#### Financial Conflict of Interest Reminder

What: Public Health Service Financial Conflict of Interest (PHS FCOI)

## **Participating PHS Agencies**

**Non-PHS** Agencies - This list has been removed due to our inability to guarantee its accuracy. Please consult directly with the private agency in question. Non-PHS agencies will typically state if they are following the PHS FCOI policy or if they have a similar FCOI policy of their own.

Why: Maintenance of the public trust is critical to the mission and reputation of the University of Colorado Denver|Anschutz Medical Campus ("the University" or "University"), which is committed to upholding the principles of transparency, integrity and accountability. The University encourages its employees to interact with business and industry, public and private organizations, and government agencies in ways that support the institution's missions. Notwithstanding the foregoing, teaching, research, outreach and other activities shall not be compromised, or perceived as compromised, by financial and/or personal benefit.

**Who:** Applies to all senior/key personnel listed on proposed or active sponsored projects to PHS Agencies or sponsors with a similar FCOI policy.

Note: Senior/key personnel is defined differently in regards to the application of the PHS FCOI policy than it is in the NIH Grants Policy Statement. In regards to the FCOI policy, senior/key personnel are defined as a Project Director or Principal Investigator and any other person who is responsible for the design, conduct and reporting of basic, animal or clinical research. This includes PRAs as well as those who obtain informed consent, those who determine eligibility, those who review data and those who conduct data analysis.

**When:** FCOI disclosures must be completed and compliant at the time of application. Applications that do not have a completed FCOI disclosure cannot be submitted to the sponsor.

For active projects, all financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable significant financial interests are obtained.

**How:** University of Colorado Denver | Anschutz Medical Campus personnel or Persons of Interest(POIs) can complete their disclosure using the following instructions – How to Complete the Conflict of Interest Disclosure Form

<u>FCOI Compliant Entities</u> – Institutions whose authorized official have certified that they are compliant with the PHS FCOI rules and regulations. Entities listed here are considered compliant and do not require disclosure when listed on a University of Colorado Denver | Anschutz Medical Campus application or active project.

Non-Compliant Entities or External Personnel – Per 42 CFR 50, Subpart F, external entities or personal must either certify that they will comply with the FCOI policy of the University of Colorado Denver|Anschutz Medical Campus or they must provide assurances to the University of Colorado Denver|Anschutz Medical Campus that they have an established policy that complies with 42 CFR 50, Subpart F. This can be done by completing the **Documentation of PHS Financial Conflict of Interest (FCOI) Policy Form (Exhibit A).** 

### References

## <u>University of Colorado Denver | Anschutz Medical Campus Policy</u>

#### **University of Colorado Denver | Anschutz Medical Campus Resources**

#### **NIH Grants and Funding FCOI**

When submitting a grant application, the signature of the <u>Authorized Organization Representative (AOR)</u> certifies the applicant institution's compliance with the requirements of 42 CFR 50, Subpart F, including that:

- 1.) There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received;
- 2.) The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests;
- 3.) The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to the NIH consistent with this subpart;
- 4.) When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
- 5.) The Institution shall fully comply with the requirements of the regulation.

## 42 CFR 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research

Institutional responsibility regarding conflicting interests of investigators. Each Institution must:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.
- (b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.
- (c) (1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
  - (i) That would reasonably appear to be affected by the research for which PHS funding is sought; and
  - (ii) In entities whose financial interests would reasonably appear to be affected by the research. (2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.



# **Documentation of PHS Financial Conflict of Interest (FCOI) Policy** University of Colorado Denver -- Office of Grants and Contracts To be completed by University of Colorado Denver Administrative Unit A. PROPOSAL INFORMATION PI Contact Phone: University of Colorado Denver PI: Prime Sponsor: Proposal/Project Title: Period of Performance: From: To: Return Form To: (Name) Return Form To: (Email) To be completed by collaborating institution **B. COLLABORATOR INFORMATION** Organizational Legal Name: Organization's Address: (Include ZIP Code/Postal Code) To be completed by collaborating organization C. COLLABORATOR FCOI POLICY STATEMENT (1) I will follow my organizations' Financial Conflict of Interest (FCOI) policy, which is compliant with the PHS Conflict of interest regulations. List participating individuals below. (2) I will follow the Conflict of Interest policy established and enforced by the University of Colorado Denver. Names of individuals working on this project who are responsible for design, conduct, or reporting of the research are shown below. PI: Investigator/Key Personnel: (Please attach additional pages if needed.) To be completed by Authorized Organizational Official D. APPROVAL I certify that the information listed above is true, complete and accurate to the best of my knowledge, and that I am an Authorized Organizational Official for my institution. The appropriate programmatic and administrative personnel involved in this disclosure are aware of agency policy and are prepared to Establish the necessary inter-institutional agreements and/or FCOI management plans consistent with those policies. Signature: Date: Printed Namer Title: To save the content you just filled In, Please Click here and select Adobe Pdf for the Printer University of Colorado Denver, Office of Grants and Contracts, Mail Stop F428 Anschutz Medical Campus, Bldg. 500, 13001 E 17th Place, Room W1124, Aurora, CO 80045-2571