



SOP: Financial Conflicts of Interest

NUMBER	DATE	PAGE
3.006 (HRP-055)	6/5/24	1 of 4

1 PURPOSE

- 1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest—a situation in which the financial interests of the institution or a Covered Official who has authority to act on behalf of the institution—may bias the design, conduct, reporting, review or oversight of research conducted by its employees.

The process begins when the Compliance Administrator, COI Monitor, or Conflicts of Interest Committee (COIC) determines that an investigator or research staff has reported a financial interest Related to the Research or an institutional conflict of interest exists relative to research.

- 1.2 The process ends when the COI Office has evaluated the reported interest and communicated the results of this evaluation to the investigator, COI Monitor, and IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 The Senior Vice President for Research appoints the members of the COIC. The Compliance Administrator or COI Monitor may have the COIC review COI disclosures of Significant Financial Interests whenever it is believed that an expert consensus is needed and/or a management plan must be issued.
- 3.2 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
- 3.2.1 The design, conduct, or reporting of research
 - 3.2.2 Research consultation
 - 3.2.3 Teaching
 - 3.2.4 Professional practice
 - 3.2.5 Institutional committee memberships
 - 3.2.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards
- 3.3 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
- 3.3.1 Joining the organization
 - 3.3.2 Financial conflict policies are revised in a manner that changes investigator requirements
 - 3.3.3 Non-compliant with financial conflicts policies and procedures
- 3.4 Individuals subject to this policy are required to disclose through the eCOI portal in the eIRB+ electronic system their institutional responsibility to conduct research and the financial interests Related to the Research:
- 3.4.1 On submission of an initial review
 - 3.4.2 At least annually
 - 3.4.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest
- 3.5 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration
- 3.6 Violations of this policy or proscribed management plans can lead to:
- 3.6.1 Loss or restriction of privileges to conduct research
 - 3.6.2 Other employment actions as allowed by Human Resources Policies and Procedures
- 3.7 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.

4 RESPONSIBILITIES



SOP: Financial Conflicts of Interest

NUMBER	DATE	PAGE
3.006 (HRP-055)	6/5/24	2 of 4

The Compliance Administrator carries out these procedures or ensures that the Conflicts of Interest Committee follows these procedures.

5 PROCEDURE

- 5.1 Ensure COIC members do not participate in the review of any conflict of interests in which the member has a Conflicting Interest.
- 5.2 Review the reported financial interest and the research protocol.
 - 5.2.1 If the financial interest and research protocol have already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing, and stop processing subsequent steps of this procedure.
- 5.3 Determine whether the reported financial interest is related to the research.
 - 5.3.1 If the financial interest is not related to the research, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.4 Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the Human Research.
 - 5.4.1 If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.5 If a conflict of interests exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:
 - 5.5.1 Subject recruitment
 - 5.5.2 Prescreening for inclusion/exclusion criteria
 - 5.5.3 The consent process
 - 5.5.4 The clinical treatment of subjects, separate from the research interventions or procedures
 - 5.5.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting
- 5.6 Create a written management plan, considering the following options:
 - 5.6.1 Public disclosure of the financial interests
 - 5.6.2 Disclosure of the financial interests to subjects
 - 5.6.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest
 - 5.6.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
 - 5.6.5 Permitting the research to proceed, with reduction or divestiture of the financial interest(s)
 - 5.6.5.1 of the University (institutional COI) and/or
 - 5.6.5.2 of individual investigators (Investigator COI).
 - 5.6.6 Severance of relationships that create financial conflicts
 - 5.6.7 Modification of the research plan
 - 5.6.8 Involvement of external individuals in key portions of the protocol
 - 5.6.9 Use of an external IRB
 - 5.6.10 A retrospective review
 - 5.6.11 A mitigation report
 - 5.6.12 A plan to monitor and enforce the implementation of the management plan
 - 5.6.13 Prohibiting the research from taking place at the University
- 5.7 Provide the written management plan to the involved individual or office for comment and review.
- 5.8 Finalize the written management plan.



SOP: Financial Conflicts of Interest

NUMBER	DATE	PAGE
3.006 (HRP-055)	6/5/24	3 of 4

- 5.9 Provide the IRB Administrator of the reviewing IRB with the pertinent elements of the management plan so that the consent forms, if applicable, may be revised and/or any changes to the discloser's participation in the study may be indicated on the file.
- 5.10 When required, provide the final determination to the funding or regulatory agencies.
- 5.11 Maintain a copy of determinations and management plans in the records for a minimum of 3 years.

6 MATERIALS

- 6.1 3.002 (HRP-001) - SOP – Definitions.

7 REFERENCES

- 7.1 42 CFR §50.
- 7.2 45 CFR §94.
- 7.3 42 CFR 50 Subpart F. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought.
- 7.4 Rutgers Policy 60.5.8 Conflicts of Interest – Faculty Professional Activities Outside the University and Outside Employment for Academic Personnel.
- 7.5 Rutgers Policy 90.2.5 Investigator Conflict of Interest.
- 7.6 Rutgers Policy TBD Institutional Conflict of Interest.

8 DEFINITIONS

- 8.1 Compliance Administrator - an Office of Research staff member responsible for processing all financial conflict of interest disclosures and facilitating reviews by the COI Committee.
- 8.2 COI Monitor - a faculty/staff member that is appointed by the school dean to review the financial disclosures within that school for potential financial conflict of interest.
- 8.3 Covered Official - An executive officer with day-to-day responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the institution.
- 8.4 Institutional Significant Financial Interest - when a research project includes human subjects and any of the following conditions applies:
 - 8.4.1 The institution holds any private equity in the outside entity; or
 - 8.4.2 The institution has the potential to receive cash payments from existing licensing arrangements with the outside entity; or
 - 8.4.3 The institution maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of research as a result of technology licensing activities.
- 8.5 Investigator Significant Financial Interest - 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:
 - 8.5.1 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;
 - 8.5.2 With regard to any publicly-traded entity, 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



SOP: Financial Conflicts of Interest

NUMBER	DATE	PAGE
3.006 (HRP-055)	6/5/24	4 of 4

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;

- 8.5.3 Greater than 1% of the ownership of stock, stock options, profits of a company with 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;
- 8.5.4 With regard to any non-publicly traded entity, significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- 8.5.5 Equity interests (or entitlement to the same) in the aggregate exceed \$5000 in a publicly-traded, financially interested company;
- 8.5.6 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), upon receipt of income related to such rights and interests.