

University Policy 544: Institutional Conflicts of Interest

Category: Operating Policies

Subcategory: General

Covered Individuals: Institutional Leaders, Researchers involved in Human Subjects Research

Responsible Executive: Vice President for Legal Affairs

Policy Custodian: Chief Compliance Officer

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544.1 PURPOSE AND SCOPE

Utah State University's (USU's) relationships with industry are important to advancing its mission and contributing to the public good. The university encourages industry relationships, while at the same time safeguarding the integrity and objectivity of the University's research, protecting university students and personnel, and ensuring the welfare of participants in USU research. At this time, Institutional Conflicts of Interest are restricted to conflicts arising from the outside interests of Institutional Leaders, as defined herein, and/or interests held by USU, itself, that involve sponsors of USU Human Subjects Research (HSR).

544.2 POLICY

USU shall maintain such controls as are necessary to protect participants in its HSR when Institutional Significant Financial Interests (ISFIs) held by USU or by its Institutional Leaders could significantly and directly affect, or reasonably be expected to affect, the design, conduct, reporting, review or oversight of human subjects research performed by USU.

2.1 The University shall maintain information related to institutionally-held ISFIs from appropriate sources in accordance with 544-PR1, "Disclosing Institutional Conflicts of Interest." This information shall be made available to the Institutional Review Board (IRB), University Ethics and Compliance (UEC), and Research Integrity and Compliance (RIC) in order to conduct appropriate screening for outside interests that could result in ICOIs or affect existing ICOIs, in accordance with 544-PR2, "Outside Interest Assessment and Institutional Conflict of Interest Determination."

2.2. The University is strictly prohibited from using non-public information to influence or appear to influence the management of its equity interests in any entity. All University personnel and agents shall act in a manner consistent with this prohibition.

2.3. Institutional officers or employees who expend or allocate financial resources on behalf of the University in their official positions, herein known as Institutional Leaders, shall disclose Significant Financial Interests as required under Policy 545, as well as any fiduciary role (director, officer or board member) in an external entity. Disclosures shall be updated annually, and whenever the individual's circumstances change such that an outside interest is created or reaches established thresholds, as required under Policy 545, "Individual Conflicts of Interest." UEC and RIC monitor financial interest disclosures from Institutional Leaders in accordance with Policy 545, and support the IRB as necessary in fulfilling its ICOI management objectives. COI officers may also assist the IRB in assessing the potential

that a disclosed SFI constitutes an ISFI that could affect the design, conduct, reporting, review or oversight of USU HSR.

2.4. The USU COIC shall receive reports of disclosed interests from Institutional Leaders as set forth in 2.3, above, and maintain access to USU-held ISFIs as processed under Section 2.1. Such interests shall be assessed both for individual Conflicts of Interest that are controlled under Policy 545, "Individual Conflicts of Interest," and for potential institutional conflicts related to their responsibilities for expending and allocating resources related to USU's HSR under their official university positions. For purposes of assessing the presence of an ICOI, equity positions held by these individuals shall be considered in accordance with thresholds established under the definition of ISFI in this policy.

2.5 The USU IRB, or such other IRB as may be authorized to review a HSR study, shall notify RIC and UEC whenever a study is identified as:

Being sponsored by an outside entity, or
Involving USU technology.

These circumstances will result in an assessment by UEC to determine if the circumstances would meet thresholds as set forth in Procedure 544-PR2 under "Notifications of Commercial Sponsors by the IRB."

2.6 When reviewing potential ICOIs related to USU's HSR, the COIC shall be expanded so that the review and deliberation of an ICOI includes two individuals who are members of the USU IRB. Identification of these individuals shall be by the Executive Director of Human Research Protections in cooperation with the Chair of the COIC. Other members may also be included as identified by the Chair of the COIC in consultation with Legal Affairs.

2.7 The COIC shall take such action as necessary to manage, reduce or eliminate outside interests held by Institutional Leaders that may be related to USU's HSR

2.8 No member of the COIC reviewing a potential ICOI may participate in deliberation or approval or disapproval of an ICOI Management Plan if the member has a conflict of interest in the ISFI, or has direct oversight of the financial interest or of a study which may be impacted by the ISFI. The Chair of the COIC shall invite members to disclose such conflicts before deliberations begin.

2.9. The expanded COIC shall promptly review the potential ICOI referred by the UEC and determine whether an ICOI exists, and if so, what management steps are necessary to mitigate, eliminate or otherwise manage an identified ICOI. Common management strategies include, but are not limited to, those outlined in procedure 544-PR3, "Development and Maintenance of Institutional Conflict of Interest Management Plans."

