

Interim Rule 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects

I. Purpose and Scope

The University of Utah recognizes that certain interests held by the University and/or by its senior leadership could have the potential to compromise, or appear to compromise, the integrity of Research with Human Subjects conducted at the University. The purpose of this policy is to establish principles and practices to identify institutional conflicts of interest (ICOI) that have the potential to adversely affect Research with Human Subjects and to manage, reduce, or eliminate such conflicts. This policy promotes transparency and consistency in the identification, elimination, and/or plan of management of institutional conflicts of interest.

This Policy applies to all Research with Human Subjects at the University. This policy shall not limit University employee obligations for disclosure and/or management of other financial interests that are required by other University policies and procedures.

II. Definitions

- A. "University of Utah" includes all academic and administrative units of the University (including colleges, schools, departments, centers, institutes, or consortiums), subsidiary entities, including the University of Utah Research Foundation (UURF) and ARUP Laboratories, and University Officials as defined in this policy.
- B. "Family" for purposes of this policy means spouse/domestic partner and/or dependent children.
- C. An "Institutional Conflict of Interest" or "ICOI" exists when the University has a Significant Institutional Financial Interest with a company that is conducting Research with Human Subjects at the University of Utah.

- D. "Officers" means the President, Senior Vice Presidents, and Vice Presidents. Members of the Board of Trustees are governed by a separate conflict of interest policy and are not governed by this policy.
- E. "Other Senior Managers" includes Deans, Associate/Assistant Vice Presidents, and other individuals who make decisions with implications for Research with Human Subjects, including chairs and directors of the Institutional Review Board, Conflict of Interest Committee, and other committees designated by the ICOI Officer.
- F. "Unit Heads" includes Department Heads, Division Chiefs, and Directors of 1 University-designated Centers, Institutes, and Bureaus, and other individuals in leadership positions designated by the President or Senior Vice Presidents.
- G. "University Officials" includes Officers, Unit Heads, and Other Senior Managers.
- H. "Significant Individual Financial Interest" means a "Significant Financial Interest" as that term is defined in the University Conflict of Interest Policy, Policy 1-006.
- I. "Significant Institutional Financial Interest" or "SIFI" includes the following:
 - 1. An ownership interest in a company (e.g., stocks, stock options, or other ownership interests) of at least 5% of the company;
 - 2. Options or licenses to a company of University technology, including the royalties received for such licensing arrangements; and
 - 3. Significant Gifts from a company to the University.

However, Significant Institutional Financial Interest does NOT include institutional financial interests held in mutual funds and/or pension funds that are managed by an external agent.
- J. "Significant Financial Transaction" means any University transaction that would result in a Significant Institutional Financial Interest.

- K. "Significant Gifts" means gifts to the University of securities, other property, or cash exceeding \$50,000.
- L. "Research with Human Subjects" includes all research under the oversight, or potentially under the oversight, of the Institutional Review Board (IRB).

III. Policy

A. Institutional Conflict of Interest Officer (ICOI Officer)

The University President shall appoint an Institutional Conflict of Interest Officer (ICOI Officer) who reports directly to the President and to the Board of Trustees. The ICOI Officer has administrative oversight of this policy and shall report to the President and the Board of Trustees periodically and at least on an annual basis. The President may not terminate the employment of the ICOI Officer or reduce his or her compensation or reduce the financial support for the office of the ICOI without the approval of the Board of Trustees.

B. Activities That Are Not Allowed and/or Require Prior Approval

The University has determined that in order to protect the integrity of Research 2 with Human Subjects, certain arrangements present institutional conflicts of interest that generally cannot be managed. For this reason, the following activities are not allowed and/or require prior approval.

1. Activities Not Allowed

- a. Below the Office of Vice President for Research, the University shall maintain separate lines of authority between the offices responsible for technology development and commercialization and the offices responsible for Research with Human Subjects.
- b. University Officials may not accept personal gifts from sponsors of Research with Human Subjects in violation of the Utah Public Officers' and Employees' Ethics Act.

