Is there anything else I should know about conflicts of interest and commitment at the university?

- Management plans must be made available within five (5) days of a request from a member of the public.
- Management plans must be signed by the faculty or employee within 10 days of receipt. A summary of the management plan must be provided to the NIH (this is applicable when there is overlap with NIH funded research).
- Federal funding cannot be used until a summary of the management plan conditions has been submitted to NIH.

What do I do if I hold a professional license through the Department of Regulatory Agencies (DORA)?

Individuals who hold professional licenses through the Department of Regulatory Agencies (DORA) are asked to update the appropriate documentation with DORA to reflect any conflict of interest changes disclosed to the University in accordance with DORA's policy and procedures.

What do I need to know about the Physician Payments Sunshine Act?

The Physician Payments Sunshine Act was passed by the federal government in 2010. Under this act, The Open Payments System database is used for tracking and reporting applicable medical provider payments from manufacturers of drugs, medical devices and biologicals. Faculty members subject to the Physician Payments Sunshine Act are responsible for annual reviewing the Open Payments System and challenging decisions. More information about the Open Payments System is available at https://openpaymentsdata.cms.gov/.

Where can I find more information about conflicts of interest and commitment?

You can view the University of Colorado's Administrative Policy Statement on conflicts of interest and commitment at: https://www.cu.edu/ope/aps/5012

You can find more information about the Conflict of Interest program at: https://research.cuanschutz.edu/regulatory-compliance/home/conflict-of-interest/coi-home

You can read the CU Anschutz Medical Campus Policy to Limit Conflicts of Interest between Health Care Professionals and Industry Representatives at:

https://research.cuanschutz.edu/docs/librariesprovider178/coi-home-page/pharmschoolinteractionspolicymay2016.pdf?sfvrsn=765e51b9_4

You can find information about the School of Medicine's policies and procedures with regard to industry-paid speaking engagements at: https://medschool.cuanschutz.edu/faculty-affairs/for-faculty/rules-and-policies/industry-talk-approval-form

Whom should I contact with my questions and concerns about conflicts of interest at the University?

- Mark Elder, Conflict of Interest Coordinator, can be reached at 303-724-0034 or mark.elder@cuanschutz.edu.
- Nicole Foley, Conflict of Interest Coordinator, can be reached at 303-724-2958 or nicole.s.foley@cuanschutz.edu.
- Christine Ahearn, JD, Director, Conflict of Interest, can be reached at 303-724-0245 or christine.ahearn@cuanschutz.edu.
- Alison Lakin, PhD, Associate Vice Chancellor for Regulatory Compliance, can be reached at 303-724-1010 or alison.lakin@cuanschutz.edu.

Conflict of Interest Program
Office of Regulatory Compliance
University of Colorado Denver | Anschutz Medical Campus
13001 E. 17th Place, Suite W1126
Aurora, CO 80045
Mail Stop F497
Email: coi@cuanschutz.edu

Conflict of Interest and Commitment Policy Fact Sheet



What is a conflict of interest?

A conflict of interest is a situation in which financial or other personal considerations may adversely affect, or have the appearance of adversely affecting, an employee's professional judgment in exercising any University of Colorado Denver | Anschutz Medical Campus ("the university") duty or responsibility in administration, management, instruction, research and/or other professional activities. Upon determining that an individual has a noteworthy financial interest, the Conflict of Interest Office will conduct a review of the individual's institutional responsibilities and/or research activity to determine if the financial interest could directly and significantly affect either the individual's institutional responsibilities or the design, conduct or reporting of research. If the review indicates that such a relationship exists, it is a potential conflict of interest. The Conflict of Interest and Commitment Committee will develop and approve a management plan in accordance with university policy.

Who is required to disclose potential conflicts of interest and/or commitment?

- 1. All university faculty (assistant professor or higher)*;
- Personnel on an IRB protocol and key personnel on a grant or contract, including but not limited to principal investigators, coinvestigators, research coordinators, professional research assistants, and anyone who is substantively involved in researchrelated activities such as obtaining informed consent, determining subject eligibility, reviewing data and/or conducting data analysis.
- 3. Research Committee Members;
- 4. Staff who negotiate or execute research agreements on behalf of the university;
- 5. Advancement Staff;
- 6. Area/program administrators;
- Campus based university officers (other offices including campus Chancellors are covered by CU System Conflict of Interest procedures).

