



Policy Title: Individual Conflict of Interest in Research & COIC

Category:

Policy Number:

Sponsor: EVP for Research

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INTRODUCTION AND PURPOSE. The discovery of knowledge through research is critical for advancing human health. Such research is often enhanced through collaborations among government, academia, and industry; yet, it is also recognized that the ability to protect the integrity of the data generated by that externally sponsored research could be compromised when bias is introduced through an investigator's financial conflict of interest. In recognition of this concern, the federal government has promulgated regulations addressing financial conflict of interest in federally-funded research. Those regulations are designed to facilitate the proper collaboration among government, academia, and industry by increasing transparency and accountability and to ensure, to the extent possible, the design, conduct, and reporting of that research is free from bias. The overall purpose is to maintain objectivity in such research.

This policy is designed to promote compliance with those federal regulations and apply its purposes and standards to all University research.

The University recognizes that the existence of a conflict of interest may also adversely impact the rights and welfare of human subjects or interfere with the ethical care and use of animals. Oversight of those specific concerns is exercised through the University's Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC), respectively.

CANCELLATION. Prior versions of this policy are cancelled.

SCOPE AND APPLICABILITY. This applies to all employed staff and faculty members, to all investigators, and members of the Conflict of Interest Committee (COIC).

POLICY STATEMENTS.

For the purpose of maintaining objectivity in all externally sponsored research conducted on behalf of the University, such research shall be performed:

- * in compliance with standards articulated in federal regulations regarding financial conflict of interest in federally-funded research (42 CFR § 50.601 *et seq.* and 45 CFR § 94.1 *et seq.*); and
- * in a manner that ensures, to the extent possible, the design, conduct, and reporting of that research is free from bias.

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 any provision in this policy shall report such matter to the Vice President for Research. As an alternative, reports may be made 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.

PROCEDURES. These procedures address situations in which disclosure reports are forwarded to the EVP for Research because a disclosure is made by a RFUMS research investigator. See Conflict of Interest Policy 111 entitled "Disclosure Reports."

1. Initial Review by Executive Vice President (EVP) for Research.

a. Whether Disclosure is Related to Research. The EVP for Research shall promptly (*normally within 7 days*) review each disclosed interest¹ to determine whether it is related to any of the investigator's research projects. A disclosed interest would be related to a research project when either:

- (1) The interest could reasonably be affected by the research (*e.g. patent relating to the experimental item or scientific question*) or
- (2) The interest is in an entity whose financial interest could reasonably be affected by the research (*e.g. ownership in a company that has a patent relating to the experimental item or scientific question*).

If the determination is no, then the final decision is that there is no conflict of interest relating to that research project. If the determination is yes, then continue within this paragraph 1.

b. Whether Disclosure is a Financial Conflict of Interest (FCOI). The EVP for Research shall promptly (*normally within 7 days*) review each disclosed interest¹ to determine whether it is a FCOI to any of the investigator's research projects. A disclosed interest would be a FCOI to a research project when it is reasonably determined that the disclosed interest could directly and significantly affect the design, conduct, or reporting of that research.

Note: The term "significantly" means that the disclosed interest would have a material effect on the research such that it would compromise the intent of this policy of maintaining objectivity in externally sponsored research.

If the determination is no, then the final decision is that there is no conflict of interest relating to that research project. If the determination is yes, then continue within this paragraph 1.

¹ The EVP for Research may seek additional information from the investigator and guidance from others, as deemed appropriate, to accomplish this initial review.

c. Implement Interim Management Plan. The EVP shall promptly implement and notify the research investigator of the implementation of an Interim Management Plan, which shall consist of:

(1) the investigator disclosing the existence and general nature of the FCOI as follows:

(a) to all members of the research team (*including students, volunteers, and trainees*), whether considered permanent or temporary, and include new additions to the research team as soon as practical after joining the research team along with a notice that any concerns they may have relating to the conflicting interest should be brought to the EVP for Research or Office of Compliance directly or through EthicsPoint and that there will be no retaliation, retribution, or reprisal for any such good faith reporting of concerns,

(b) to all members of any research team(s) of any investigators collaborating in the research,

(c) when applicable, to the IRB (*which will determine whether additional requirements are appropriate to protect the rights and welfare of the human subjects*) or to the IACUC (*which will determine whether additional requirements are appropriate to promote the ethical care and use of animals*), and

(d) to any external sponsor of the research.