C. Reporting, Evaluation, and Management of ICOIs Related to Significant Institutional Financial Interests

1. Reporting of Significant Institutional Financial Interests (SIFIs)

- a. On a quarterly basis (or more frequently if requested by the ICOI Officer), the following University offices shall report University's SIFIs to the ICOI Officer:
 - i. The Investment Management Office shall provide a copy of its Investment Report.
 - ii. The Technology Venture Commercialization Office shall provide a list of companies that hold options or licensing rights to University of Utah intellectual property.
 - iii. The TVC / UURF shall provide a list of companies in which the University of Utah holds an equity interest of 5% or greater.
 - iv. Component Units of the University (e.g., ARUP Laboratories, the University Hospital Foundation, etc.) shall report to the ICOI Officer any significant institutional financial interests that the units hold in companies, excluding investments in mutual funds or pension funds.
 - v. The Office of Institutional Advancement shall provide a list of corporate donors whose contributions exceed \$100,000 dollars in any 4-year period of time.
- b. Prior to entering into any Significant Financial Transaction with a pharmaceutical company, medical device manufacturer, or any other company that is likely to engage in Research with Human Subjects, the University offices/units referenced above shall inform the ICOI Officer of the proposed transaction and request an ICOI determination before proceeding with the Significant Financial Transaction.

2. Reporting of Research with Human Subjects
 - a. On at least a quarterly basis (or more frequently if requested by the ICOI Officer), the Office of Sponsored Projects shall provide the ICOI Officer with a list of companies that are sponsoring Research with Human Subjects at the University.
 - b. Prior to entering into any new sponsored Research with Human Subjects, the Institutional Review Board (IRB) shall inform the ICOI Officer of the name of the sponsoring company(ies) and the nature of the human subjects research and request an ICOI determination before proceeding with Research with Human Subjects project. The IRB shall report any company that provides funding, materials, drugs, devices, and/or biologics used in the research.
3. Identification, Evaluation, and Management of Potential ICOIs for Proposed Research with Human Subjects
 - a. **Identification of Potential ICOIs:** Upon notification of proposed new Human Subjects Research, the ICOI Officer shall determine whether the proposed research, if allowed, would create an ICOI with an existing University SIFI. If the proposed research would not create an ICOI, the ICOI Officer shall inform the IRB that there is no conflict.
 - b. **Evaluation and Management of Potential Institutional Conflicts of Interest:** If the ICOI Officer determines that the proposed research would create an ICOI with an existing SIFI, the ICOI Officer shall conduct the following evaluation:
 - i. The ICOI Officer shall consult with the IRB to determine whether the proposed Research with Human Subjects presents a greater than minimal risk to the research participants.

- ii. If the Research with Human Subjects presents a greater than minimal risk, the ICOI Officer shall determine if an effective management plan can mitigate the effects of the ICOI. If the ICOI Officer determines that an effective management plan cannot be implemented, the University must choose either to retain its existing SIFI, or to eliminate the SIFI and pursue the Research with Human Subjects, but not both.
- iii. If the Research with Human Subjects presents only a minimal risk to research participants, the ICOI Officer may permit the research to proceed so long as the ICOI Officer is able to implement an effective management plan to mitigate the effects of the ICOI. If an effective management plan cannot be implemented, the University must choose either to retain its existing SIFI, or to eliminate the SIFI and pursue the Research with Human Subjects, but not both.
- iv. The ICOI Officer will convey this determination to the effected University units, which shall abide by that determination or appeal the decision as provided below.

4. Identification, Evaluation, and Management of Potential ICOIs for a Proposed Significant Financial Transactions

- a. **Identification of Potential ICOIs:** Upon notification of a new Significant Financial Transaction, the ICOI Officer shall determine whether the proposed transaction, if allowed, would create an ICOI with existing Research with Human Subjects. If the proposed transaction would not create an ICOI, the ICOI Officer shall permit the transaction to proceed.
- b. **Evaluation and Management of Potential Institutional Conflicts of Interest:** If the ICOI Officer determines that the proposed transaction would create an ICOI with existing Research with Human Subjects, the ICOI Officer shall conduct the following evaluation:

