



Policy Title: Disclosure Reports  
Category: Conflict of Interest  
Policy Number: 111  
Sponsor: Compliance Counsel  
Effective Date: January 18, 2017

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**INTRODUCTION AND PURPOSE.** This policy describes the formal steps implemented to protect the integrity of the decision-making process of certain individuals from bias and avoid even the appearance of impropriety by increasing transparency and accountability. These steps are in addition to those described in the conflict of interest section of the Code of Conduct.

**CANCELLATION.** COI Policy 111 entitled “Written Disclosure Reports” is cancelled.

**SCOPE AND APPLICABILITY.** This applies to employees and others who exercise authority delegated by Rosalind Franklin University of Medicine and Science (RFUMS) and/or Rosalind Franklin University Health Clinics (RFUHC). For purposes of this policy, RFUMS and RFUHC collectively are referred to as "University."

### **POLICY STATEMENTS.**

Individuals identified in this policy have been delegated a significant degree of authority by the University and, therefore, in order to protect the integrity of the decision-making process of those individuals from bias and avoid even the appearance of impropriety, those individuals must timely submit disclosure reports and comply with any management plans implemented by the cognizant authority overseeing any disclosed conflict, as further described in this policy.

The Compliance Counsel is the individual responsible for administering this policy. Within that role, the Compliance Counsel will: (1) develop and maintain an online computerized process to timely gather relevant information that meets the standards in federal regulations regarding conflict of interest in research as well as other foreseeable conflicts within the University environments, (2) assist cognizant oversight authorities to address disclosed potential conflict of interests in their respective areas, and (3) provide general advice and counsel on conflict of interest matters.

Violation of any of the provisions of this policy is prohibited and could result in sanctions, including termination. Any person seeking guidance or who becomes aware of any potential, known, or suspected violation of this policy shall report such matter to the Office of Compliance directly or through EthicsPoint, Inc. (<http://rosalindfranklin.ethicspoint.com> or 800-254-0460), which allows anonymity. No person will be subjected to retaliation, retribution, or reprisal for making a good faith report of, seeking guidance regarding, or participating in the investigation or resolution of a potential, known, or suspected violation of any provision in this policy.

**DEFINITIONS.**

***Equity interest*** includes any stock, stock option, or other ownership interest.

***Financial interest*** means anything of monetary value, whether or not the value is readily ascertainable.

***Institution of higher education*** means an educational institution in a State that

- (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of 20 USC § 1091(d)(3);
- (2) is legally authorized within such State to provide a program of education beyond secondary education;
- (3) provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary of the U.S. Department of Education;
- (4) is a public or other nonprofit institution; and
- (5) is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted preaccreditation status by such an agency or association that has been recognized by the Secretary of the U.S. Department of Education for the granting of preaccreditation status, and the Secretary has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

***Investigator*** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

***Remuneration*** includes salary and any payment for services not otherwise identified as salary (*e.g., consulting fees, honoraria, paid authorship*).

***Sponsored travel*** means that which is paid on behalf of the individual and not reimbursed to the individual (*in such situations, the exact monetary value might not be readily available*).

***University responsibilities***, as it relates to an individual, means that individual's responsibilities on behalf of RFUMS and/or RFUHC, including administrative or staff, research or research consultation, teaching, the professional practice of health care delivery, and service on committees or boards.

## **PROCEDURES.**

**1. Individuals Required to Submit Disclosure Reports.** The following individuals shall submit a disclosure report, as described in this policy:

- a. Administrators of RFUMS;
- b. Employed faculty of RFUMS;
- c. Research investigators of RFUMS;
- d. Employees of RFUHC; and
- e. Others as determined by senior administration.

**2. Timing of Disclosure.** Disclosure reports, as described in this policy, shall be submitted for each of the following:

- a. Annually, which will normally be solicited during the month of January.
- b. Within 30 days of hire or affiliation with the University.
- c. Within 30 days acquiring or discovering a significant financial interest (SFI), as further described in subparagraphs 3.a of this policy.
- d. As it relates to engaging in new externally sponsored research conducted on behalf of RFUMS, prior to submitting an application for funding to the external sponsor or prior to initiating that research, whichever is earlier.

