child's school;
- Consulting - outside of your expertise, for example, a member of the science faculty being paid to perform in a play;
- Other paid work – writing a novel, jury duty.

You only need to disclose Significant Financial Interests related to your Institutional Responsibilities as described above. For example if you have SFI in the form of income from consulting in your area of professional expertise, the SFI is related to your Institutional Responsibilities and should be disclosed.

"Significant Financial Interests" (SFI) include certain payments, ownership interests and intellectual property rights and interests as defined by 42 CFR Part 50 and 45 CFR Part 94 and described here.

SFI includes:

- A Significant Financial Interest exists, related to a publicly traded company, if the value of any compensation or payment in the preceding twelve (12) months and the value of any equity interest as of the date of this disclosure when aggregated, exceeds \$5,000. This includes salary, payment for services, stock, stock options or other ownership interest.

For example, if Acme paid you \$3,000 for consulting and you own \$1,000 of Acme stock, you need not disclose this. However, if you were paid \$3,000 for consulting and own \$2,500 of stock, you should disclose as the aggregated amount exceeds \$5,000.

- A Significant Financial Interest exists, related to a non-publicly traded entity, if the value of any compensation or payment in the preceding twelve (12) months exceeds \$5,000. Additionally, you should disclose if you have any equity interest in the entity such as stock, stock options or other ownership interest.
- A Significant Financial Interest exists when you have income from intellectual property rights and interests such as patents and copyright, upon receipt of income, where the payments are not from CMU.

SFI *does not* include (you need not disclose):

- Salary, royalties, or other payments from CMU.
- Income from investments such as mutual funds or retirement accounts where you do not directly control investment decisions.
- Income from seminars, lectures, teaching engagements sponsored by a U.S. government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. These forms of income are not exempt from disclosure when they come from foreign entities.
- Income from service on an advisory committee or review panel for a U.S. government agency, institution of higher education, academic teaching hospital, medical center or research institute affiliated with an institution of higher education. These forms of income are not exempt from disclosure when they come from foreign entities.

“Financial Conflict of Interest” (COI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Investigators participating in PHS funded research are to submit an updated certification at least annually. If during the course of the year, you discover or acquire (e.g. through marriage, purchase or inheritance) an SFI, you are to update your disclosure within 30 days.

Before a new funding proposal is submitted to a PHS agency, Investigators listed on the proposal will receive an email reminding them of their current Significant Financial Interests listed in SPARCS. It is your responsibility to review this email and, if you find your information is out of date, to log in to SPARCS and submit an Update Certification prior to the proposal’s submission.

At the time each proposal is submitted, CMU is required to certify its compliance with the PHS COI requirements.

Sponsored and Reimbursed Travel for PHS Funded Investigators

PHS funded Investigators are required by regulation to disclose the occurrence of certain types of reimbursed or sponsored travel related to the Investigator’s Institutional Responsibilities.

You do not need to disclose travel if it was sponsored or reimbursed by any of the following:

- A US federal, state or local government entity,
- A US institution of higher learning,ⁱⁱⁱ
- A US academic teaching hospital,
- A US medical center, or
- A US research institute affiliated with an institution of higher learning.

You are not required to disclose travel unless the total value of travel sponsored by a single organization in a 12-month period exceeds \$5,000.

When you disclose sponsored and reimbursed travel, you should provide the following information:

- Purpose of the trip,

- Identity of the sponsor/organizer,
- The destination, and
- Duration.

Travel paid for by CMU or covered by a sponsored award does not need to be disclosed.

Disclosure of sponsored and reimbursed travel should be made by submitting an Update Certification within SPARCS. If you are funded by a PHS agency, you should complete this update within 30 days of the travel total for the year reaching \$5,000. You may choose to report travel as it occurs rather than tracking total value for the year.

Training Requirements for PHS Funded Researchers

Investigators receiving PHS funds are required to participate in training regarding Financial Conflicts of Interest in research every four years. The university is required to track training for all PHS researchers.

COI training is built into the online COI module in SPARCS. The training pages will appear automatically when first disclosing in SPARCS, and every three years thereafter. SEI staff members, or other faculty/staff/students who collaborate with the SEI on research, will see the training pages every year to comply with the SEI's contractual requirements.

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

Reporting to PHS

In the event an Investigator has a financial conflict of interest related to PHS funding, CMU is required to report certain situations to PHS funding agencies. These reports are made by staff in ORIC. Investigators do not need to

report directly to PHS. Reports are triggered by certain events as outlined below.

- Determination of a COI. If it is determined that a PHS funded Investigator has a financial conflict of interest, a report must be made to the funding agency prior to the expenditure of any funds under the award. This report must 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 \$240,000 - \$100,00 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.

This report must be submitted to the funding agency within sixty (60) days of determining that a COI exists.

