

# University of Rochester

## Frequently Asked Questions Revised UR Policy on Faculty Conflict of Interest and Commitment

### Definitions

### COI Training

### Reporting of External Compensation and Sponsored or Reimbursed Travel Interactions with Institutions that Subcontract to the UR

### Definitions

***Question:*** Which faculty members are subject to the University of Rochester (UR) faculty conflict of interest policy?

***Answer:*** The faculty members subject to the policy include “all individuals holding a paid academic, clinical, or research appointment within the UR”.

***Question:*** Who is an “investigator” and therefore subject to the policy?

***Answer:*** Any individual who is “responsible for the administration, design, conduct or reporting of research” is an investigator subject to the policy. Typically, this will include the principal investigator (PI), Co-PIs, co-Investigators, and study coordinators, and may include others as well.

***Question:*** Who determines that an individual is considered an investigator on a research project and, therefore, subject to the policy?

***Answer:*** The PI of the research project is responsible for identifying those individuals that serve as an investigator in a particular research project, sometimes in conjunction with the academic advisor, department chair or Dean.

***Question:*** Are study coordinators considered to be investigators under the policy?

***Answer:*** Yes. They will therefore be required to submit annual and ad hoc disclosures, starting with the 2012 reporting cycle (typically conducted in February-March for the previous calendar year).

***Question:*** Are graduate students and postdoctoral appointees ever considered to be investigators?

***Answer:*** Sometimes. Graduate students and postdoctoral appointees are “investigators” subject to the policy if they are independently responsible for the design, conduct or reporting of research. While graduate students and postdoctoral appointees are ordinarily under supervision and/or guidance from a faculty mentor or advisor, graduate students and postdoctoral appointees may, on rare occasion, independently perform these responsibilities, and they will be subject to the policy.

***Question:*** Are consultants or collaborators named on grant applications/awards considered to be investigators under the policy?

***Answer:*** It depends. Consultants or collaborators are considered investigators under the policy if they are independently responsible for the design, conduct or reporting of research. Ordinarily, consultants are directed to perform specific tasks on a research project, and would not be viewed as independently responsible for these tasks. Collaborators typically provide insight in areas of their expertise, but are not be responsible for the design, conduct or reporting.

## **COI Training**

***Question:*** Does every investigator need to complete the on-line training course?

***Answer:*** No. Only those investigators with PHS funded projects need to complete the training. This must be done prior to receipt of a PHS award (competing or non-competing) funded after August 24, 2012. The training should be completed as soon as possible, to avoid any potential delay in the UR's release of the PHS award. In the future, Deans may require that all faculty in their schools complete the training, regardless of whether they have PHS funded research. At this point in time, only PHS investigators are required to complete the training.

***Question:*** Do scientific consultants on PHS-funded projects need to complete the on-line training course?

***Answer:*** Possibly. A consultant must complete the training if he/she exercises independence in the planning, conduct and/or reporting of any aspect of the research. At this time, if a consultant is defined as an investigator, the training will be done off-line (manual reading of course materials and completion of the course quiz).

***Question:*** Are study coordinators required to complete the on-line training course?

***Answer:*** Yes. Study coordinators are now defined as "investigators" under the revised UR policy. Thus, study coordinators will need to complete the mandatory on-line training, if any portion of their salary is paid from PHS funding.

***Question:*** A faculty member has a K award. Their mentor has left the UR but will continue to act as mentor; however, the mentor will not be paid (either individually or through a UR subcontract with her new institution). Is the mentor required to complete the conflict of interest training?

***Answer:*** No, the mentor does not need to complete the training, because she serves only in an advisory capacity. The K award recipient, and not the mentor, is the named individual with independent responsibility for the design, conduct or reporting of the funded research.

***Question:*** In addition to the PI, a PHS funded project names a project coordinator, a full-time research assistant, a graduate student research assistant, and an undergraduate research assistant who are working on the project for independent study credit. All of these individuals are assisting in the conduct of the study. With the exception of the PI and the graduate research assistant, the remaining personnel are not publishing or benefiting from the research. Do these study team members need to complete the on-line training?

***Answer:*** Probably not. The training must be completed by individuals who have the independent responsibility for design, conduct or reporting of PHS funded research. If the activities of the students are reviewed or overseen by the PI, they are not "independent." However, the determination of who has independence, or who does not, is subjective. The PI's judgment is relied upon in assessing the independence of the individuals working on the project and therefore whether they need to complete the COI training.

***Question:*** If a faculty member is required to complete a different (non-UR) COI training course by a sponsor (e.g. the CITI course or NIH tutorial), is it necessary to also complete the UR course?

***Answer:*** Yes. The faculty member must take the UR training it covers specifics of the UR policy and UR reporting requirements. This is required by the PHS regulations.