- i. The ICOI Officer shall consult with the IRB to determine whether the Research with Human Subjects at issue presents a greater than minimal risk to the research participants.
- ii. If the Research with Human Subjects presents a greater than minimal risk, the ICOI Officer shall determine if an effective management plan can mitigate the effects of the ICOI. If the ICOI Officer determines that an effective management plan cannot be implemented, the ICOI Officer shall not permit the Significant Financial Transaction to proceed unless the University terminates its Research with Human Subjects.
- iii. If the Research with Human Subjects presents only a minimal risk to research participants, the ICOI Officer may permit the Significant Financial Transaction to proceed so long as the ICOI Officer is able to implement an effective management plan to mitigate the effects of the ICOI. If an effective management plan cannot be implemented, the University must choose to pursue the Significant Financial Transaction or the Research with Human Subjects, but not both.
- iv. The ICOI Officer will convey his or her determination to the effected University units, which shall abide by that determination or appeal the decision as provided below.

D. Reporting, Evaluation, and Management of ICOIs Related to Significant Individual Financial or Other Interests of University Officials Employees at the University who have senior leadership responsibility may, by virtue of their University positions, have some ability to affect the design, conduct, or reporting of Research with Human Subjects conducted at the University. For this reason, employees in senior leadership positions are required to report their Significant Individual Financial Interests, and the University must ensure that these interests do not improperly influence Research with Human Subjects.

1. Reporting of Significant Individual Financial

- a. On an annual basis, every University Officer, every Unit Head and Other Senior Manager within the University of Utah Health Sciences Center, and every Unit Head and Other Senior Manager having any responsibility for Research with Human Subjects at the University, shall submit a report to the University (in the current individual COI reporting system) of their, and their family's, Significant Individual Financial Interests.
 - b. Individuals identified in the foregoing paragraph shall update their conflict of interest report within 30 days of when they acquire, or a family member acquires, a new Significant Individual Financial Interest.
2. Management of University Official Conflicts
- a. **Identification of Conflicts:** The ICOI Officer shall compare the interests disclosed by University Officials pursuant to this policy to the University's active Research with Human Subjects projects and identify any instances where a University Official or his or her family holds a Significant Individual Financial Interest relating to a sponsor of Research with Human Subjects.
 - b. **Reporting to Individual Conflict of Interest Committee:** The ICOI Officer shall report to the Individual Conflict of Interest Committee any circumstance where a University Official or his or her family holds a Significant Individual Financial Interest relating to a sponsor of Research with Human Subjects.
 - c. **Management of Potential Conflicts:** The University's Individual Conflict of Interest Committee shall determine whether an interest reported from the ICOI Officer has been previously considered by the Individual Conflict of Interest Committee. If the interest has not been previously considered, the Individual Conflict of Interest Committee shall proceed as follows:
 - i. The Individual Conflict of Interest Committee shall first determine whether the roles and responsibilities of the University Official give that

official any ability to influence the design, conduct, or reporting of the Research with Human Subjects. If the Committee answers this question in the negative, the Committee shall find no conflict.

- ii. If the Committee determines that the University Official's roles and responsibilities for the University make it possible for the individual to influence the design, conduct, or reporting of the Research with Human Subjects, the Individual Conflict of Interest Committee will find the individual to be an "investigator" within the meaning of Policy 1-006 and shall review and process the reported interest pursuant to its regular processes as set forth in Policy 1-006.

- d. **Analysis of New Research with Human Subjects Projects:** Upon receiving reports of new proposed Research with Human Subjects projects, the ICOI Officer shall determine whether any University Officials have reported Significant Individual Financial Interests relating to the research sponsor and shall report those interests to the Individual Conflict of Interest Committee for consideration and management as described above. The new Research with Human Subjects project shall not proceed until the Individual Conflict of Interest Committee completes its evaluation process pursuant to Policy 1-006.