- Annual report. For every COI, an annual report must be submitted that addresses the status of the financial interests and any changes to the management plan. Annual COI 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.** If an Investigator does not timely disclose a significant financial interest or CMU does not timely review a disclosed SFI and it is determined that a COI exists, a report must be made.
- **Retrospective review.** In the event CMU determines that an Investigator has failed to comply with the disclosure requirements, the university is required to complete a retrospective review of the Investigator's research activities. The purpose is to determine whether any PHS funded research was biased in the design, conduct or reporting of the research.

Public Disclosure of COIs for PHS Funded Investigators

In the event it is determined that a researcher has a financial conflict of interest as it relates to

PHS funded research, the regulation requires that certain information be made available to the public. The information that CMU is required to 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.);
- approximate dollar value of the SFI in dollar ranges (\$0 - \$4,999, \$5,000 - \$9,999, \$10,000 - \$19,999, amounts between \$240,000 - \$100,00 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.

The law provides the university with a choice between posting information about COIs on the internet and making the information available within five (5) days of a written request. CMU has chosen to make information available upon written request to the Office of Research Integrity and Compliance.

GENERAL

Conflicts of Interest

Certifications will initially be reviewed by staff in ORIC. If it is determined that a conflict of interest may exist, the Investigator will be contacted for additional information. At that time, the Investigator's disclosure may be shared with the Vice President for Research, the Conflict of Interest Committee, legal counsel or the Investigator's department head. Typically, the Investigator will be asked to assist in determining the best course of action for managing a conflict.

Examples of Potential Conflicts of Interest:

Dr. Karl is a founder of a company that utilizes technology developed in her lab at CMU. She has an equity interest in the company and receives remuneration from the company. This is related to Dr. Karl's institutional responsibility. These financial interests should be disclosed. They may or may not constitute a conflict of interest.

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 is related to Dr. Smart's institutional responsibilities. These financial interests should

be disclosed if Dr. Smart is funded by PHS however this financial interest may not need to be reported if Dr. Smart only has funding from other sources. If the bank is sponsoring Dr. Smart's work at CMU this is likely a conflict of interest and must be disclosed.

Dr. Singh patented technology he developed at Great Eastern University. Dr. Singh is currently on faculty at CMU doing similar work. Dr. Singh receives royalties from Great Eastern University. This is related to his institutional responsibilities and must be disclosed if she is funded by PHS. This may or may not result in a conflict of interest.

Dr. Bing is a founder of a company that utilizes technology developed in her lab at CMU. Equity interests and remuneration from this company are related to Dr. Bing's institutional responsibility. Dr. Bing receives federal funding for further development of the technology. Dr. Bing would like to subcontract with her company for a portion of the work to be done. This is a conflict of interest and must be disclosed.

Organizational Conflicts of Interest

DARPA, IARPA, and a few other sponsors include requirements in their BAAs for additional statements from CMU regarding a particular type of conflict of interest called Organizational Conflict of Interest. The policy linked on page 2 of this document describes OCIs in more detail. When the BAA includes this type of requirement, ORIC may need to ask you to complete an additional COI statement to fulfill this requirement. This is typically handled via email. ORIC will work with you and your department to satisfy the particular needs of the specific BAA.

Management of Conflicts of Interest

In some instances it is necessary to manage, reduce or eliminate conflicts of interest. CMU

works with Investigators to find structures that allow researchers to continue their work when there is a conflict. Examples of mechanisms that are used to manage conflicts include:

- Public disclosure of SFIs;
- Monitoring of research by independent reviewers;
- Modification of the research plan; or
- Change of personnel.
- Divestment of the financial interest

Once agreed to, ORIC monitors compliance with the management plan. Management plans are sometimes updated to reflect changes in research personnel, financial interests or other factors.

If a management plan is established for a PHS funded project, CMU is required by law to report details of the management plan to the funding agency. 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.

ORIC staff is happy to consult with researchers prior to submission of a proposal to assist them in structuring the proposal in a manner that minimizes concerns about conflicts of interest.

Compliance

In the event there is a significant violation of the CMU policy on Financial Conflicts of Interest in Research, the offending Investigator may be subject to sanctions set forth in the relevant disciplinary policy. Action taken will depend on

a number of factors including the individual's status as faculty, student or staff.

Record Keeping

Records related to research, disclosures of significant financial interests, financial conflicts of interest and related management plans are required to be maintained for a period of three years beyond the end of the award.

Certifications and the information contained therein are used for the purpose of reviewing and managing financial conflicts of interest and as required by law. The information is treated

as private and confidential. As discussed elsewhere in this guidance, CMU is also required to make certain information available to federal funding agencies and the public.

References

[CMU ORIC COI website](#)

[CMU COI FAQs](#)

[HHS COI regulation](#)

[HHS COI website](#)

[HHS FAQs](#)

[NSF COI policy](#)

ⁱ 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), 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), Office of Public Health and Science (OPHS), Substance Abuse and Mental Health Services Administration (SAMHSA), 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), Susan G. Komen for the Cure.

ⁱⁱ From CMU's Policy on Conflict of Interest and Commitment.

ⁱⁱⁱ 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.