UNIVERSITY OF COLORADO DENVER NEW PHS/NIH CONFLICT OF INTEREST RULES!

EFFECTIVE AUGUST 24, 2012

The Office of Grants and Contracts will be unable to submit proposals to NIH or any other Public Health Service Sponsor on or after August 24, 2012 that include budgets with key or senior personnel who have not filed a Conflict of Interest Disclosure with the UCD COI Office.

All proposals will be reviewed in PreAward following normal procedures.

At the time of PreAward's review, if it is determined the proposal budget includes key personnel who have not filed a COI Disclosure or updated a COI Disclosure within the UCD normal time frame, the proposal will be returned to the PI/Contact requesting the disclosure be filed with the UCD COI Office prior to the submission deadline.

<u>Key/ senior personnel</u> include the Project Director/Principal Investigator and any other person who is responsible for the design, conduct and reporting of basic, animal or clinical research, this includes PRAs, or anyone who obtains informed consents, those who determine eligibility, and those who review data or conduct data analysis.

<u>Don't put your proposals at risk and wait until proposal submission deadlines to file</u> <u>COI Disclosures – be sure COI Disclosures are filed now and be sure they are updated</u> <u>on or as soon as possible after August 24th, 2012</u>

Federal regulations prohibit the Office of Grants and Contracts – UCD from submitting proposals that include key/senior personnel in proposal budgets who have not filed or update their COI.

What is defined as a Financial Conflict of Interest?

For faculty and employees that have a significant financial interest, the COIC Office has to review all research activity and/or institutional responsibilities to determine if the significant financial interest could directly and significantly affect the design, conduct or reporting of research or their institutional responsibilities.

If this determination is made then the faculty or employee has a financial conflict of interest that must be appropriately managed in accordance with UCD policy. Each overlapping research protocol, grant, or research contract will need to have a separate management plan developed and approved by the COIC Office and signed by the faculty or employee.

What are the penalties if I fail to make the appropriate disclosures?

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

Additionally -

- 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

What about subcontracts?

If a subcontracted organization has a COI policy and process, UCD will rely on that organization's policy to satisfy this regulatory process. Each subcontract will include UCD's requirements of the organization to fulfill the COI responsibilities.

If a subcontracted organization does not have a COI policy and process, UCD will require key personnel from the subcontracted organization to file a COI disclosure through the UCD Conflict of Interest Office. This process will be a requirement included in the subcontract.

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