

Regulations Library

The University of Utah

Policy: 1-006 Rev: 10

Date: March 8, 2004

Policy 1-006: Conflict of Interest Policy

I. Purpose

The central mission of the University is to educate the individual through the dissemination, discovery, and refinement of knowledge. In its pursuit of excellence in teaching, research and service, the University is an institution based on the shared values of learning, diversity and inclusiveness, entrepreneurship, independent inquiry, respect for resources, collegiality, and community. Even when members of the University community work to accomplish this mission with these shared values, conflicts of interests may naturally arise that have the potential to impair the judgment of the individual in that work.

II. Policy

This Policy :

- A. describes the process by which the University identifies, evaluates and manages individual financial conflicts of interest without violating its central mission,
- B. uses disclosure as the key mechanism to bring potential conflicts of interest to light for evaluation and possible oversight,
- C. identifies individual conflicts of interest that are not allowed because they are a violation of law or are judged by the University to be a violation of its central mission.

It is the duty of every member of the University community to immediately disclose his or her personal or family involvement in activities listed in Activities Requiring Disclosure (**Section V**). Approval of the Conflict of Interest Committee must be obtained before engaging in these activities. It is forbidden for University employees to engage in any Activities That Are Not Allowed (**Section VI**).

III. References

- A. 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. National Science Foundation Policy; Grant Policy Manual 510, Investigator Disclosure Policy, 60 F.R.132, pp. 35810-823 (July 11, 1995).
- C. U.S. Department of Health and Human Services, Objectivity in Research Subpart F- 19 Responsibility of Applicants for Promoting Objectivity in Research for Which Funding is Sought, 42 CFR Part 50, Subpart F (for NIH Contracts, 45 CFR Part 94, Responsible Prospective Contractors).
- D. U.S. Department of Health and Human Services, Financial Disclosure by Clinical Investigators, 21 CFR Part 54.
- E. Anti-Kickback Act of 1986 (41 U.S.C. 51-58) and OMB A-110.
- F. **Policy 5-111**, Disciplinary Actions and Dismissal of Staff Employees.
- G. **Policy 5-210**, Employee Relations Procedures for Alleging Discrimination or Harassment

and for Initiating Staff Employment Grievances.

- H. **Policy 3-192**, Restricted Purchases and Special Procurement.
- I. **Policy 7-001**, Policy for Research Misconduct.
- J. **Policy 7-003**, Copyright Policy: Ownership Purpose and Scope.
- K. **Policy 6-400**, Code of Student Rights and Responsibilities.
- L. **Policy 6-316**, Code of Faculty Rights and Responsibilities.

IV. Definitions

- A. **Business entity** means a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation, or other organization or entity used in carrying on a trade or business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.
- B. **Clinical research** includes any research project dealing with humans, including trials sponsored by a medical industry corporation, or other private industry, departmental sponsored research, studies utilizing human tissues, social science research, and medical chart reviews.
- C. **Compensation** means anything of economic value, however designated, which is paid, loaned, granted, given, donated, or transferred to any person or business entity for or in consideration of personal services, materials, property, or the like.
- D. **Disclosure Form** is the form prepared by the Conflict of Interest Committee and used to disclose individual potential conflicts of interest.
- E. **Employee** means any person who is employed by the University, whether full or part time, and includes but is not limited to staff, faculty, postdoctoral appointees, residents and students. It also includes investigators as defined by the referenced federal policies and individuals who are not paid on a project (i.e., volunteers). However, this designation does not apply to members of the Board of Trustees nor to any other advisory commission, board, or committee serving on a part-time basis.
- F. **Family** means, for the purposes of this policy, spouse/domestic partner and/or dependent children.
- G. **Gift** includes money, non-pecuniary gifts, excessive compensation or non-commercial loans. For the purpose of this policy a gift does not apply to occasional non-pecuniary gifts that have an insignificant monetary value, as defined by the Utah Public Officers' and Employees' Ethics Act¹, that would not tend to improperly influence an employee in the discharge of his/her duties.
- H. **Intellectual property** means any ideas, inventions, technology, creative expression and embodiments thereof, in which a proprietary interest may be claimed, including but not limited to patents, copyrights, trademarks, know-how, and biological materials.
- I. **Investigator** includes the principal investigator and all faculty, staff, postdoctoral appointees, residents or students, whether paid by the University or not, who are responsible for the design, conduct or reporting of research or scholarly activities conducted in whole or in part at the University.
- J. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a sponsoring entity (see 42 CFR Part 50, Subpart F).
- K. **Significant financial or other interest** means anything of significant monetary value, including but not limited to salary or other payments for services; equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights). "Significant financial or other interest" also means the holding of a position as an officer, director, agent, or employee of a

business entity. "Significant financial and other interest" includes such interests held by the employee and by the employee's family members.

