

## PHS (NIH) Conflict of Interest Disclosure Guidelines

### A. Background

The University of Colorado Colorado Springs (UCCS) is required to have processes in place to identify any relationships involving financial gain that could compromise or appear to compromise its integrity. UCCS is also required to have processes in place to manage, reduce, or eliminate any real or perceived financial conflict of interest (COI). These requirements and processes are described in the [University of Colorado Administrative Policy Statement 5012](#) titled, “Conflicts of Interest and Commitment in Research and Training” and the UCCS Human Resources Office’s, “[Conflict of Interest and Commitment Procedures](#).”

In addition, the Department of Health and Human Services (DHHS), pursuant to 42 CFR Part 50 Subpart F and CFR Part 94, places additional requirements on entities proposing or receiving Public Health Services (PHS) funding.

The Public Health Service (PHS) agencies include the following:

- National Institutes of Health (NIH),
- Office of the Assistant Secretary for Preparedness and Response (ASPR),
- Office of Global Affairs (OGA),
- 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), and
- Substance Abuse and Mental Health Services Administration (SAMHSA).

An expanded list of DHHS agencies can be found at the following website:  
<https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>

**These guidelines implement the additional requirements imposed by DHHS.**

**All Principal Investigator’s (PI) who have proposed or received funds from a PHS agency are responsible for complying with these guidelines.**

### B. Key Definitions

#### **Investigator**

The PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may

include for example, collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

### **Financial Conflict of Interest (FCOI)**

A *financial conflict of interest* exists when the institution's designated official(s) reasonably determines that an [investigator's significant financial interest \(SFI\)](#) could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The institution is required to review each Investigator SFI disclosure to determine if an SFI:

1. is related to the NIH-supported research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research), *and*
2. could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

### **Significant Financial Interest (SFI)**

*Significant financial interest* means:

- 1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - i. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and 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;
  - ii. (With regard to any non-publicly traded entity, a *significant financial interest* 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not

apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

- 3) The term *significant financial interest* does not include the following types of financial interests salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

See [regulatory definition of SFI](#), including NIH's FAQs [D.8.](#), [E.9.](#) and [E.20.](#)

### **C. Individuals are required to submit a Disclosure of Financial Interests**

All individuals who are responsible for the design, conduct or reporting of basic, animal, or clinical research (including, but not limited to, obtaining informed consent, making decisions about eligibility to participate in research, collecting data, entering data, analyzing data, assisting in writing and submission of research manuscripts for publication or presentation) must submit a conflict of interest disclosure to the Human Resource Office.

#### **a) Sponsored Travel**

PHS requires that Sponsored Travel be included in determining whether the Aggregate value of an Investigator's financial interests rises to the level of a Significant Financial Interest. Sponsored Travel comprises (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf by a single entity in any 12-month period and (b) travel reimbursed to or paid on behalf of an Investigator's family by a single entity in any 12-month period, **ONLY** if such travel reasonably appears to be related to the Investigator's institutional responsibilities.

NIH states that looking back over the previous twelve-month period provides baseline information that allows UCCS to consider whether Investigators have an ongoing financial relationship with an entity providing payment or reimbursement or whether the payment or reimbursement was limited in duration.

In order to ensure compliance with PHS regulations, therefore, an Investigator must update their COI disclosure to include Sponsored Travel if the Sponsored Travel equals or exceeds \$5,000, either alone or in combination with other salary and payments for services or equity Interests:

- at the time of submission of a proposal to PHS, looking back over the previous 12 months; and
- thereafter, within 30 days following reimbursement or within 30 days following the completion of a trip, if the PHS Investigator has an active award or pending proposal with a PHS agency.

An Investigator need not disclose Sponsored Travel paid for or reimbursed by:

- UCCS (e.g., paid from UCCS funds or from sponsored awards funds managed at UCCS)
- U.S. federal, state or local governmental agencies
- U.S. institutes of higher education
- U.S. research institutions affiliated with institutions of higher education
- U.S. academic teaching hospitals and medical centers

The disclosure must include, at a minimum, the purpose, cost of the trip (estimate if unknown), the identity of the organization or entity funding the travel, the destination, and the duration of the trip (usually days).

## **b) Clinical Research**

If the PHS Grantee determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by UCCS, the PHS Grantee shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

In the event of non-compliance with reporting and/or management of a Financial Conflict of Interest involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by PHS and these guidelines, the Investigator must disclose the Financial Conflicts of Interest

in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

#### **D. Timing of Disclosure**

##### **Initial filing:**

Prior to submitting an application/proposal, all individuals named in a PHS agency proposal are required to have a current COI disclosure on file with the Human Resources Office prior to submitting the proposal to the PHS granting agency.

Individuals not named in the proposal at the time of submission must have a financial COI disclosure on file with the Human Resources Office prior to beginning work on the grant or contract.

In cases where an individual is named in a proposal but does not have access to the online COI disclosure form (e.g., an individual who is in the process of being appointed, consultants, or volunteers), the Offices of Sponsored Programs and Research Integrity (OSPRI) is to be contacted as soon as possible in order to provide the individual with access to the COI disclosure form.