*Exceptions: Individuals who hold the ranks of instructor, lecturer, adjunct professor, retiree, clinical faculty, <u>unless they are conducting research</u> (as in number 2 above).

How often do I need to disclose potential conflicts of interest and/or commitment?

- Annually—as noted below:
 - Mid-August to October 31
 OR
 - For applicable sponsors, before a grant proposal may be sent to the funding entity and
 - o Before an IRB protocol submission will be reviewed;
- Within 30 days of a change, addition or elimination of a previously disclosed interest;
- For new employees, within 60 days of being hired;
- Upon request by the COI Office.

Where do I disclose potential conflicts of interest and/or commitment? Complete the Conflict of Interest and Commitment (COIC) Disclosure Form at https://era.cu.edu.

Instructions for completing the COIC Disclosure Form can be found on the COI website. Under Resources click on How-To Guides and select COI Form Instructions.

What do I need to disclose?

The university has a zero threshold for disclosure. This means that any and all relationships-paid or unpaid-that reasonably appear to relate to the covered individual's university responsibilities must be disclosed. This includes but is not limited to the financial interest of a covered individual's spouse/domestic partner and/or dependent children.

Information about relationships within the twelve (12) preceding months must be disclosed. Similarly, relationships that will likely occur or continue in the 12 months following the disclosure should be disclosed.

NOTE: Compensation from university research (e.g., grant, contract, protocol) should not be disclosed as an outside relationship.

What is considered a significant financial interest?

- Equity value greater than \$5,000 or 5% ownership in a single *publicly* traded entity;
- Equity interests, including stock options, of any amount, in a nonpublicly traded company;
- Receiving compensation for services as a consultant or advisor to a commercial sponsor of research in excess of \$5000 annually;
- Personally accepting payment from the research sponsor, for nonresearch related gifts equal in value to more than \$5.000;
- Serving as a director, officer or other decision-maker for a commercial sponsor;
- Royalty income or the right to receive future royalties under a patent, license or copyright.

What is NOT considered a significant financial interest?

- Salary, royalties, or other compensation from the university or its affiliates* if the investigator is currently employed or otherwise appointed by university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- Income from service on an advisory committee or review panels for a federal, state or local government agency, an institute of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education entities (e.g., Denver Public Schools, income from review boards and NIH peer review boards);
- Interest in mutual funds or similar investment vehicles where the individual has no control over the selection of holdings.

*University affiliates include the Veteran's Administration Medical Center of Denver, Children's Hospital Colorado, UCHealth, National Jewish Health, CPC Clinical Research, and Denver Health and Hospital Authority.

Do I have to report any changes in my activities and/or interests before the next annual due date?

Yes, you must update your Conflict of Interest and Commitment Disclosure Form within 30 days of the change, addition, or elimination of any of your activities and/or interests.

Do I have to complete the COIC Disclosure Form if I have no activities to disclose?

Yes.

Do I have to complete the COIC Disclosure Form if my interests are less than the amounts defined as "significant financial interests"? Yes.

What are the penalties that may apply if I fail to complete and submit my COIC Disclosure Form?

- Cannot submit for PHS or NSF funding opportunities;
- Termination of the activity that creates the conflict of interest, including inability to draw funds from grant and contract speed types or participate in IRB protocols;
- Funds drawn from a federally funded grant may need to be returned.
- Divestiture of significant financial interests;
- Deactivation of employee's badge access to parking and labs;
- Disciplinary action against the employee up to and including termination;
- In the case of violation of criminal or civil law, violation may be subject to civil or criminal penalties;
- Reporting to applicable federal agencies.

When do I need to disclose reimbursed travel?

Individuals must disclose within 30 days of each occurrence (completion of the trip) 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 the individual's institutional responsibilities.

Disclosure is NOT required if the travel is reimbursed or sponsored by the following:

- A federal, state or local government agency;
- An institution of higher education;
- An academic teaching hospital or
- A research institute that is affiliated with an institution of higher education.

How do I disclose my reimbursed travel?

Reimbursed travel is disclosed by using a *separate* form from the COIC Form in InfoEd.

Click here to submit a travel disclosure.

DO NOT update the COIC Disclosure Form if you are *only* updating travel reimbursement.