L. **However, significant financial or other interest does NOT include:**

1. salary, royalties, or other remuneration from the University;
2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. income from service on advisory committees or review panels for public or nonprofit entities;
4. an equity interest that when aggregated for the employee and the employee's family meets both of the following tests: less than \$10,000 in value as determined through reference to public prices or other reasonable measure of fair market value, and less than a five percent (5%) ownership interest in any single entity;
5. annual salary, royalties or other payments from any source other than those referenced in subparagraphs (1) and (2) above that individually do not exceed \$10,000 or, when aggregated for the employee and the employee's family over twelve months, are not expected to exceed \$10,000. The University does not consider royalties to present a potential conflict of interest other than those from educational materials required by a professor to be purchased for his/her class at the University;
6. income from mutual funds and/or pension funds;
7. a percentage of income received from the Veteran's Administration Medical Center as part of physician reimbursement for University faculty;
8. any ownership interests in a business entity if the business entity is an applicant for Phase I support under the Small Business Innovation Research (SBIR) Program.

M. **Small Business Innovation Research (SBIR) Program** means the extramural research program for small businesses that is established by the Awarding Components of certain Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For the purposes of this policy, the term SBIR includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

N. **Transaction** means a formal or informal contract or agreement, express or implied, to which the University is a party.

V. Activities Requiring Disclosure

A. Research and Scholarly Activity

1. Disclosure is required when an investigator has a significant financial or other interest that could affect the approval, design, conduct, or reporting of funded research.
2. Disclosure is also required when all of the following apply: 1) an employee or family member has a significant financial or other interest in a sponsor of research; 2) the employee has responsibility for designing, conducting or reporting the research; 3) the research will involve subordinates; and 4) the employee will provide an academic or employment evaluation of the subordinate based in part upon the subordinate's work on the research project, or restrictions will be placed on the publication rights of the subordinate.

B. Clinical Research

Disclosure is required when an investigator has significant financial or other interest involved with clinical research.

C. Intellectual Property

Disclosure is required when an employee is a named inventor of intellectual property

owned by the University and the employee has a significant financial or other interest in a business entity related to the intellectual property.

D. Procurement

1. Disclosure is required when a University employee, officer or a member of their family has a significant financial or other interest in a business entity proposing to enter into a transaction with the University, and that University employee, officer, or family member is in a position to influence the outcome of the University's decision on that transaction. Early disclosure prior to the procurement negotiation is encouraged.
2. Disclosure is required when an employee or family member has a significant financial or other interest in a business entity that provides goods or services, the University provides the same or similar goods and services, and the employee is in a position to direct potential purchasers of the goods and services away from the University and to the business entity. This provision does not cover consulting by faculty or staff.
3. The Utah Public Officers' and Employees' Ethics Act, Utah Code Annotated § 67-16-1 et seq. (the Ethics Act) requires disclosure of certain conflicts of interest to other entities including the state Attorney General's Office. University employees are responsible for complying with the Ethics Act.

VI. Activities That Are Not Allowed

The following activities present conflicts of interest that are not allowed because they are a violation of law or are judged by the University to be a violation of its central mission.

A. Academic Freedom Restrictions

1. Secrecy or confidentiality requirements are not allowed if they impact evaluation of a student, faculty member, or other employee, or if they delay fulfillment of degree requirements by more than the time contractually allowed for publication and/or protection of intellectual property rights (up to 6 months).
2. Arrangements are not allowed that permit a sponsor to interfere in the scientific analysis or with publication of research results or its conclusions except as mandated by force of law or governmental regulation.
3. Evaluation of faculty, postdoctoral appointees, staff, or students is not allowed to be based on participation in (or refusal to participate in) outside activities involving business entities in which the evaluating employee has a significant financial or other interest.

B. Clinical Research

1. Individual employees involved in a study, or their families, may not themselves, directly or indirectly, accept payments, incentives or gifts from sponsors of human subjects research.
2. Payments are not allowed from sponsors of human subjects research to accounts other than the investigators' restricted project account.

C. Intellectual Property

Involvement by an employee in the process of negotiating a license on behalf of the University with a business entity in which the employee has a significant financial or other interest is not allowed.

D. Solicitation or Receipt of Gifts

Solicitation or receipt of a gift by a University employee, whether directly or indirectly through the institution, is not allowed, where (1) the purpose or effect of the gift is likely to improperly influence the employee in the discharge of his/her University responsibilities; (2) the gift is given to reward the employee for official action taken; or

(3) the gift is given in close proximity² to recent past, present or future transactions between the University and the giver of the gift.