##### **Subrecipients:**

COI disclosure requirements apply to subrecipients. Subrecipients will be required to certify they are in compliance with DHHS COI regulations or will be required to complete a disclosure through UCCS prior to proposal submission.

If HR determines a conflict as being unmanageable or if a COI cannot be eliminated, HR may refer the matter to the COI committee or the appropriate Vice Chancellor or the Vice Chancellor for Administration and Finance for resolution.

##### **Updates:**

Individuals are required to update their COI disclosure as follows:

- a. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and
- b. Annually

#### **E. Review of Financial Conflict of Interest Disclosures**

COI disclosures will be reviewed by the Human Resource Office.

##### **COI Management:**

Prior to the Institution's expenditure of any funds under a PHS-funded research project, HR shall, consistent with [§ 50.604\(f\)](#): review all Investigator disclosures of Significant Financial Interests; determine whether any Significant Financial Interests relate to PHS-funded research; determine whether a Financial Conflict of Interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such Financial Conflict of Interest. Examples of conditions or restrictions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

- i. Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research);
- ii. For research projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants;
- iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
- iv. Modification of the research plan;
- v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- vii. Severance of relationships that create financial conflicts.

### **Investigator Non-Compliance:**

#### **Disciplinary Action**

Violations of PHS requirements and these guidelines will follow the process outlined in the [UCCS Policy 300-006 - Disclosure and Management of Conflicts of Interest or Commitment](#).

#### **Retrospective Review**

In cases where a Financial Conflict of Interest is not identified or managed in a timely manner, including due to:

1. failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
2. failure by UCCS to review or manage such a Financial Conflict of Interest; or
3. failure by the Investigator to comply with a Financial Conflict of Interest management plan

UCCS must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted

during the period of noncompliance, was biased. Retrospective reviews will be conducted by HR and, when applicable, the campus Conflict of Interest Committee.

UCCS is required to document the retrospective review and report detailed findings to PHS, including at least the following key elements:

1. project number;
2. project title;
3. Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
4. name of the Investigator with the Financial Conflict of Interest;
5. name of the Entity with which the Investigator has a Financial Conflict of Interest;
6. reason(s) for the retrospective review;
7. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. findings of the review;
9. if applicable, a description of the impact of the bias ([42 CFR 50.605\(a\)\(3\)\(iii\)](#)) on the research and the plan to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative state to support any actual or future harm; analysis or whether the research project is salvageable); and
10. conclusions of the review.

The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

## **F. Record Retention**

The Human Resources Office (HR) maintains records of all Financial Conflicts of Interest disclosures, conflict management plans, and all actions taken to resolve real or perceived Financial Conflicts of Interest. HR will keep a copy of COI management plans and any other documents supplied by the Human Resources Office in the OSPRI grant file. Records will be maintained in accordance with the UCCS record retention schedule.

## **G. Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and records of actions taken to resolve Conflicts of Interest will be confidential. However, the University in some instances may be required to disclose Conflict of Interest forms and associated details. If disclosure by the university is required, the individual will be informed.

## **H. Training**

All individuals responsible for the design, conduct or reporting of basic, animal, or clinical research (including, but not limited to, obtaining informed consent, making decisions about eligibility to participate in research, collecting data, entering data, analyzing data, assisting in writing and submission of research manuscripts for publication or presentation) are required to complete training before engaging in research related to any PHS-funded grant or contract. The required training “Conflicts of Interest” is provided online by Collaborative Institutional Training Initiative (CITI). <https://www.citiprogram.org/default.asp>

Individuals are required to renew their training with CITI every four (4) years.

## **I. Reporting/ Requesting Financial Conflicts of Interest**

In accordance with DHHS regulations, any Conflict of Interest that, in the determination of the Human Resources Office, requires reporting to NIH/PHS will be reported by OSPRI within sixty (60) days and annually when UCCS is required to submit the annual progress report, or when applicable.

The report will provide the status of the FCOI and any changes and, if applicable, any changes to the management plan until the completion of the project.

## **J. Public Accessibility**

Individuals may request in writing information concerning any significant financial interest disclosed to UCCS by submitting a request via email to [composp@uccs.edu](mailto:composp@uccs.edu) or [osp@uccs.edu](mailto:osp@uccs.edu).

The minimum amount of information that must be made available includes the following:

1. The Investigator’s name;
2. The Investigator’s title and role with respect to the research;
3. The name of the entity in which the Significant Financial Interest is held or from which it is received;
4. The nature of the Significant Financial Interest; and
5. The approximate value of the Significant Financial Interest, which value may be expressed as being within a range: \$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 a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

## **K. References**

- Administrative Policy Statement (APS Number 5012) (<https://www.cu.edu/ope/aps/5012>)



- UCCS Policy 300-006 - Disclosure and Management of Conflicts of Interest or Commitment (<https://www.uccs.edu/vcaf/policies/uccs/policies>)
- **UCCS HR COI Page** (<https://hr.uccs.edu/document-library/conflict-of-interest>)
- Policies and regulations of the National Institute of Health (<http://grants.nih.gov/grants/policy/coi/>)