(2) any other measure deemed proper to protect the design, conduct, and reporting of that research from bias associated with the FCOI while the situation is pending COIC review.

d. Notify and Refer to COIC. The EVP for Research will notify the Chair of the COIC and refer the matter to that committee for review.

e. During Absence of EVP for Research. The EVP for Research may authorize the Chair of the COIC to perform the functions of the EVP for Research described in this paragraph 1 of this policy during anticipated periods of absence of the EVP for Research. In such situations, the Chair of the COIC shall debrief the EVP for Research of actions taken upon return.

2. Conflict of Interest Committee (COIC). The EVP for Research will forward each case in which a FCOI was determined to exist to the COIC for review in order to timely implement an effective Management Plan. In addition, the EVP for Research will forward other cases, as described in the Institutional Conflict of Interest in Research policy, to the COIC for review in order to timely implement an effective Management Plan.

a. Composition of COIC. The COIC consists of five or more members, appointed in writing by the EVP for Research, for a term of three years, and will normally include:

- (1) faculty who is currently or was within the past 12 months a member of the University's Institutional Review Board (IRB);
- (2) faculty who is currently or was within the past 12 months a member of the University's Institutional Animal Care and Use Committee (IACUC);
- (3) faculty with experience in basic science research;
- (4) faculty with experience in clinical research; and
- (5) faculty representation from each of schools/colleges of the University.

b. Chair of COIC. The Chair of the COIC is appointed in writing by the EVP for Research from among the membership of the COIC. The Chair calls for and schedules meetings, controls the agenda, remains a voting member, and communicates on behalf of the COIC. In the event the Chair of the COIC is not reasonably available, as determined by the EVP for Research, the EVP for Research may appoint an Acting Chair of the COIC from among the membership of the COIC. The Acting Chair of the COIC has all of the authority and responsibilities of and will perform the function of the Chair of the COIC during the time appointed. The appointment of an Acting Chair need not be in writing.

c. Quorum and Manner of Acting. The COIC may act only during a meeting when a quorum exists. A quorum exists for a meeting when at least three current members (*one of which shall be the Chair or Acting Chair*) are present and are qualified to participate. Qualified to participate means the member does not have a conflicting interest regarding the matter under review. An action by the COIC during a meeting is in accordance with a majority vote of the members forming the quorum. To vote, a member must be present and qualified to participate; voting by proxy is not permitted.

d. Factors to Consider By COIC. The COIC will consider during its review:

- (1) the specifics of the research activities, including the involvement of the affected investigator in those research activities;
- (2) the nature and specifics of the FCOI, including how the FCOI might be affected by the research results;
- (3) the effectiveness of the management plan to protect the design, conduct, and reporting of the research from bias associated with the FCOI and, thereby, further the overall purpose of maintaining objectivity in research; and
- (4) the appearance to a reasonable scientist and to a reasonable lay person in the public whether objectivity in research is being maintained.

e. Effective Management Plan. The COIC will approve a Management Plan that it determines will be effective in protecting the design, conduct, and reporting of the research from bias associated with the FCOI and/or COI and, thereby, further the overall purpose of maintaining objectivity in research.

(1) This Management Plan will normally include the required disclosures of an Interim Management Plan as described in this policy.

(2) In addition, this Management Plan may include, as deemed appropriate by the COIC, any the following:

(a) a disclosure by the investigator of the existence and general nature of a FCOI and/or COI in any presentation or publication of the result results.

(b) the appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

(c) a modification of the research plan;

(d) a change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; and/or

(e) a requirement to reduce or eliminate the FCOI (*e.g., sale of an equity interest*) or sever the relationship that creates the FCOI.

f. Communicating Determinations. The Chair of the COIC will communicate, in writing, the determination(s) of the COIC to the affected investigator and provide a copy to the Office of Research.

g. Time Limits for Completion of Implementation of Management Plan. For any existing research project that involves a FCOI, the following time limits apply:

(1) Implementation of a management plan must occur prior to the expenditure of any funds under an externally sponsored research project (*note: coordination with OSR is necessary*).

(2) Implementation of a Management Plan *or* an Interim Management Plan must occur prior to the expiration of 60 days from the disclosure of the SFI to the EVP for Research. When an Interim Management Plan has been implemented, a Management Plan implemented by the COIC must occur prior to the expiration of 60 days from implementation of the Interim Management Plan.

3. Retrospective Review in Cases of Noncompliance. A retrospective review will be completed within 120 days of a determination of noncompliance, as further described below.

a. Noncompliance Triggering a Review. An instance of noncompliance that will trigger a respective review is when, as determined by the EVP for Research, an investigator has a FCOI *plus* any of the following had occurred:

(1) Noncompliance with any of the following timeliness requirements for submitting a disclosure *report* (see *Conflict of Interest Policy III entitled "Disclosure Reports"*):

- (a) Annually.
- (b) Within 30 days of hire or affiliation with the University.
- (c) Within 30 days acquiring or discovering a significant financial interest.
- (d) As it relates to engaging in new externally sponsored research conducted on behalf of the University, prior to submitting an application for funding to the external sponsor or prior to initiating that research, whichever is earlier.

