

# PROCEDURE 2300-PR3

## Development and Maintenance of Institutional Conflict of Interest Management Plans

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Associated Policy: 2300, Institutional Conflicts of Interest  
Effective Date: 08 MAR 2024  
Latest Revision: 29 NOV 2023  
Category: General Administration

### PURPOSE

This procedure sets forth the process for the development and maintenance of Institutional Conflict of Interest Management Plans. Outside financial interests held by Institutional Leaders, and financial interests held by USU that give rise to an Institutional Conflict of Interest (ICOI) must be managed, reduced or eliminated. This procedure is associated with USU Policy 2300, "Institutional Conflicts of Interest." Policy requirements associated with this procedure include 2300.2.7-2.11, setting forth the requirements for the management and maintenance 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

#### Development of ICOI Management Plans

When a potential ICOI is identified to be considered by the COIC, UEC will begin to develop a management plan in conjunction with the lead investigator of the proposed study and the IRB. The following mitigation strategies may be considered as common means to manage ICOIs:

- Registration of the study, if appropriate
- Disclosure of the ICOI in the Informed Consent, and in presentations and publications based on findings from the study
- Use of a Data and Safety Management Committee with members drawn from individuals not affiliated with USU or with the outside entity
- Reporting of final data in an open-source repository
- Recusal from decision-making by the financially-interested Institutional Leader and disclosure of the recusal to appropriate individuals to ensure oversight
- Reduction of the magnitude of the financial interest to an amount below the designated threshold
- Severance of the relationship with the sponsor of the HSR
- Disclosure of the ICOI to the Sponsor
- Withdrawal by USU from the HSR
- Assignment of the review to an outside IRB
- Establishment of an independent advisory board to monitor the project

The COIC will review the outside financial interests in the context of the proposed project and recommend an ICOI Management Plan to the IRB for its review and approval. An ICOI Management Plan that has been referred to the IRB may be accepted for implementation, altered by the IRB with notification to UEC of alterations, referred back to the COIC with a recommendation for further deliberation, or rejected. Any appeal regarding a plan that has been accepted for implementation by the IRB, or rejected by the IRB must be made to the IRB. No HSR may be conducted under USU's auspices that has not been approved

by the appropriate Institutional Review Board, including the implementation of any required approved ICOI Management Plan.

### Implementation, Oversight and Maintenance of ICOI Management Plans

Once an ICOI Management Plan has been approved by the COIC and accepted by the IRB, it shall be appended to the previous COI Committee Meeting Minutes (where it was last considered) and UEC will work with responsible executives and unit leaders to ensure that the plan is implemented. UEC will monitor and review the ICOI plan annually and will ensure the plan is assessed and maintained until the ICOI is eliminated. ICOI Management Plans will be maintained in the Quali system and will be available for COIC review annually and upon request.

## HISTORY

DEC 2023 First Review Draft for consideration by the COI Committee

## RESOURCES

Policy 2300, Institutional Conflicts of Interest

## ADDITIONAL INFORMATION

### Contacts

Compliance Officer  
Office of University Ethics and Compliance  
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Institutional Review Board  
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