VII. Conflict of Interest Committee

- A. The Conflict of Interest Committee shall be a University standing committee whose voting members are nominated by the Personnel and Elections Committee of the Academic Senate and appointed by the President for three year terms.
- B. The Committee shall follow the Procedures set forth in Procedure (Section VIII) to:
 1. gather conflict of interest disclosures,
 2. determine whether a conflict of interest exists; and, if so,
 3. determine the proper level of management of the conflict.
- C. The Committee shall be a University-wide committee, comprising 15 voting members: 3 staff members from across the University, 3 faculty from Health Sciences, 2 faculty from the College of Engineering, 2 faculty from the College of Science, 4 faculty from the other academic units of the University, and one at-large member. The Committee shall also include 6 non-voting, ex-officio participants including the Director of Sponsored Projects, the Director of Technology Transfer, the Director of the Institutional Review Board, the Conflict of Interest Officer, the Director of Procurement & Supply Management, and a representative from the University's Office of General Counsel. The Committee may choose to include other non-voting 'ad-hoc' participants to assist in discussions and decisions as needed.
- D. A Conflict of Interest Officer and other Committee staff as needed shall be employed by the University and adequate resources allocated to support the duties of the Conflict of Interest Committee.
- E. A committee member shall be recused from discussion and voting on a particular case if:
 1. The committee member has a compelling personal interest in the case (such as research or academic collaboration with the employee whose case is under consideration); or
 2. The committee member has a financial interest in the case under consideration.

VIII. Procedure

This policy uses disclosures as the key mechanism to bring potential conflicts of interest to light for evaluation and possible oversight.

- A. Disclosure consists of completing and submitting a conflict of interest Disclosure Form prior to engaging in any activities specified in Section III. When making a conflict of interest disclosure, an employee may, at his or her option, include a proposed management plan. A proposed management plan shall include the name and position of the person responsible for plan oversight.
- B. Conflict of interest Disclosure Forms must be filed any time a new potential conflict of interest arises.
- C. Questions concerning activities specified in Sections III and IV should be submitted to the Conflict of Interest Committee through the Conflict of Interest Officer.
- D. Employees must submit the conflict of interest Disclosure Form to the Conflict of Interest Committee through the Conflict of Interest Officer.
- E. The Conflict of Interest Officer, on behalf of the Conflict of Interest Committee, will determine, for each disclosure, whether a conflict of interest exists that requires the review of the Conflict of Interest Committee. The employee and his/her department chair will be notified if the Conflict of Interest Officer has referred a disclosure to the Conflict of Interest Committee.
- F. The Conflict of Interest Committee will review each disclosure received from its Conflict of

Interest Officer.

1. The Conflict of Interest Officer shall be available to consult with any employee to help develop an acceptable management plan.
 2. If the Disclosure contains a proposed management plan, the Conflict of Interest Committee will first determine whether a conflict of interest exists. If it is determined that a conflict of interest exists, then the Conflict of Interest Committee will determine whether the proposed management plan is acceptable. The employee will be given an opportunity to provide any additional information pertaining to the potential conflict or the proposed management plan to the Conflict of Interest Committee.
 3. If the Disclosure does not contain a proposed management plan, the Conflict of Interest Committee will determine whether a conflict of interest exists. The employee will be given an opportunity to provide any additional information pertaining to the potential conflict of interest. If the committee determines that a conflict of interest exists, it will notify the employee and the employee's chair or supervisor. For the activity to proceed the employee shall then propose a management plan including the name and position of the person responsible for plan oversight.
 4. Upon receiving a proposed management plan from the employee, the Conflict of Interest Committee will determine whether the Management plan is acceptable. The Conflict of Interest Committee will transmit its decision to the employee, the employee's chair, and the appropriate University entities (e.g., Institutional Review Board, Office of Sponsored Projects, Technology Transfer Office, Procurement & Supply Management, Graduate School)
 5. The University will adhere to research sponsor requirements for reporting of disclosure and management, reduction or elimination of conflicts of interest.
- G. Appeals of any decision of the Conflict of Interest Committee concerning the existence of a conflict of interest or acceptability of a proposed management plan may be made to the cognizant vice-president.
- H. Subject to the requirements of confidentiality specified in the following section, and upon request of any employee, the Conflict of Interest Officer shall communicate decisions by the Conflict of Interest Committee in connection with any determination of whether a conflict of interest exists and whether a management plan is acceptable. Such communication shall contain the salient facts for the situation, the relevant sections of the Conflict of Interest Policy, and the decision of the Conflict of Interest Committee. Such public disclosures shall not contain the name of any employee or any other information deemed to be confidential.

