



Approvals:  4/17/12  
Michael Hardman, Interim Sr. Vice President for Academic Affairs Date  
 4/17/12  
Vivian Lee, Sr. Vice President for Health Sciences Date

**Memorandum**

To: Interim Sr. Vice President for Academic Affairs Michael Hardman, Sr. Vice President for Health Sciences Vivian Lee.

From: Jeffrey R. Botkin, Associate Vice President for Research Integrity  
Bruce K. Gale, Conflict of Interest Committee Chair

**Subject: Proposed revisions of University Policy 1-006, Individual Financial Conflicts of Interest**

Date: April 16, 2012

This is a proposal for revising University Policy 1-006 regarding individual conflicts of interest.

**I. Background**

Revision of the University Individual Financial Conflict of Interest Policy (1-006) was initially undertaken in response to an Internal Audit Report issued on January 7, 2009. A policy revision team was formed under the direction of Dr. Jeffrey R. Botkin, Associate Vice President for Research. The policy revision team met regularly during 2009 and presented a draft of the revised policy to the Conflict of Interest Committee in February 2010. In response to the COI Committee's review and recommendations, additional modifications were made during March and April 2010.

On May 21, 2010, the Department of Health and Human Services (DHHS) issued a Notice of Proposed Rule Making for Financial Conflicts of Interests in the Federal Register. Dr. Botkin submitted comments about the proposed rule on behalf of the University to DHHS in July 2010. A decision was made to delay University policy changes pending final rules from DHHS. On August 25, 2011, DHHS issued a Final Rule<sup>1</sup> in the Federal Register. The policy revision team was reconvened in the Fall of 2011 to incorporate the requirements of the final rule into the University policy. The University must comply with the new DHHS regulations by August 24, 2012.

The University policy has traditionally required COI disclosures when faculty or staff are involved in relevant activities such as research, intellectual property development, or procurement activities. That is, the COI policy does not require an annual disclosure of financial relationships for all faculty and staff (although annual disclosure of external financial relationships is required by the SOM for faculty). This "event-based" approach has been maintained in this revision to reduce the administrative burden and privacy concerns for faculty and staff who are not involved in activities for which financial COI's are considered relevant.

## II. Summary of Major Changes incorporated in the proposed revision, as Recommended by the COI Policy Revision Team

One feature of the proposal is to remove certain topics from within Policy 1-006 itself, and move them into other accompanying Regulations, including a new University Rule, and “Procedures.” More importantly, it is proposed that significant substantive changes be made within the Policy (or in the former contents of the Policy being moved into other forms of Regulations).

The proposed substantive changes in University policy are in compliance with NIH, NSF, and FDA requirements. In general, the revised policy, rules and procedures apply the same requirements for the whole University community regardless of the source of funding. In certain circumstances highlighted in italics below, we propose applying DHHS standards only to DHHS funded research. In certain circumstances, as highlighted in italics below, the proposed policy establishes disclosure and management requirements that exceed the minimum requirements of DHHS policy.

### **Disclosure Requirements**

#### **Significant Financial Interest**

The revised definition of a “significant financial interest” to be reported to the University lowers the de minimis thresholds to include:

1. For publicly traded business entities, any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the business entity as of the date of disclosure, when aggregated, exceeds \$5,000.
2. For non-publicly traded business entities, any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest.
3. Intellectual property rights and interests (e.g., patents, copyrights), when the patent application is filed or when the copyright is asserted or upon receipt of income related to such rights and interests, including royalty income from intellectual property owned by the University of Utah Research Foundation. *Disclosure is only required upon the receipt of income related to intellectual property rights in the DHHS policy, not anticipated future income.*

The revised University policy requires disclosure of royalties received from the University for University owned IP. *Disclosure of royalties from the University is not required by federal policy.*

The exemption for SBIR/STTR Phase I projects is eliminated.  
*This exemption is not eliminated in the DHHS policy.*

#### **Disclosure of a wider array of financial interests to the University**

Disclosers are required to provide information about all significant financial interests that reasonably appear to be related to their institutional responsibilities, as defined by an individual’s department or job description. The University, rather than the investigator or employee, assumes responsibility for determining if a significant financial interest is relevant to a particular project or activity.

#### **Disclosure of travel**

*(applies only to investigators participating in PHS sponsored research)*

The occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the discloser’s institutional responsibilities must be disclosed unless the travel is reimbursed or sponsored by the following: federal, state, or local government agency, an

institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. All travel expenses reimbursed through the University are exempt from disclosure.

**Disclosures updated on a more frequent basis**

The policy retains the current trigger mechanisms for soliciting disclosures from investigators and employees engaged in the following: research and scholarly activities, intellectual property commercialization and procurement. Additionally, investigators and employees are required to update their disclosures at least annually and within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest that is related to their professional responsibilities to the University.

**Stricter Standard for Human Subjects Research**

The revised policy incorporates the “rebuttable presumption” for human subjects research, as recommended by the AAMC-AAU.<sup>2</sup> This stricter standard requires the Conflict of Interest Committee to apply a presumption against the conduct of research with human subjects in any circumstance where the individual has a conflict of interest relating to the research. The Committee may approve conduct of the research by the individual only upon a finding of compelling circumstances and only when the Committee can craft an effective management plan to mitigate the conflict. Otherwise, the conflict must be eliminated or the conflicted individual may not be involved in the research project. *The “rebuttable presumption” standard is not required by DHHS policy.*

**Confidentiality and Public Accessibility**

The revised policy clarifies that the University will comply with federal and state laws that may require public disclosure of information relating to identified conflicts of interest. This includes making certain required information<sup>3</sup> available to the public about the conflicts of interest of senior/key personnel participating in PHS funded research. This information will be made available on a publicly available web site. Additionally, the University may require public disclosure on the web site as part of a conflict management plan when appropriate under other circumstances, such as conflicts of interest involving human subjects research.