**3. Content of Disclosure.**

a. **Significant Financial Interests (SFI).** The disclosure report shall contain disclosure(s) relating to any existing significant financial interest (SFI). Subject to the exceptions described in subparagraph 3.b of this policy, an SFI exists when the individual, the individual's spouse, and/or the individual's dependent children have, individually or collectively, any of the following financial interests that reasonably appear to be related to any of the individual's University responsibilities:

- (1) Any combination of remuneration from and equity interest in a single publicly traded entity where the total value of remuneration received in the twelve months preceding the disclosure plus the value of any equity interest in that entity as of the date of disclosure exceeds \$5,000.
- (2) Any form(s) of remuneration received from a single non-publicly traded entity where the total value in the twelve months preceding the disclosure exceeds \$5,000.
- (3) Equity interests in a single non-publicly traded entity.
- (4) Intellectual property rights and interests where there has been a receipt of income related to such rights and interests.
- (5) Any reimbursed or sponsored travel from a single entity where the total value in the twelve months preceding the disclosure exceeds \$5,000.

b. Not Significant Financial Interests. The following financial interests are not considered SFI and, therefore, will not be included in the disclosure report:

(1) Salary, royalties, or other remuneration paid by the University to the investigator if the investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights (*note: obligations may be imposed relating to these institutional patent rights, as described in the policy on institutional conflict of interest*).

(2) 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.

(3) Income from seminars, lectures, or teaching engagements sponsored by any of the following:

- (a) a Federal, state, or local government agency,
- (b) an institution of higher education,
- (c) an academic teaching hospital,
- (d) a medical center, or
- (e) a research institute affiliated with an institution of higher education.

(4) Income from service on advisory committees or review panels for any of the entities listed in subparagraph 3.b(3) of this policy.

(5) Travel that is reimbursed or sponsored by any of the entities listed in subparagraph 3.b(3) of this policy.

c. Other Matters. The Disclosure Report shall also contain disclosures relating to other interests that may relate to the University role(s) of the individual and other specifics tailored to the role(s) of the individual.

**4. Cognizant Oversight Authority**. The cognizant oversight authority depends upon the specifics of the disclosures and the specifics of the role(s) held by the individual. A single set of disclosures by one individual might be subject to review by more than one cognizant oversight authority.

a. The cognizant oversight authority is normally the first-level or second-level supervisor of the individual as it relates to the role that may be affected by the content of the disclosure.

b. In addition, the cognizant oversight authority for disclosures made by a RFUMS research investigator would be the Executive Vice President for Research. Such situations will be reviewed and resolved in accordance with the policy entitled “Individual Conflict of Interest in Research & COIC.”

**5. Standard of Review and Resolution.** The cognizant oversight authority who reviews disclosures pursuant to this policy will normally make one of the following determinations:

a. No Conflict of Interest. This determination would be appropriate when it is clear that the disclosed interest does *not* create an actual or apparent bias or improper influence upon the individual's judgment relating to his/her University responsibilities.

b. Manage the Conflict of Interest. In instances where there is a conflict of interest, the cognizant oversight authority will implement a plan to effectively manage that conflict such that the integrity of the decision making process is protected from bias, including avoiding the appearance of impropriety. Management plans involve imposing conditions, such as additional disclosures, additional oversight, segregation of duties, re-assignment of responsibilities to others, and/or a reduction of the conflicting interest.

**6. Factors to Consider.** Relevant factors to be used in making the decisions described in subparagraph 5 of this policy are as follows:

a. the specifics of the University role and responsibilities of the individual;

b. the nature and specifics of the disclosed interest of the individual, including how that interest may be affected by University decisions made by that individual; and

c. the effectiveness of the management plan to protect the decisions from bias from that interest and avoid the appearance of impropriety.

**7. Document Retention and Confidentiality of Information.** Information gathered during the disclosure process and resolution process shall be retained for a minimum of three years. Such information is considered confidential and, as such, may be disclosed upon the consent of the individual, within the University on a need-to-know basis, or as otherwise required or permitted by law or University policy.