

UNIVERSITY POLICY

Policy Name:	Investigator Conflict of Interest				
Section #:	90.2.5	Section Title:	Research	Formerly Book:	00-01-05-10:05
Approval Authority:	President	Adopted:	09/18/1995	Reviewed:	6/29/2016
Responsible Executive:	Senior Vice President for Research and Economic Development	Revised:	08/07/2012; 7/1/2013; 06/29/2016		
Responsible Office:	Office of Research and Economic Development	Contact:	Office of Research Regulatory Affairs		

1. Policy Statement

The University has adopted this policy for identifying and managing actual or perceived conflicts of interest that may arise in research to ensure the integrity, objectivity and freedom of inquiry of its investigators, and the safety and welfare of its human research subjects.

2. Reason for Policy

To ensure that the University is adequately reimbursed for the use of its facilities, utilities, personnel and for all other indirect costs associated with the conduct of industry-sponsored clinical trials.

3. Who Should Read This Policy

This policy shall apply to all University faculty, non-faculty employees, students and other individuals who, in the course of their association with the University (1) apply for or receive funds for any research or research training purpose, by grant or subgrant, or by contract or subcontract, or by cooperative agreement (individually and collectively referred to herein as "Funding Agreement(s)"); or (2) wish to conduct unsponsored research.

4. Resources

- A. Policy for Human Subjects Protection and the Institutional Review Board Policy 90.2.11
- B. Code of Ethics for Administrative and Professional Staff Members Policy 60.4.2
- C. New Jersey state statute governing conflict of interests and agreements for the development of scientific and technological discoveries or innovations N.J.S.A. 52:13D-19.1
- D. Public Health Service Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought Rule 42 C.F.R. Part 50, Subpart F
- E. Uniform Requirements for Manuscripts submitted to Biomedical Journals

5. Definitions

- A. Compelling Circumstances are facts that convince the Conflict-of-Interest Committee (see definition below) that an individual with a conflict of interest which is relevant to the proposed research project should be permitted to conduct the proposed research under requirements established by the Committee. These facts may include, but are not limited to: the nature of the research, the magnitude of the financial or other personal interest, the degree to which these interests are related to the research, the extent to which these interests could be affected by the research and in the case of human subjects research, the degree of risk to the human research subjects.
- B. Conflict of Interest is a divergence between an investigator's financial or other personal interests and the obligation to abide by principles of the ethical conduct of research, especially the obligation to protect the rights and welfare of human subjects, such that considerations of personal gain, financial or otherwise, may influence or create the perception of influencing that investigator and compromise the objectivity or appropriate design, conduct or reporting of the research.
- C. Conflict-of-Interest Committee (COIC) is a University committee whose role is to review disclosures of significant interests (see definition below) 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 members are appointed by the Senior Vice President for Research and Economic Development.
- D. Conflict of Interest Training is required of all "investigators" (defined below) prior to engaging in sponsored or unsponsored research and every four years thereafter, and immediately under designated circumstances.
- E. Financial Conflict of Interest (FCOI) Report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- F. Financially Interested Company means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research, or any entity acting as the agent of or with an equity interest in such an entity. This term includes companies that sponsor the research, are the manufacturers or licensees of an investigational product, or the investment industry (individual stockbrokers and analysts, investment bankers, venture capital firms and investment firms).
- G. Human Subjects Research includes all "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
- H. Immediate Family means spouse (by marriage or civil union), domestic partner, children, parents, or siblings who reside in the same household.
- I. Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution including: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- J. Institutional Review Board (IRB) is a committee established in accord with federal Common Rule (45 C.F.R. Part 46) with the authority to approve, require modifications in, or disapprove all University research activities involving human subjects.
- K. Interest is a financial or other personal involvement of the investigator, 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, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- L. Investigator means the Principal Investigator, co-principal investigator, co-investigators and any other University personnel (including faculty, non-faculty employees, residents, postdoctoral trainees and students) who, in the course of their association with the University are or will be responsible for the design, conduct and/or reporting of either research, funded or of unsponsored research activities. As used herein, the term "investigator" also covers collaborators, grantors or contractors.
- M. Manage means taking action to address a real or apparent financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- N. Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development (e.g., a diagnostic test or drug, software, devices, or any marketable product). For the purposes of this policy, research shall include research training activities.
- O. Significant Interest means:
 - 1. A financial or other personal interests of the investigator, his or her spouse, domestic partner, children, parent or siblings that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. Service as an officer, director or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service;
 - b. Intellectual property rights (e.g., pending patent applications, patents, licenses, material transfer agreements, copyrights and royalties of any amount from such rights, including those royalties distributed by the University);
 - c. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes compensation, royalties, consulting fees, honoraria, gifts or other emoluments, bonuses, enrollment incentives or milestone payments, and "in kind" compensation or entitlement to same made directly or indirectly

