University of Vermont
Sponsored Project Administration

New PHS Financial Conflict of Interest (FCOI) Regulations

Effective
August 24th, 2012

Ruth Farrell, Associate Vice President for Research Administration

http://www.uvm.edu/policies/grants/researchcoi.pdf

Ruth.Farrell@uvm.edu
802-656-3360
Financial Conflict of Interest in Sponsored Research

• The new UVM policy and PHS (NIH) regulations went into effect on August 24th, 2012.

• On or after that date, PHS Investigators are required to have taken COI training and indicated whether or not they have Significant Financial Interests
  – Before proposal submission
  – Before engaging in research under an award with an issue date (including continuations) after that date, whichever is first.

• Investigators with other funding, must take training and disclose under new policy with initial disclosure, or next annual disclosure.

• Disclosures must be updated annually.
What is a Significant Financial Interest?

**Significant Financial Interest (SFI)** means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) related to the Investigator’s institutional responsibilities:

- With regard to any publicly traded entity, any remuneration or holdings exceeding $5,000 in value (including equity) over the twelve months preceding disclosure.
- With regard to any non-publicly traded entity, any equity interest, regardless of value, or any remuneration exceeding $5,000 in value over the twelve months preceding disclosure.
- Intellectual property rights exceeding $5,000 over the twelve months preceding disclosure.
Excluding . . .

- Income paid by UVM, and Fletcher Allen for faculty with dual appointments,
- income from seminars, lectures, or teaching engagements sponsored by:
  - a federal, state, or local government agency,
  - a domestic institution of higher education,
  - an academic teaching hospital or a medical center,
  - or a research institute that is affiliated with a higher ed institution,
- income from service on advisory committees or review panels for:
  - a federal, state, or local government agency,
  - a domestic institution of higher education,
  - an academic teaching hospital or a medical center,
  - or a research institute that is affiliated with a higher ed institution.
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.
For PHS funded investigators only, any travel expenses reimbursed directly to an investigator or paid directly on the investigator’s behalf, regardless of amount or value, related to his/her institutional responsibilities, excluding travel that is reimbursed or paid by a federal, state, or local government agency, a domestic institution of higher education (including the University of Vermont), an academic teaching hospital (including Fletcher Allen Health Care), a medical center, or a research institute that is affiliated with an institution of higher education.
Who is an investigator?

As used in the policy, Investigator means the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research, or research proposed for sponsored funding. For the purpose of this policy, this includes principal investigators, co-investigators and other faculty, key personnel, post-doctoral associates, and statistical analysts with independent responsibility for these tasks.
Then what?

• Disclosures are reviewed by designated institutional official, with help from review committee as needed.
• Many SFI’s are not Financial Conflicts of Interest (FCOI).
• If there is an FCOI, investigators will need to follow a management plan.
Other Requirements

• Public accessibility – consider both sponsor requirements and VT open records.

• University annual reporting of FCOIs to NIH.

• Sub-recipient requirements for also following policy.
What SPA will do

• Check to make sure that all investigators have submitted disclosures on or after 8-24-12 before submitting NIH proposals.
• Check that all investigators have submitted disclosures on or after 8-24-12 before setting up NIH awards.
• Check that all disclosures of SFIs have been reviewed before setting up NIH awards.
What Department Administrators Should do

• Because we have to make sure everyone has filed a disclosure on or after 8-24-12 before engaging in PHS (NIH) supported work, Department Administrators are being asked to take the following actions:
  – Check disclosure status and date when distributing faculty, post-docs, statisticians to PHS grants IF they were not named in the application.
  – Communicate with the designated institutional official when you do add someone new.
Department Administrator Interface

• Allows department administrators to view investigator disclosure status and date disclosure submitted.
  – Can be used to check when preparing salary distributions.
  – Can be used to check during proposal preparation to remind investigators.
How to make a disclosure:

https://spogi.uvm.edu/UVM_COI/
Significant Financial Interest in Sponsored Research Disclosure System:

Your COI Training has been completed and will not need to be renewed until 9/3/2016.

Your disclosure on file states that you have a Significant Financial Interest related to your Institutional Responsibilities (UVM and/or Fletcher Allen for Clinical Faculty).

Your disclosure was submitted on 9/7/2012 and will expire on 9/7/2013. To renew your disclosure at any time simply create a new disclosure.

If you wish to modify that disclosure, contact Ruth Farrell at ConflictofInterest@uvm.edu or 802-656-3360.

What would you like to do?

- Complete COI Training
- Create a new travel disclosure. (For travel not previously disclosed in annual disclosure)
- Create a new financial interest disclosure.
- View your current disclosure.
- View the Investigator's User's Guide.
- View the COIAs' Guide.
- View a list of the awarded and pending research proposals upon which you are named.
- Open the Administrator Application.
- Open the Department Administrator Application.

If you have questions contact Ruth Farrell at ConflictofInterest@uvm.edu or 802-656-3360.
No disclosure, cannot submit NIH proposal or be distributed to NIH grant if “investigator”
If nothing comes up at all, also means no disclosure, cannot submit NIH proposal or be distributed to NIH grant if “investigator.”
Potential Conflict – check before investigator salary distributed to NIH. Disclosure date after 8-24-12; OK to submit NIH proposal.
Disclosure is before 8-24-12. Must be updated before submitting or being distributed to NIH grants.
Disclosed after 8-24-12, ok to submit NIH proposal; no potential conflict, ok to distribute to NIH grant.