IX. Confidentiality

All records and information provided by an employee for the purpose of disclosure and management and all official records of disclosure and management shall be considered confidential. Any information disclosed by an employee as required by this policy shall be used solely for the purpose of administering this policy and may not be used for any other purpose unless required by law. Unauthorized disclosure of any such information by an employee shall be deemed to be unethical behavior and shall be punishable under **Policy 5-111** or **Policy 6-316, Section 4 & Policy 6-316, Section 5**

X. Violations and Sanctions

A. Investigation of Violations

Reports of violations of this policy, including violations of a prescribed management plan, shall be presented to the Conflicts of Interest Committee through the Conflict of Interest Officer. Within five (5) business days of receiving a report, the Conflicts of Interest Committee shall provide a copy of the report to the subject of the allegations and request a written response for the Committee's consideration. Within thirty (30) days of receiving notice of an alleged violation, the Committee shall conduct an investigation into the allegations and determine whether the policy has been violated.

During the investigation, the Committee shall review the report of violation, any response, and any other relevant documentary material. The Committee may also conduct interviews of the person submitting the report, the subject of the allegations, and any other persons believed to have pertinent factual knowledge of the allegations.

B. Sanctions and Discipline

1. For violations of this policy, the Committee may recommend one or more of the following disciplinary and/or administrative actions
 - a. Proceedings for employee or student discipline (including but not restricted to: reprimands, fines, probation, suspension, dismissal, the freezing of research funds, other research restrictions, etc.) pursuant to 1) the Code of Faculty Rights and Responsibilities, **Policy 6-316, Section 5, Sanctions & 6-316, Section 6**, Procedures: Complaints) staff disciplinary policies and procedures, **Policy 5-111 & 5-210, Section 5**) the Code of Student Rights and Responsibilities, **Policy 6-400**; or 4) the Policy for Research Misconduct, **Policy 7-001**;
 - b. Withholding payment owed under a procurement contract relating to the conflict;
 - c. Legal action to rescind University contracts entered into in violation of this Conflict of Interest Policy or of state law;
 - d. Legal action to recover the amount of financial benefit received by an employee as a result of his or her violation of this policy;
 - e. Other similar and appropriate actions.
2. If the Committee determines that the subject of the allegations has not violated this policy, the Committee shall provide written notice of its findings to the person providing the report and to the subject of the allegations. This determination may be appealed pursuant to Section VIII(G) of this policy.
3. If the Committee determines that the subject of the allegations has violated this policy, the Committee shall present its findings and recommendations to the cognizant vice president. The Committee shall also provide contemporaneous notice of the findings and recommendations to the person submitting the original report and the subject of the allegations.
4. Within ten (10) business days of delivery of notice of the Committee's findings and recommendations, the subject of the allegations may provide the cognizant vice president with a written response to the Committee's findings and recommendations.
5. The cognizant vice president shall consider the Committee's findings and recommendations and any timely written response from the subject of the allegations. The vice president shall, within thirty (30) days of receiving notice of the Committee's findings and recommendations, provide written notice of his/her intended course of action to the Committee, to the subject of the allegations, and to the person who submitted the original report. Thereafter, the vice president may pursue any disciplinary action and/or impose that course of action.
6. In situations involving (1) the health or safety of any person or (2) the potential loss of significant University resources, the Committee may recommend and/or the cognizant 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.
7. Violations of this policy may also result in criminal penalties pursuant to the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1, et seq.
8. The remedies provided or referenced above are cumulative and shall be deemed to include any other remedies required or provided by applicable state or federal law.

9. Conflict of interest violations will be reported to external agencies and sponsors to the extent required by law.

XI. Related Topics Not Addressed by this Policy

- A. **Policy 5-204**, Remunerative Consultation and Other Employment Activities, and **5-403**, Additional Compensation and Overload Policy, discuss conflicts of commitment of time and use of University name, property, facilities or resource.
- B. **Policy 4-005**, Use and Security of Property, discusses use of property, supplies and services purchased with University funds.
- C. **Policy 7-004**, University Faculty Profit-Making Corporations, discusses conflicts of commitment.
- D. **Policy 7-013**, Patents and Inventions, discusses requirements for transfer of University technology and other intellectual property.
- E. **Policy 6-316**, Code of Faculty Rights and Responsibilities, discusses use of the University's name or property.
- F. Institutional Conflicts of Interest are not covered by this policy.

XII. Rules, Procedures, Guidelines, Forms and other related resources.

- A. Rules
 1. Rule 1-001 (**R1-001**)
- B. Procedures
- C. Guidelines
- D. Forms
- E. Other related resource materials.
 1. School of Medicine Industry Relations: Supplemental Rule **SOM-001**

XIII. Contacts:

Policy Owner: Questions about this Policy and any related Rules, Procedures, and Guidelines should be directed to **General Counsel** or **Chair of the Conflict of Interest Committee**

Policy Officer: Only the **Vice President and General Counsel, Vice President for Research**, or their designee have the authority to grant exceptions to this policy.

(1) As of January 2003, the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq. permitted occasional nonpecuniary gifts not exceeding \$50.00.

(2) In conformity with the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-5 et seq.

Approved Academic Senate: 2/02/04

Approved Board of Trustees: 3/08/04