to the investigator by a financially interested company (or entitlement to the same), whether for consulting, lecturing, travel (including reimbursed travel or sponsored travel), service on an advisory board, or for any purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement between the sponsor and the University), as determined through reference to public prices or other reasonable measures of fair market value, either in the year prior to the grant application or initiation of unsponsored research and submission of the accompanying Disclosure in the Rutgers eCOI System (ecoi.rutgers.edu), or in the twelve months following the grant application or initiation of unsponsored research;

- d. Greater than 1% of the ownership of stock, assets or profits of a company which has, or seeks to have an agreement with the University, where the agreement is for the development of scientific or technological discoveries or innovations in which the University has or will have a property right.
 - e. Equity interests, including stock options, of any amount in a non-publicly traded financially interested company (or entitlement to the same);
 - f. Equity interests (or entitlement to the same) that in aggregate exceed \$5,000 in a publicly-traded financially interested company;
2. Investigators must disclose at ecoi.rutgers.edu the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education. This disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
3. The term “significant interest” does NOT include:
- a. Salary or other remuneration from the University unrelated to the investigator’s Institutional responsibilities;
 - b. Reimbursement and/or income from seminars, lectures, or teaching engagements sponsored by, reimbursed travel or sponsored travel, and service on advisory or review panels for federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
 - c. 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;
 - d. A significant interest does not necessarily constitute a conflict of interest or the appearance of a conflict of interest as defined above.

6. The Policy

I. PURPOSE

The University recognizes the importance and potential benefits of transferring to the private sector knowledge developed through University research and scholarship. It also recognizes the risks inherent when researchers have financial or other personal interests in their research or research training activities, and the need to avoid arrangements that might compromise, or seem to compromise, the intellectual principles, independence and responsibility to the public that underlie the ethical conduct of research. Of critical importance to the University is ensuring the integrity of its research, protecting the rights and welfare of human subjects, maintaining the intellectual freedom of faculty, students, postdoctoral appointees and other trainees, and safeguarding the freedom to publish, communicate and discuss research results. Therefore, while welcoming industry sponsorship, collaboration and licensing of its technology, the University has adopted this policy for identifying and managing actual or perceived conflicts of interest that may arise in research to ensure the integrity, objectivity and freedom of inquiry of its investigators, and the safety and welfare of its human research subjects.

This policy is intended to implement the U.S. Department of Health and Human Services (HHS) final rule published September 26, 2011 in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) and to provide the reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator financial conflicts of interest.

A. Conduct of Research

1. Disclosure of Interests

- a. Prior to the submission of applications to sponsors for funds, or prior to the commencement of unsponsored research, or approval of an IRB protocol, or prior to the execution of a licensing agreement with a publicly-traded company in which the investigator has either an equity interest that exceeds \$5,000 or a greater than one percent (1%) ownership interest, whichever is less, or prior to the execution of a licensing agreement with a non-publicly traded company in which the investigator has an equity interest of any amount, all investigators must complete Disclosure Certification in ecoi.rutgers.edu and include any such interests related to their Institutional responsibilities described in Section IV.K above for themselves and/or members of their immediate family. If the investigator has no such interest, the investigator must certify as such.
- b. All Disclosures must be completed in full and in detail with sufficient information to determine if the interests meet the definition of "significant interest," when associated with a Research Certification in ecoi.rutgers.edu.
- c. No proposal may be submitted to a funding agency, nor can unsponsored research commence, without a fully completed Disclosure in ecoi.rutgers.edu.
- d. On an annual basis during the duration of the research, or within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) new interests with respect to potential conflict of interest which otherwise changes since the original disclosure, each investigator shall be responsible for updating their Disclosures in ecoi.rutgers.edu.