(2) Noncompliance with a timeliness requirement in any part of paragraph 2.g of this policy, as it relates to that FCOI.

(3) Noncompliance with an implemented management plan or interim management plan that addresses that FCOI.

b. Immediate Interim Management Plan. Prior to conducting the retrospective review, the EVP for Research shall immediately implement an interim management plan consisting of the disclosures described in this policy while the matter is pending retrospective review.

c. Retrospective Review. The retrospective review shall consist of a review of the investigator's activities and the research project to determine whether any portion of the research conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

d. Documentation of Review. This review shall be documented and include all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the investigator with the FCOI;
- (5) Name of the entity with which the investigator has a FCOI;
- (6) Reason(s) for the retrospective review;

- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

e. Actions After Retrospective Review. Based on the results of the retrospective review, the EVP for Research shall take the following actions:

- (1) Ensure the investigator's current Disclosure Report has been updated, if applicable.
- (2) Ensure a Management Plan has been implemented for future research conduct, if applicable.
- (3) If bias was found, then:
 - (a) Notify the external sponsor (*normally, through OSR*), if any. If the external sponsor was PHS, then notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable*).
 - (b) Require the investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

4. Public Access to Certain FCOI Information. The EVP for Research shall ensure public accessibility of certain information concerning each FCOI.

a. Accessibility shall be accomplished by responding to a requestor in writing within five (5) business days of receiving a written request. Any such written request shall be addressed to the EVP for Research, Rosalind Franklin University of Medicine and Science, 3333 Green Bay Road, North Chicago, Illinois 60064.

b. The information to be made available for each FCOI is:

- (1) the investigator's name;
- (2) the investigator's title and role with respect to the research project;
- (3) the name of the entity in which the SFI is held;
- (4) the nature of the SFI; and

(5) the approximate dollar value of the SFI using ranges (*\$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000*), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

c. The EVP for Research shall note in the written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new FCOI, which, if sought, should be requested subsequently by the requestor.

d. This information shall remain available for at least three years from the date that the information was most recently updated.

5. Reports to PHS. The reporting of FCOI to PHS shall be conducted by OSR consistent with PHS regulations and University policies.

6. Training.

a. Initial Training. New investigators (i.e. newly employed by RFUMS or newly affiliated with RFUMS) shall complete training on conflict of interest in research no later than the due date for that person's Disclosure Report.

b. Refresher Training. Refresher training is required for existing investigators as follows:

- (1) at least once every four years;
- (2) upon modification of this policy in a manner that affects the obligations of investigators.
- (3) upon a determination that an investigator has violated this policy as it applies to disclosure obligations or complying with a management plan.

c. Content of Training. The EVP for Research shall oversee the content of this training and ensure it includes the following:

- (1) the content of this policy;
- (2) the obligations regarding disclosure; and
- (3) the requirements of the federal regulations regarding conflict of interest in federally sponsored research

7. Subrecipients. When the University carries out the research through a subrecipient (*e.g., subcontractors or consortium members*), the University (*i.e. awardee Institution*) will take reasonable steps to ensure that any subrecipient investigator complies with the applicable federal regulations on financial conflict of interest in federally-supported research and this policy by:

a. 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.

(1) When Subrecipient's Policy Applies.

(a) 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 the applicable federal regulations on financial conflict of interest in federally-supported research (*e.g.* 42 CFR § 50.604). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient investigators are subject to the financial conflicts of interest policy of the University for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(b) Additionally, 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 the University to provide timely FCOI reports, as necessary, to the PHS as required by the applicable federal regulations on financial conflict of interest in federally-supported research;

(2) When University's Policy Applies. Alternatively, if the subrecipient's investigators must comply with the University's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under the applicable federal regulations on financial conflict of interest in federally-supported research.

b. Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient investigators consistent with the applicable federal regulations on financial conflict of interest in federally-supported research (*i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI*).

8. Administrative Support, Records, and Confidentiality.

a. The Office of Compliance will provide consultation and administrative support for the COIC and EVP for Research.

b. 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 (e.g. see paragraph 4 of this policy for information required to be made available to the public).

c. Training records shall be retained for a period of 5 years.

9. Policy Posted on Publically Available Website. An electronic version of this policy shall be posted on the portion of the University's website that is publically accessible.