E. Appeals of ICOI Officer Determinations:

Any University Official, office, or unit of the University affected by a decision of the ICOI Officer may appeal the decision to an appeals panel comprised of the two Senior Vice Presidents of the University and the Vice President of Research. In the event that the ICOI involves a Senior Vice President or the Vice President for Research, the President of the University or his or designee shall serve as the third member of the Panel in place of the conflicted vice president. The President and the Executive Committee of the Board of Trustees will be notified of all appeals at the time of the appeal. The decision of the Panel is final.

F. Consultation on ICOI Concerns

University Officials or any other faculty, staff, or students may consult the ICOI Officer on matters relevant to potential institutional conflicts of interest in the conduct of Research with Human Subjects. The ICOI Officer may initiate investigations and make determinations regarding potential ICOIs based on consults or queries from anyone in the University community or the general Utah community.

G. Violations and Sanctions

1. Investigation of Violations - Any allegation of a violation of this policy, including violations of a prescribed management plan, shall be presented to the ICOI Officer. The ICOI Officer shall promptly investigate the allegations. At the conclusion of the investigation, the ICOI Officer shall report his/her findings and recommendations to the University President who shall make the final determination on the recommendations.
2. Disciplinary and Other Administrative Actions
 - a. For violations of this Policy, the ICOI Officer may recommend to the cognizant vice president(s) that disciplinary action be taken against the individual, including but not limited to a reprimand, fine, probation, suspension, or dismissal. The ICOI Officer may proceed with a complaint against the individual before the appropriate University hearing body.
 - b. Other Administrative Actions - For violations of this policy, the ICOI Officer may recommend to the cognizant vice president(s) that one or more of the following administrative actions be taken:
 - i. Freeze research funds or otherwise suspend a project related to the policy violation;
 - ii. Withhold payment owed under a contract relating to the conflict;

- iii. Legal action to rescind University contracts entered into in violation of this Institutional Conflict of Interest Policy or of state law;
- iv. Criminal penalties pursuant to the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1, et seq.

3. Reporting to External Agencies and Sponsors

Conflict of interest violations will be reported to external agencies and sponsors to the extent necessary and appropriate as determined by the ICOI Officer.

4. Interim Administrative Action

In situations involving (1) the health or safety of any person or (2) the potential loss of significant University resources, the ICOI Officer may recommend, and/or a Senior Vice President may implement, any administrative action necessary to protect these persons and resources pending the outcome of the foregoing Procedures. Otherwise, no disciplinary or administrative action shall occur until the conclusion of the violation evaluation process set forth in this policy.

- H. **Records:** Case records of the ICOI Officer will be maintained in a secure manner for a minimum of seven (7) years after final case determinations are made or 8 retained as otherwise required by State or Federal law.

IV. Rules, Procedures, Guidelines, Forms and other Related Resources

- A. Rules
- B. Procedures
- C. Guidelines
- D. Forms

- E. Other related resource material

V. References

- A. Federal, State, and Local Laws:

1. Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq. 15 Utah Criminal Code, Utah Code Ann. § 76-8-105(1)

- B. Relevant University Regulations

1. [Policy 1-006](#), Individual Financial Conflict of Interest Policy
2. [Policy 5-111](#), Corrective Action and Termination Policy for Staff Employees
3. [Policy 6-316](#), Code of Faculty Rights and Responsibilities

VI. Contacts

The designated contact officials for this Policy are:

- A. Policy Owner (primary contact person for questions and advice): Research Integrity Officer
- B. Policy Officer: Vice President for Research
- C. These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provided in University Rule 1-001:

"A 'Policy Officer' will be assigned by the President for each University Policy, and will typically be someone at the executive level of the University (i.e., the President and his/her Cabinet Officers). The assigned Policy Officer is authorized to allow exceptions to the Policy in appropriate cases.... "

"The Policy Officer will identify an 'Owner' for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide

interpretation of the Policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to whom the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... [and] bears the responsibility for determining requirements of particular Policies... ." University Rule 1-001-III-B & E

VII. History

Policy 7-006 was implemented as an Interim Rule on _____to satisfy the University's accreditation requirements for the Accreditation of Human Research Protection Programs, Inc., pending final approval by the Academic Senate and the Board of Trustees.

Originally approved by the Academic Senate: _____

Originally approved by the Board of Trustees: _____