

# PROCEDURE 2300-PR2

## Outside Interest Assessment and Institutional Conflict of Interest Determination

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Associated Policy: 2300, Institutional Conflicts of Interest  
Effective Date: 8 MAR 2024  
Latest Revision: 9 JAN 2024  
Category: General Administration

### PURPOSE

This procedure sets forth the process for assessing outside financial interests held by Institutional Leaders, and financial interests held by USU to determine if they give rise to an Institutional Conflict of Interest (ICOI). This procedure is associated with USU Policy 2300, "Institutional Conflicts of Interest." Policy requirements associated with this procedure include 2300.2.4, setting forth the need for the assessment and determination of financial interests held in outside entities that could affect the design, conduct or reporting of Human Subjects Research (HSR). USU manages conflicts of interest to prevent biases that may arise based on financial interests held by USU or its employees from affecting USU's decision-making processes.

### PROCEDURES

#### Notification of Commercial Sponsors by the IRB

Notification by the Institutional Review Board (IRB) of funding or cooperation with a commercial sponsor, or of use of Intellectual Property owned by USU or contributed by a commercial sponsor shall be made to the University Ethics & Compliance (UEC).

Based on this notification, the UEC coordinates with the IRB through an ancillary review process in Kual. UEC and the IRB identify when identified outside entities are listed among the entities that have been identified in the ISFI disclosure process, as outlined in 2300-PR1, "Disclosing Institutional Conflicts of Interest." The IRB may also request UEC support in assessing any HSR where the IRB identifies circumstances that may indicate the presence of an ISFI related to HSR at USU.

#### Determination of an ICOI

When a potential ICOI is identified, it will be screened by UEC based on established thresholds. If the UEC assessment concludes that the ISFI cannot rise to the level of an ICOI, it will notify both the IRB and the Conflict of Interest Committee (COIC) of its conclusion and will complete its review process, permitting the IRB to include any conditions in its approval that satisfy its responsibilities to protect the rights and welfare of Human Subjects. If the UEC assessment concludes that an ISFI could give rise to an ICOI, UEC shall place the item on the COIC meeting agenda, and shall notify the IRB, members of the COIC, and the Principal Investigator of the pending COI Committee determination.

At the following meeting of the COIC, which may be a regular meeting or may be a special meeting called to expedite an ICOI determination, the determination will be made by the COIC. When acting on a potential ICOI, the COIC will be augmented with two members of the IRB, at least one of whom shall be considered a scientist under AAHRPP Accreditation Standards. These members shall be authorized to participate in the deliberation and vote on the ICOI determination. The two members appointed by the IRB shall be excused when other business is before the COIC.

If the COIC determines that an ICOI exists, it shall consider means for management of the ICOI as set forth in Procedure 2300-PR3, "Development and Maintenance of Institutional Conflict of Interest Management Plans."

## **HISTORY**

DEC 2023 First Review Draft for consideration by the COI Committee

## **RESOURCES**

Policy 2300, Institutional Conflicts of Interest

## **ADDITIONAL INFORMATION**

### **Contacts**

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