***Question:*** *A faculty member with no current PHS funding has recently submitted a proposal to a PHS agency. It has been reviewed, but a decision has not been made regarding whether it will be funded or not. Is it necessary for the faculty member to complete the COI training at this time?*

***Answer:*** No. However, the training must be completed if the PHS award is funded, and prior to any expenditure of funds on the PHS project. The Office of Research and Project Administration (ORPA) will not release a sub-ledger 5 account number for the project until all investigators (as defined in UR's policy) associated with the project complete the training.

***Question:*** *How can individuals confirm that they have received credit for completing the training?*

***Answer:*** When a score of at least eighty (80) is obtained on the course quiz and the course evaluation is completed, it will be reflected in the individual's HRMS training record. This might take up to three (3) days after completion of the course evaluation. Physicians with appointments at the School of Medicine and Dentistry may also request a course completion certificate valid for one continuing medical education credit by answering "yes" to the last question on the course evaluation form.

## **Reporting of External Compensation and Sponsored or Reimbursed Travel**

***Question:*** *How frequently must faculty members and other investigators report their financial interests?*

***Answer:*** All faculty members and other investigators are required to submit annual reports, ordinarily in the February-March timeframe for the prior calendar year. In addition, all faculty members and investigators must disclose any additional financial interests that they acquire, within thirty (30) days of discovering or acquiring the financial interest.

***Question:*** *How do faculty and non-faculty investigators report their financial interests?*

***Answer:*** The UR schools/colleges have developed reporting mechanisms to capture annual and ad hoc reporting. School/college conflict of interest forms or reporting systems can be found by accessing <http://www.rochester.edu/orpa/COI.html> . The URMC reporting system is located at: <https://coi.urmc-sh.rochester.edu/public/home.aspx> . The AS&E reporting system is located at: <https://www.rochester.edu/asei/index.php> .

***Question:*** *Do all faculty also need to report reimbursed or sponsored travel related to their institutional responsibilities?*

***Answer:*** No, only investigators that are funded by PHS must report their sponsored and reimbursed travel.

***Question:*** *How do PHS-funded investigators report their sponsored or reimbursed travel?*

***Answer:*** The schools/colleges have developed reporting mechanisms to capture sponsored and reimbursed travel. School/college conflict of interest forms or reporting systems can be found by accessing <http://www.rochester.edu/orpa/COI.html> . The AS&E reporting system is located at: <https://www.rochester.edu/asei/index.php> .

***Question:*** A PHS investigator is reimbursed by an outside entity for travel that is related to his/her institutional responsibilities. Are they required to disclose this travel, even if it is not related to PHS-funded research?

***Answer:*** Maybe, depending on what entity sponsors the travel. The travel must be reported unless it is sponsored or reimbursed by a Federal, state or local governmental agency, an institution of higher education, a research institute affiliated with an institution of higher education, an academic teaching hospital, or an academic medical center.

***Question:*** If a PHS-funded investigator travels to a scientific conference and is reimbursed by the UR for the travel, are they required to report this travel reimbursement?

***Answer:*** No. Travel reimbursed by the UR is not included in the definition of sponsored or reimbursed travel for purposes of the PHS regulation and UR policy's reporting requirements.

***Question:*** If a PHS funded investigator serves on an NIH study section and is compensated for these services, does that compensation need to be reported?

***Answer:*** No, it is not necessary to report compensation from a Federal, state or local governmental agency.

***Question:*** A PHS funded faculty member travels abroad to attend a conference. The travel has been partially sponsored (i.e., hotel and meals were reimbursed, but airfare was paid from a UR discretionary account). Are they required to report the non-UR reimbursement?

***Answer:*** Yes. Assuming the travel relates to the faculty member's institutional responsibilities, and if the travel sponsorship is not from an exempt entity (as described above), then the hotel and meal charges must be reported.

***Question:*** If a faculty member attends a study section sponsored by a professional society, for example, the American Heart Association or the American Cancer Society. The professional society pays for travel (which they arrange for and pay for in advance), and also reimburses participants for incidental expenses. Does this need to be reported to the UR?

***Answer:*** Yes. The federal regulations only exempt travel reimbursement from federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education; and academic teaching hospitals and medical centers. Thus, travel reimbursement from voluntary health associations would need to be reported.

## **Interactions with Institutions that Subcontract to the UR**

***Question:*** UR is a sub-recipient on a grant issued to a peer institution (e.g., Cornell University). The peer institution asks UR whether UR's COI policy complies with the PHS conflict of interest regulations. What is the proper response?

***Answer:*** The proper response is that the UR COI policy is compliant with the PHS regulations. Inform the prime grantee that the Federal Demonstration Partnership (a cooperative initiative among 10 federal agencies and 119 institutional recipients of which UR is a member) website [http://sites.nationalacademies.org/PGA/fdp/PDG\\_061001](http://sites.nationalacademies.org/PGA/fdp/PDG_061001) that includes a publicly-available list of institutions (FCP Institutional Clearinghouse) who have attested that they will be compliant with the new PHS FCOI regulations as of August 24, 2012. The UR is named on this list.