

PHS (NIH) Conflict of Interest Disclosure Guidelines

Background:

The University of Colorado Colorado Springs (UCCS) is required to have in place processes 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” and the UCCS Human Resources Office, 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:

<http://www.hhs.gov/about/orgchart/#text>

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.

A. Individuals 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.

B. Timing of Disclosure.

Initial filing:

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 Office 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.

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 OSPRI determines a conflict as being unmanageable or if a COI cannot be eliminated, OSPRI may refer the matter to the COI committee or to the appropriate Vice Chancellor and/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

C. Review of Financial Conflict of Interest Disclosures.

COI disclosures will be reviewed by the Human Resource Office.

D. Record Retention

The Human Resources Office maintains records of all financial conflicts of interest disclosures, conflict management plans and of all actions taken to resolve real or perceived financial conflicts

of interest. OSPRI 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 record retention schedule.

E. 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.

F. Training

1. 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” as provided online by Collaborative Institutional Training Initiative (CITI). <https://www.citiprogram.org/default.asp>
2. Individuals are required to renew their training with CITI every four (4) years.

G. Reporting Financial Conflicts of Interest to NIH/PHS. 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.

H. 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>)
- Policies and regulations of the National Institute of Health (<http://grants.nih.gov/grants/policy/coi/>)