

Questions Regarding Conflict of Interest

What is a conflict of interest?

A conflict of interest is a situation in which the potential exists for an individual's personal financial interests to impair his/her judgment in the execution of his/her responsibilities to Rutgers University.

Why do you need to disclose?

Rutgers University <u>Policy 90.2.5</u> requires that PIs and personnel working on research projects, *regardless of source of funding or lack thereof*, disclose financial information that may reasonably be perceived to influence their work. This policy is intended to implement:

- Responsibility of Applicants for Promoting Objectivity in Research
- The reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator financial conflicts of interest.

Please note that having a conflict of interest does not necessarily imply wrongdoing or inappropriate activities. The emphasis is on disclosure of financial interests to comply with regulations, University Policy, journal requirements, etc.

Who needs to disclose?

The Investigator Conflict of Interest Policy 90.2.5 applies to all University faculty, non-faculty employees, students (graduate and undergraduate, part-time or full-time) and other individuals who, in the course of their association with the University:

- 1) apply for or receive funds for any research or training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement, or are engaged in research as personnel (That is, are responsible for the design, conduct, or reporting of research. For example, an undergraduate student entering data must disclose because they are engaged in the conduct of the study); or
- 2) conduct unsponsored/unfunded research.

What do you need to disclose?

The Investigator Conflict of Interest policy applies to <u>all</u> research, regardless of source or lack of funding.

A "financial interest" is defined as the following:

a financial or other personal involvement of the investigator [defined broadly as anyone who is involved in the design, conduct, administration, collaboration, analysis, and/or reporting of the research], or his or her immediate family that are related to the individual's Institutional responsibilities.



Financial interest means anything of monetary value, whether or not the value is readily ascertainable. Interests include, but are not limited to: income; honoraria or other payment for services; equity such as stock, stock options or other ownership rights (except interests of any amount in publicly traded, diversified mutual funds, pension funds, or other institutional investment funds over which the faculty member does not exercise control); patents and copyrights; contracts, licensing and other agreements; royalties (including those royalties distributed by the University); employment; reimbursed travel or sponsored travel; and services, relationships or positions, even if uncompensated.

Excluded from the disclosure requirement are:

income from seminars, lectures, or teaching engagements, reimbursed travel or sponsored travel, and service on advisory or review panels sponsored by a federal, state, or local government agency, a **domestic** institution of higher education as defined at 20 U.S.C. 1001(a), a **domestic** academic teaching hospital, a **domestic** medical center, or a research institute that is affiliated with a **domestic** institution of higher education.

Note that foreign institution income may not be excluded.

(Rutgers University Policy 90.2.5 "Investigator Conflict of Interest", p.3-4)

For more information on the type of interests to disclose, review <u>Rutgers Policy 90.2.5</u> "Investigator Conflict of Interest".

What are the deadlines for disclosing?

A financial Conflict of Interest Disclosure must be submitted to Rutgers University:

- At Proposal Submission: A Financial Conflict of Interest Disclosure must be submitted and be active (research certification made within the past 12 months) at the time a proposal is submitted for sponsor funding.
- At Award Set-up: For a new award, a Research Certification must be created in the eCOI system once the award is received. If a disclosure has never been submitted before, the Investigator must submit a disclosure now. The award will not be processed for set-up until all study team members have certified in the eCOI system. A Research Certification does not need to be created for incoming awards that are not new.
- **Annually**: Your disclosure must be submitted at least annually (within 12 months of your last submission/update).
- Within 30 days of a new Significant Financial Interest (SFI): A revised COI disclosure must be made within thirty days of discovering or acquiring a new significant financial interest (e.g., through purchase, marriage, or inheritance).



Examples are provided below:

- **Example A**: Dr. Smith has no financial interests. Dr. Smith must still log-in to eCOI and submit a disclosure that indicates Dr. Smith has nothing to disclose.
- **Example B**: Dr. Smith plans to submit a proposal on August 31, 2015, but Dr. Smith has never submitted a disclosure before. Dr. Smith must submit a disclosure before the proposal submission deadline, even if Dr. Smith has nothing to disclose.
- **Example C**: Dr. Smith submitted a COI disclosure on July 1, 2015. Dr. Smith submitted a proposal on October 5, 2015. No update to Dr. Smith's COI disclosure was needed.
- **Example D**: On December 1, 2015, Dr. Smith receives an award letter. Dr. Smith's administrator creates a Research Certification in the eCOI system. Dr. Smith and the identified study team log into the eCOI system and verify their disclosures are accurate.
- **Example E**: Dr. Smith got married and Dr. Smith's spouse is the CEO for a pharmaceutical company. Dr. Smith must submit an updated disclosure within 30 days to include any financial interests held by Dr. Smith's spouse.

Who gets to see the financial information I provide in my disclosure?

Within the University, the information provided in your disclosure is confidential and is only used for the purposes of administering the policy by the Conflict of Interest Committee and other University offices with oversight responsibilities, as appropriate. Under certain circumstances, the University is required to make personal financial information publicly available to comply with federal and state law.

Are all significant financial interests considered a conflict of interest?

No, many significant financial interests do not create a conflict of interest. You are required to disclose all financial interests. The University is responsible for determining whether the significant financial interest creates a conflict of interest.

What are the Conflict of Interest training requirements?

The Office of the Vice President for Research and Economic Development will create training content and be responsible for the implementation of a University-wide webbased training module. Each investigator must complete the COI training prior to engaging in sponsored or unsponsored research and at least every four years, or immediately if the University's conflict of interest policy changes in a manner that affects investigator requirements, an investigator is new to the University, or the University finds an investigator non-compliant with the University's COI policy.

What is the Conflict of Interest Committee (COIC)?

Conflict-of-Interest Committee (COIC) is a University-wide committee whose role is to review disclosures of significant interests and determine if these constitute a conflict of interest and, if so, to decide how such conflicts will be managed, reduced or eliminated.



The Committee is appointed by the Executive Vice President for Academic and Clinical Affairs, and comprises the Senior Vice President and General Counsel (or designee), the Vice President for Research and Economic Development (or designee), Senior Vice President/Chief Ethics & Compliance Officer (or designee), University Chief Financial Officer (or designee), and Executive Director, Office of Technology Transfer and Business Development, three faculty members (at least one engaged in clinical research and one engaged in laboratory research) from the New Brunswick/Piscataway Campus, three faculty members (at least one engaged in clinical research and one engaged in laboratory research) from the Newark Campus, and one faculty member from the Camden Campus. At its inception, one-half of the faculty members and all of the non-faculty members of the COIC shall serve three (3)-year terms, and the other half of the faculty members shall serve two (2)-year terms. All subsequent terms shall be for three (3) years. At its first meeting, the Chair of the Committee shall be selected from among the faculty members of the Committee by majority vote.

Where can I view the Investigator Conflict of Interest policy?

The investigator conflict of interest policy (# 90.2.5) can be viewed at the following:

• http//policies.rutgers.edu/view-policies/research-section-90