

Conflicts of Interest Training for NIH/PHS Researchers – Written Transcript

Link: <https://www.youtube.com/watch?v=iHxVfDXzcMI>

The University of Colorado Boulder is committed to the highest standards of ethics and compliance.

As a part of that commitment, university policies require various groups of our campus community to report financial conflicts of interest, also called FCOI.

In addition, federal agencies hold the university, as a whole, and individuals within the university, equally responsible for meeting FCOI reporting requirements; this training is part of those requirements.

Conflicts of interest and conflicts of commitment are two different, but related, concepts.

First, let's talk about conflicts of commitment: the focus of conflicts of commitment is the amount of time spent on activities away from those that are performed as part of an individual's expected university responsibilities to students, obligations to colleagues, and other scholarly work, including research.

Conflicts of commitment are reported in terms of days and months on activities outside of the university.

Academic and researcher financial conflicts of interest are more complex than conflicts of commitment in that they predominantly relate to the nature or type of a professional relationship with an entity outside of the university.

A conflict of interest exists when financial or personal considerations compromise, appear to compromise, or have the potential to compromise personal judgment in research and other academic activities (academic and researcher financial conflicts of interest include an actual conflict, the appearance of a conflict, or the potential for a conflict).

For example, suppose researcher, Della Stross, works on a NIH-funded project in bioengineering: recently, Dr. Stross purchased stock in a bioengineering company, currently valued at \$20,000.

A reasonable person might conclude that this financial arrangement could influence Dr. Stross' designs, conduct, or reporting of her university research – it is important to note that this might occur intentionally or unintentionally.

Research bias is especially significant when the research involves human subjects; for these situations, there is a concern that the researcher's relationship with an outside entity could result in bias to the benefit of a company, and in doing so, minimize the attention to risks for human subjects involved in a research study.

Another aspect of academic conflicts of interest is related to how students and subordinates are affected by a superior's relationship with an outside entity.

Care must be taken so that students are not diverted from their academic preferences and/or university work to the benefit of a superior's outside interests.

Similarly, subordinates must not be diverted from their university responsibilities to the benefit of a supervisor's outside business.

Student and subordinate research work should be free from biases that might result from a superior's relationship with an outside entity.

So, who is required to submit a conflicts of interest report?

The National Institutes of Health defines any person who is responsible for the design, conduct, or reporting of research as key personnel, meaning these individuals are in positions that could affect the outcomes of a research project.

NIH regulations require all key personnel to report conflicts of interest and to complete this course (note: this definition of key personnel may differ from other definitions that you have encountered with research proposal application and funding processes).

At the University of Colorado Boulder, several job types, as well as graduate students, are required to submit a conflict of interest report on an annual basis.

The requirement also applies to contractors and subcontractors receiving federal funding through the university.

Campus-wide emails are sent out to remind individuals about this reporting requirement.

The Office of Conflicts of Interest and Commitment website provides a complete list of those who should report and when they should report.

If you are the principal investigator on a research project, it is your responsibility to ensure that all personnel on the project meet the conflicts of interest reporting requirements, including this training.

What information needs to be reported on a conflicts of interest disclosure?

The conflicts of interest disclosure form is designed to collect significant financial interest, or SFI.

In general, SFI can be defined as anything of monetary value received outside of the university that exceeds threshold values, and that reasonably appears related to the discloser's institutional responsibilities.

SFI is monies and relationships outside of CU that appear to be related or similar to university responsibilities, including salary and consulting fees; royalties and dividends; stock and equity; as well as being a founder or co-founder, an advisor, or a member of the executive or director's board.

The questions on the conflicts of interest disclosure form represents the types of significant financial interest with which federal funding agencies are concerned.

These SFIs are listed both in terms of monetary thresholds as well as types of relationships to external entities.

In addition, PHS and NIH researchers are required to include sponsored travel, in any amount, as part of their reporting of SFI.

If significant changes occur, updates are required within 30 days of the change.

For example, purchasing stocks, forming a new company, non-profit, or foundation, or entering into a partnership, agreeing to consult, or becoming an advisor to a company.

It is helpful to remember that the following do not represent a financial conflict of interest; please take a moment to review these items: CU monies (including salary or reimbursement, as well as travel), government entities (including compensation or travel from federal, state, or local governments within the United States), academic institutions in the United States (including compensation or travel from other institutions of higher education), and medical and research institutions in the United States (including compensation or travel from a teaching hospital, medical center, or research institute affiliated with higher education).

Mutual, retirement, or pension funds do not need to be reported as long as the discloser does not directly control the investment decisions made in these vehicles.

Conflicts of interest disclosures are required for proposal submissions, award monies to be distributed, and human subjects review, as well as for internal audit and legal inquiries.

If SFIs are not reported adequately, disciplinary, legal, and federal actions, including a loss of funding, may occur.

For these types of irregularities, NIH regulations specifically require the following: a retrospective review of the discloser's research must occur; the review must be conducted within timelines specified by the federal regulations; and, if bias is found, the NIH must be notified, a management plan developed, and a mitigation report submitted.

When conflicts of interest are determined to exist, many times they can be managed.

The University of Colorado Boulder utilizes memorandums of understanding to manage academic and research conflicts of interest.

This type of management plan outlines strategies targeted to address the issues of research bias, and protections for human subjects and students; it also provides disclosers with information about other university policies and procedures that are often relevant in academic conflicts of interest situations.

This concludes the conflicts of interest training for PHS and NIH researchers.

To meet federal requirements, this training must be tracked.

To do that, please follow these steps: return to the conflicts of interest reporting form; then, following the printed instructions, certify and submit.

You must answer and submit all of the COI reporting questions at least once a year; however, you are welcome to revisit this training video at any time.

You are encouraged to contact the Office of Conflicts of Interest and Commitment for any questions, comments, or concerns regarding this topic.

Samantha Hertzog, Director of Conflicts of Interest and Commitment, can be reached by phone at 303-492-3024 or by email at coi@colorado.edu. The COIC webpage can be found at <https://www.colorado.edu/researchinnovation/coi>.

We appreciate your time and attention.

Thank you!