



Policy Title: Institutional Conflict of Interest in Research

Sponsor: Executive Vice President for Research

Effective Date: December 18, 2019

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**INTRODUCTION AND PURPOSE.** An “institutional conflict of interest in research” is when a significant financial interest held by one is imputed to another because of the authority structure within the University that the one has over the other. For this policy, it is either:

\* when a significant financial interest held by the University itself influences or appears to influence the judgment of University employees who are tasked with responsibilities involving the design, conduct, reporting, or review of research or

\* when a significant financial interest held by certain individuals with supervisory or other high level of authority within the University influences or appears to influence the judgment of certain University employees who are tasked with responsibilities involving the design, conduct, reporting, or review research.

This policy addresses the concept of *institutional* conflict of interest in research by increasing transparency and accountability and to ensure, to the extent possible, the design, conduct, reporting, and review of research conducted on behalf of the University is free from bias. The overall purpose is to maintain objectivity in such research.

**SCOPE AND APPLICABILITY.** This applies to all employed University faculty and staff.

### **POLICY STATEMENTS.**

All research activities conducted on behalf of the University shall be conducted in a manner that ensures, to the extent possible, the design, conduct, reporting, and review of research conducted on behalf of the University is free from bias introduced by a significant financial interest held by:

- \* the University itself or
- \* certain individuals having authority over University employees who are tasked with responsibilities involving the design, conduct, reporting, or review of research.

Violation of any of the provision 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 Executive 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.**

**1. List of Certain External Sponsors.** The Executive Vice President for Research, through the Office of Sponsored Research, shall maintain a list of *all* external sponsors of research conducted on behalf of the University *except* sponsors that are:

- 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.

## **2. The President, Chief of Staff, Provost, and Executive Vice President for Research.**

a. Not Hold or Acquire SFI in External Sponsors. The President, the Chief of Staff, the Provost, and the Executive Vice President for Research will not acquire or continue to hold any significant financial interest (SFI) in any external sponsor named on the list described in paragraph 1 of this policy.

b. Definition of SFI for this Paragraph. For purposes of this paragraph of this policy, a SFI, subject to the exceptions in subparagraph 2.c, is any of the following:

(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.

c. Not SFI. For purposes of this paragraph of this policy, the following financial interests are *not* considered a SFI:

(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.

(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.

d. Requests for Exceptions. Requested exceptions to the provisions of this paragraph of this policy may be sought as follows:

(1) Requests by the Chief of Staff, the Provost, or the Executive Vice President for Research will be reviewed by the President, who will determine whether the SFI is a financial conflict of interest (FCOI), as described in the policy entitled “Individual Conflict of Interest in Research & COIC” and, if so, implement a management plan, as deemed appropriate. Obtaining guidance from the Conflict of Interest Committee is recommended.

(2) Requests by the President will be reviewed by the Audit Committee of the Board of Trustees. That committee will determine whether the SFI is a FCOI, as described in the policy entitled “Individual Conflict of Interest in Research & COIC” and, if so, implement a management plan, as deemed appropriate. Obtaining guidance from the Conflict of Interest Committee is recommended.

### **3. Deans, Department Chairs, and Directors of Research Centers and Institutes.**

a. Annual. On an annual basis, each Dean, Department Chair, and Director of a Research Center or Institute will review a copy of the list described in paragraph 1 of this policy and will disclose in writing whether or not he/she has any significant financial interest (SFI) in that sponsor. If so, the specifics of that significant financial interest will also be disclosed.

b. Routing Sheet for Proposed Research. The routing sheet to conduct externally sponsored research shall include a provision for the Director of the cognizant Research Center or Institute and, if none, then the Department Chair of the investigator to indicate whether he/she has a SFI in the external sponsor of the proposed research. If so, the individual will also disclose the specifics of that SFI to the Executive Vice President for Research.

c. Review of Disclosed SFI. The Executive Vice President for Research will review each disclosed SFI and determine whether the SFI is a financial conflict of interest (FCOI), as described in the policy entitled “Individual Conflict of Interest in Research & COIC.” If so, the Executive Vice President for Research will implement a management plan, as deemed appropriate. Obtaining guidance from the Conflict of Interest Committee is recommended.

### **4. Charitable Contributions/Donations to the University.**

a. Disclosure of SFI by Vice President for Institutional Advancement. On an annual basis, the Vice President for Institutional Advancement will review a copy of the list described in paragraph 1 of this policy and will disclose in writing whether or not the University has a significant financial interest (SFI) in that external sponsor. If so, the Vice President for Institutional Advancement will also describe the specifics of the SFI, including any conditions

associated with the use of the gift and whether the gift was solicited, and, if so, by whom and for what purpose.

b. Definition of SFI for this Paragraph. For purposes of this paragraph of this policy, a SFI is one or more charitable contributions or donations to the University from the external sponsor that were received by the University or pledged by the external sponsor during the past twelve months that totals \$100,000 or more.

c. Review of Disclosed SFI. The Executive Vice President for Research will review each disclosed SFI and determine whether the SFI is a financial conflict of interest (FCOI), as described in the policy entitled “Individual Conflict of Interest in Research & COIC.” If so, the Executive Vice President for Research will implement a management plan, as deemed appropriate. Obtaining guidance from the Conflict of Interest Committee is recommended.

## 5. Investments of the University.

a. Disclosure of SFI by Chief Financial Officer. On an annual basis, the Chief Financial Officer will review a copy of the list described in paragraph 1 of this policy and will disclose in writing whether or not the University has a significant financial interest (SFI) in that external sponsor. If so, the Chief Financial Officer will also describe the specifics of the SFI, including its total value.

b. Definition of SFI for this Paragraph. For purposes of this paragraph of this policy, a SFI is one or more investments (*e.g. equity holdings*) by the University in the external sponsor with a total value of \$100,000 or more.

c. Review of Disclosed SFI. The Executive Vice President for Research will review each disclosed SFI and determine whether the SFI is a financial conflict of interest (FCOI), as described in the policy entitled “Individual Conflict of Interest in Research & COIC.” If so, the Executive Vice President for Research will implement a management plan, as deemed appropriate. Obtaining guidance from the Conflict of Interest Committee is recommended.

## 6. Intellectual Property.

a. List of Intellectual Property Rights and Interests. The Executive Vice President for Research, through the Office of Sponsored Research, shall maintain a list of all research-related intellectual property (IP) rights and interests held by the University *whether or not the research is externally sponsored*. This list will include its title or name, the type of IP interest or right (*e.g. pending patent, granted patent, or copyright*), and whether any revenue has been received from that IP interest or right.

b. IP Right or Interest that Generated Revenue is a SFI. Any IP right or interest that has generated revenue to the University is deemed a significant financial interest (SFI) of the

University and a SFI of any individual developer(s) who has entered into a revenue sharing agreement with the University regarding that intellectual property right or interest.

c. SFI is a FCOI. The Executive Vice President for Research will review each SFI and determine whether it is a financial conflict of interest (FCOI). For purposes of this paragraph of this policy, a SFI is deemed a FCOI for all University employees as it relates to research activities that could reasonably affect the potential value of the intellectual property right or interest (*e.g. when the research addresses the efficacy of the subject matter of the intellectual property right or interest*).

d. Review of FCOI. The Executive Vice President for Research will refer instances of FCOI to the COIC for review with instructions to implement a management plan by using, as guidance, the policy entitled “Individual Conflict of Interest in Research & COIC” and include a requirement that, in the case of human research, the principal investigator utilize an IRB external to the University.