2.10. The USU IRB, or such other review board as USU may have been engaged to review USU HSR, shall have authority to review any ICOI management plan and approve it, require modifications to it, or reject it with regard to any research study under its jurisdiction as set forth in 544-PR3. No human subjects research may be conducted under USU's auspices that has not been approved by the appropriate Institutional Review Board.

544.3 RESPONSIBILITIES

3.1 UEC provides oversight of the ICOI process and coordinates the COIC when it is reviewing potential ICOIs. Under the direction of the Chief Compliance Officer, the UEC collaborates with Advancement, the Technology Transfer Office, Sponsored Programs, the Office of General Counsel, the IRB and others as

necessary to gather information about university-held financial positions as set forth in Procedure 544-PR1, "Disclosing Institutional Conflicts of Interest." The office also has responsibility for gathering disclosures of outside interests held by its employees and other agents, including Institutional Leaders as defined in this policy. UEC provides support in analyzing and implementing internal controls that manage ICOIs and maintains access to information about the university's interests in outside donors, sponsors and licensees that could give rise to ICOIs when those interests cannot be adequately managed through other existing internal controls.

3.2. Institutional Leaders are required to provide annual disclosures of their SFIs and other outside interests using the Quali System.

3.3. The COIC provides oversight of ICOIs as set forth in Section 2.4 through 2.7, above.

3.4. The USU IRB, or such other IRB as has been designated as the IRB of record for the HSR study, provides support to the COIC during deliberation and has final authority to accept, modify or reject the ICOI Management Plan with regard to HSR under its jurisdiction.

544.4 REFERENCES

- Title 2, Code of Federal Regulations, Section 200.112, "Conflict of Interest"
- Association for the Accreditation of Human Research Protection Programs, Element I.6.A of the Accreditation Standards

544.5 RELATED USU POLICIES

- Policy 545, "Individual Conflicts of Interest"
- Policy 517, "Investment Policy"
- Policy 529, "Procurement Policy"

544.6 DEFINITIONS

6.1 Institutional Conflict of Interest. The presence of an Institutional Significant Financial interest (ISFI) of the University or an Institutional Leader when it affects, or could reasonably be expected to affect, the design, conduct, reporting, review, oversight or related decision-making processes of the University related to USU's Human Subjects Research.

6.2. Institutional Leader. Any officer or employee of the university that has responsibility for the expenditure or allocation of university resources or has responsibility for the supervision of University programs and personnel. Individuals identified as Institutional Leaders shall include:

President

Vice presidents and associate vice presidents

Provosts and vice provosts

Deans and associate deans

General counsel and associate counsels

University signatories and designees

Department heads

Center directors

Others as identified by the Conflict of Interest Committee

Disclosures of Institutional Leaders shall include the Significant Financial Interests of close relatives or others the Institutional Leader reasonably knows may benefit personally from actions taken by the Institutional Leader on behalf of USU. If disclosure by relatives is required, the system or form collecting disclosures shall so indicate.

6.3. Institutional Significant Financial Interest. Institutional Significant Financial Interest means one or more of the following:

- If received by an Institutional Leader - consulting fees, advisory board fees, remuneration, or honoraria from an external entity that, when combined, exceeds \$5,000 annually from a single entity.
- If held by an Institutional Leader - a fiduciary role such as an officer or director in an external entity.
- If held by an Institutional Leader – an equity interest in a publicly traded business entity in excess of 5% of the outstanding equity of the entity.
- If held by an Institutional Leader or by USU itself - a directly held equity interest in a non-publicly traded business entity of any amount.
- If received by USU - cash or in-kind gifts which are restricted for use by a specific Department, Center or Institution that in total exceed a value of \$25,000 in any calendar year from an external entity, including any of the entity's affiliates.
- If received by USU – royalties or other technology licensing payments, including equity or entitlement to equity in a publicly traded company that sponsors research at USU, which taken together over a calendar year exceed \$25,000.
- If received by USU – Sponsored Research and other development agreements in excess or \$25,000 with outside entities if those agreements create any restrictions on disposition of intellectual property or data sharing.

Information below is not included as part of the contents of the official policy. It is provided only as a convenience for readers/users and may be changed at any time by persons authorized by the president.

RESOURCES

Procedures

- 544-PR1, Disclosing Institutional Conflicts of Interest
- 544-PR2, Outside Interest Assessment and Institutional Conflict of Interest Determination
- 544-PR3, Development and Maintenance of Institutional Conflict of Interest Management Plans

Guidance

- 546- G1, Common examples of Institutional Conflicts of Interest

Contacts

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