- e. For projects involving contracts, subcontracts or collaborations with outside institutions or groups, Rutgers will take steps to ensure that any subrecipient Investigator complies with the Public Health Service, pursuant to 42 CFR Part 50, Subpart F by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy for disclosing significant financial interests that are directly related to the subrecipient's work for Rutgers. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable Rutgers to provide timely COI reports, as necessary, to PHS as required by this subpart. If the outside entity is an agency of the State of New Jersey, its policy must meet the requirements of New Jersey Law, Conflicts of Interest Law, N.J.S.A. 52:13D-19.1, and of the Public Health Service pursuant to 42 CFR Part 50, Subpart F. In the event the outside entity has no investigator conflict-of-interest policy, the written agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Rutgers. Such time period(s) shall be sufficient to enable Rutgers to comply timely with its review, management, and reporting obligations under this subpart.

2. Assessment of Significant Interests by a COIC

- a. It is the responsibility of each member of a COIC to divulge potential conflicts of interest. In the event that any member of a COIC has any real or apparent personal or professional conflicts of interest or bias with respect to the disclosure being considered, that member shall be recused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the investigator, and a previous or ongoing close professional or academic relationship with the investigator, the sponsor, or competitor of the sponsor.
- b. A COIC will review all Disclosures of significant financial interests:
- c. In making these determinations, a COIC may:
 - (1) Ask the investigator to appear before it to provide additional information to assist in the Committee's deliberations. In the event the Committee determines that the investigator has a conflict of interest or an appearance of such conflict, the investigator must present compelling circumstances that the research can go forward as proposed, or with modifications imposed by the Committee.
 - (2) Consult with individuals such as other faculty, scientists, financial experts, patents and licensing experts, IRB representatives, the pertinent Dean or Vice President and others from inside or outside the University.

- e. Outcome of a COIC's decisions:
- (1) A COIC will report its decision, including an explanation of its decision and a description of conditions or restrictions, if any, in a system to the investigator(s) and the investigator's COI Monitor. If the research involves human subjects, the Committee will also notify the appropriate IRB. In the case of PHS funded research, the COI Monitor will notify the PHS funding agency within 60 days of the existence of the conflict of interest prior to any expenditure of any funds under the Funding Agreement in an Initial FCOI Report.
 - (2) If a COIC's decision is that the research cannot proceed, the investigator(s), the investigator's COI Monitor and ORSP will be notified of this decision. The funding agency or sponsor will be notified of the existence of the conflict of interest prior to any expenditure of any funds under the Funding Agreement and in the case of a PHS award, with an Initial Report as described above.
 - (3) If the final decision includes conditions or restrictions to manage, reduce or eliminate a conflict of interest, the investigator shall document his or her compliance with such conditions or restrictions prior to the expenditure of any funds under the Funding Agreement or the commencement of unsponsored research.
 - (4) If the final decision is that a conflict of interest exists but can go forward under conditions specified, the COI Monitor shall note this interest in an initial report to the PHS funding agency or sponsor of the identification of the conflict of interest prior to the expenditure of any funds under the Funding Agreement. If the final decision includes conditions or restrictions to manage, reduce or eliminate the conflict, the COI Monitor shall provide within the initial report to the funding agency or sponsor details of how the conflict of interest has been eliminated or acceptably managed or reduced.
 - (5) Whenever an Investigator discloses a significant financial interest that was not previously disclosed or, for whatever reason, was not previously reviewed by a COIC during an ongoing research project (or was not timely reviewed or reported by a subrecipient) a COIC shall, within sixty days: review the significant financial interest; determine whether it is related to the research; determine whether a financial conflict of interest exists; and, if so implement a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
 - (6) For any interest that a COIC identifies as a conflict of interest subsequent to a COIC's initial report under the Funding Agreement, and after the expenditure of funds, the Institution will conduct a retrospective review of these cases of non-compliance to determine the impact of the bias on the research project. In instances where bias of the research has been found to exist, the COI Monitor will file a report to sponsor indicating what was found and what actions the Institution has taken, or will take, to

eliminate or mitigate the effect of the bias within 120 days of that identification. In case of PHS-funded research, the COI Monitor will document the retrospective review to the agency.

