

## **FCOI Disclosure Process and Management**

### **COI Designated Official**

The COI Designated Official (Director ORC) is designated to solicit and review conflict of interest disclosures, provide information and training about conflicts of interest to the University community, and to facilitate compliance with conflict of interest policies and regulations.

Disclosures with one or more “Yes” responses to the COI screening questions are reviewed by the COI Designated Official. In this review, the COI Designated Official determines whether a significant financial interest, external relationship, paid travel, constitutes a potential conflict of interest situation and if further review is required. The COI Designated Official may seek additional information before making this determination.

If it is determined that the faculty/researcher does not have a conflict of interest situation, the researcher will receive an email notifying them of the determination, with a reminder to update their disclosure within 30 days of acquiring or discovering a new significant financial interest, external relationship.

If the COI Designated Official determines that a potential conflict of interest situation has been disclosed, the disclosure will be forwarded for detailed review by the COI Committee (i.e., VPRED, Chair; Dir ORC., Asst. Dir. ORC, AVPRA).

### **COI Committee review**

Multiple factors are considered during the review of a FCOI disclosure, for example:

- The value of the financial interest – financial interests with higher values may be considered higher risk.
- The scope of the relationship with an external entity – longer and closer associations may increase risk.
- The level of the employee’s ability to make decisions on behalf of the University regarding an outside entity.
- The seriousness of possible harm that could occur if the employee’s decisions or actions were unduly influenced by the external interest.

If the COI Committee determines that faculty/researcher does not have a conflict of interest situation, the individual will receive an email notifying them of the determination, with a reminder to update their disclosure within 30 days of acquiring or discovering a reportable significant financial interest, external relationship or paid travel.

If the COI Committee determines that a conflict of interest exists, it then recommends actions to manage or eliminate the risk.

## **Conflict of interest management**

If the COI Committee determines that the risks involved in FCOI situation can be minimized to an acceptable level through management, the COI Committee makes recommendations for a FCOI Management Plan. The Director of ORC or designee will serve as COI Management Plan Administrator to implement the plan, monitor compliance, and produce status reports to the VP for Research and Economic Development.

The FCOI Management Plan must be approved and signed by the faculty/researcher, the individual's department chair or director, dean or vice president, and the Vice President for Research and Economic Development.

## **Elements of a FCOI Management Plan**

The elements in FCOI Management Plan vary depending on the nature of the situation and can involve:

- Requirements to disclose the conflict of interest to faculty, staff, students and collaborators; on publications; and in presentations.
- Requirements about the use of University resources.
- Information about invention disclosures and intellectual property rights.
- Mechanisms to reduce, eliminate or manage the risk of bias in the design, conduct or reporting of research.
- Requirements for the approval of contracts with and invoices from the external entity.
- Requirement for the employee to recuse themselves from University deliberations, decisions, and negotiations regarding the external entity.
- Conflict of Interest training requirements.
- Any other conditions necessary to reduce or eliminate the risk that the employee's external interest could unduly influence their professional or research responsibilities.

## **Notifying sponsors about conflicts of interest**

The University is committed to compliance with all sponsor requirements regarding the disclosure and management of conflicts of interest. If a sponsor requires that Principal Investigators (PI) have a current COI disclosure on file at the time of proposal submission, ORA will notify the PI of this requirement and will not submit a proposal until this requirement is met.

The AVP for Research Administration will notify sponsors about conflicts of interest that arise during the course of a project if the terms and conditions of the award include this requirement. The University will comply with the sponsor's requirements for management or elimination of the conflict of interests.

## **Monitoring compliance with FCOI Management Plans**

The Director of ORC is responsible for monitoring compliance with the terms of the plan on a regular basis, and must submit a status report to the VP for Research and Economic Development at least annually.

## **Renewing or revising FCOI Management Plans**

FCOI Management Plans are typically valid for one year. Upon review of the FCOI Management Plan Status Report, the plan may be extended for an additional year at the discretion of the VP for Research and Economic Development. If conditions change or if there is evidence of non-compliance with the plan, the COI Committee will review the plan and may recommend revisions.

## **Terminating a FCOI Management Plan**

FCOI Management Plans are terminated when the conflict of interest situation no longer exists or when the COI Committee determines that the risk is no longer manageable and must be eliminated.

## **Eliminating conflicts of interest**

Under certain circumstances, the University may require elimination of the conflict of interest rather than management. For example, the conflict of interest situation may be one that is prohibited under institutional or other policies or the risk of harm outweighs the benefit of continuing the situation.

Possible actions to eliminate the conflict of interest include:

- Reducing a financial interest to a level that is not considered significant
- Divestment of the financial interest that is causing the conflict of interest
- Termination of the relationship that is causing the conflict of interest
- Changing supervisory structures
- Prohibiting transactions and/or relationships between the University and an external entity
- Modifying a researcher's role on a project
- Terminating employment at the University

The decision to eliminate a conflict rather than managing it is made after careful deliberation by the COI Committee in conjunction with the Vice President of Research and Economic Development, Provost, and when necessary, General Counsel.

### **Appealing a conflict of interest decision**

A Faculty/Researcher may appeal a conflict of interest determination through written notification to the Vice President for Research and Economic Development for a research-related conflict of interest situation.

Faculty/Researcher may appeal concerning the decision of the Vice President for Research and Economic Development to the Provost; and if unsatisfied to the President of the University. The President's decision on this appeal is final.

### **Reporting potential conflict of interest situations**

The FCOI disclosure process is the primary method of identifying financial conflict of interest situations. However, FCOI concerns may be brought to the attention of the COI Designated Official directly, or may be reported anonymously