B. Publication and Other Communications of Research Results

1. Contracts with research sponsors may not include provisions that prevent the investigator from independently accessing, examining, analyzing and interpreting the research data, or that restrict publication or other public communications of the methods, data and results of the research. Sponsors may be given up to thirty (30) days in which to review a manuscript, presentation or abstract that originates from the sponsored research prior to submission for publication or otherwise publicly communicated. Such review shall be limited to protection of confidential information furnished by the sponsor to the investigator, if any, or for the purpose of protection of patent or other intellectual property rights covered under the contract. The sponsor does not have the right to approve or consent to the publication or other communication of the research results.
2. In the event that the proposed publication or other communication contains patentable subject matter or confidential information, the University will, upon written request from the sponsor within the thirty (30)-day review period, delay the publication or other communication for a maximum of an additional sixty (60) days to allow the sponsor to file a patent application, or to modify the proposed publication or communication to delete sponsor-provided confidential information and/or to present the results in a manner that will not compromise such confidential information.
3. Publications should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals with regard to conflicts of interest.
4. In the case of multi-site clinical trials, the contract should state: how the results will be published; how authorship will be decided; how each investigator will have access to all data from all sites (and not simply to summary tables) in order to be able to analyze the full data independently if there is no multi-site publication within one year of the termination of the study; and that such one-year delay in publication or presentation of data results by the investigator can be waived if the investigator has a good faith belief that publication or presentation should not be delayed for reasons of public health, safety or public welfare.

C. Protection of Students, Postdoctoral Appointees and other Trainees

Contracts with research sponsors may not include restrictions on the activities of students, postdoctoral appointees or other trainees, and may not include non-disclosure provisions regarding such individuals beyond those specified above (Sections VI.B.1 and 2). Exceptions must be approved by a COIC and must be fully disclosed to all students, postdoctoral appointees and other trainees prior to their involvement in the research. However students, postdoctoral appointees and other trainees may not, under any circumstances, be permitted to participate in research if such participation would prevent them from meeting pertinent University degree requirements, such as completion and public defense of a thesis or dissertation.

D. Investigator Conflict of Interest Training

The Senior Vice President for Research and Economic Development will create training content and be responsible for the implementation of a University training module within the Rutgers eCOI system.

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 noncompliant with the University's COI policy.

E Enforcement and Sanctions

Non-compliance with any provision of this policy shall be subject to sanctions up to and including dismissal or termination for cause. Non-compliance shall be reported by any knowledgeable individual to a COIC, and the IRB if human subjects are involved. A COIC, and the IRB if human subjects are involved, shall investigate the allegation, reach a conclusion and recommend sanctions or dismissal of the charges to the Senior Vice President for Research and Economic Development who shall have the final decision. Recommendations will also involve the notification of the sponsor and/or journal editors if non-compliance may have resulted in compromise of the integrity of the research and/or resulting publications or other communications.

F. Reports and Record Keeping:

1. The Associate Vice President for Research Regulatory Affairs shall maintain records of all disclosures of financial and other personal interests in ecoi.rutgers.edu, COIC determinations and recommendations, final decisions, actions taken to resolve conflicts of interest and the outcomes thereof for at least three (3) years from the date of submission of the final expenditure report of the project, or from the conclusion of unsponsored research, or until the resolution of any governmental or legal actions involving these records, whichever is longer.
2. Annually in January, the Associate Vice President for Research Regulatory Affairs shall summarize for the Senior Vice President for Research and Economic Development all disclosures of significant interests, Committee determinations and recommendations, final decisions, actions taken and the outcomes thereof during the previous calendar year.

G. Standards set by governmental agencies will be monitored and considered in the University's routine review of this policy.