**Conflict of Interest Training**

All disclosers are required to complete COI training prior to submitting a disclosure. Investigators participating in PHS funded research will be required to complete COI training at least every four years and under certain other circumstances outlined in the rule.<sup>4</sup>

**Strengthened Compliance Monitoring**

*(required for most conflicts including all conflicted investigators participating in PHS sponsored research)*

When the COI Committee determines that a conflict of interest exists that requires a management plan, the management plan will in most cases require investigators and employees to submit reports on a regular interval (usually annually) to certify their compliance with the approved management plan.

**Non-compliance: retrospective reviews and a mitigation reports**

*(required only for investigators participating in PHS sponsored research)*

Whenever a conflict of interest is not identified or managed in a timely manner,<sup>5</sup> the University must complete a “retrospective review”<sup>6</sup> of the investigator’s activities and the PHS funded research project to determine whether any PHS funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. If bias is found, the University must notify NIH promptly and submit a mitigation report<sup>7</sup> to the NIH.

### **Strengthened Committee Authority**

For non-compliance with the COI policy, the Committee has the authority to:

- a. Freeze research funds, or otherwise suspend, a project or projects related to the policy violation;
- b. Remove the individual found to be in violation from a role as Principal Investigator or Investigator on a project or projects related to the policy violation;
- c. Prohibit submission of new applications to the Institutional Review Board and/or the Office of Sponsored Projects until resolution of the relevant COI issues or for a specified period of time;
- d. Other restrictions as may be deemed appropriate by the Committee.

### **Modified Appeals Process**

In the current policy, the decisions made by the COI Committee may be appealed to the cognizant vice president. As revised, decisions made by the COI Committee may be appealed to a panel that includes the Senior Vice President for Academic Affairs, the Senior Vice President for Health Sciences, and the Vice President for Research.

### **Ongoing work on a companion policy on institutional conflicts of interest.**

An Institutional Conflict of Interest Policy was drafted in 2010 pursuant to a request from President Young. This draft policy addresses potential conflicts of interest at the institutional level and addresses conflicts that may arise in University ownership interests, licensing arrangements, gifts to the University, and external financial interests of senior administration officials. The draft policy calls for a separate Institutional Conflict of Interest Committee and Institutional Conflict of Interest Officer than in Policy 1-006. The Officers and Committees will communicate and collaborate when issues or conflicts are individual and institutional in nature.

### **III. Proposal development process—consultation.**

This proposal was developed by revision team consisting of  
Jeffrey R. Botkin, Associate Vice President for Research  
Past and present COI Committee Chairs:

James Herron (Pharmaceutical Chemistry)  
Richard Kanner (Internal Medicine)  
Bruce Gale (Mechanical Engineering)

Past and present COI Committee Members:  
Daniel Levin (Political Science)  
Howard Mann (Radiology)  
Leslie Francis (Law)

Ex-Officio COI Committee Members:  
Robert Payne (Office of General Counsel)  
Jahn Barlow (Conflict of Interest Office)

Also consulted:  
Brent Brown (Office of Sponsored Projects)  
Rajiv Kulkarni (Technology Commercialization Office)

The revised policy was presented to the Conflict of Interest Committee on January 5, 2012. The proposal was also discussed with Dr. Lorris Betz, Dr. David Pershing, Dr. Lee, Dr. Thomas Parks and John Morris on February 21, 2012. It was reviewed by the Institutional Policy Committee on March 30, 2012.

**Contact information:** Questions or concerns about this proposal may be directed to Jeff Botkin, Associate Vice President for Research Integrity, Jeffrey.Botkin@hsc.utah.edu, (801) 581-7170.

#### **IV. Proposal contents.**

The proposal materials consist of (i) this memorandum, (ii) "clean" versions of the revised contents of Policy 1-006 and drafts of Rules 1-006A, 1-006B and Procedures 1-006 and (iii) redline marked versions showing specific changes being proposed from current to new Policy 1-006.

If you approve of the proposal, **please sign and forward for consideration by the Academic Senate and Board of Trustees.**

#### ***Footnotes:***

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<sup>1</sup> Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)

<sup>2</sup> AAMC-AAU (Association of American Medical Colleges-Association of American Universities). Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research. Washington, DC: AAMC; 2008. Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research

<sup>3</sup> The information that the institution makes available via a publicly accessible web site or written response shall include, at a minimum, the following: Investigator's name; Investigator's title and role with respect to the research project; Name of the entity in which the Significant Financial Interest is held; Nature of the Significant Financial Interest; and Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

<sup>4</sup> Investigators participating in PHS sponsored research are required to complete COI training immediately under these designated circumstances: COI policies change in a manner that affects Investigator requirements, an investigator is new to an institution or the institution finds that an investigator is not in compliance with the COI policy or management plan.

<sup>5</sup> Failure to identify and manage a conflict of interest in a timely manner includes Failure by the Investigator to disclose a Significant Financial Interest that is determined by the University to constitute a Financial Conflict of Interest; Failure by the University to review or manage such a Financial Conflict of Interest; or Failure by the Investigator to comply with a Financial Conflict of Interest management plan.

<sup>6</sup> The Institution must document the "retrospective review" and include at least the following key elements: Project number; Project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; Name of the Investigator with the FCOI; Name of the entity with which the Investigator has a financial conflict of interest; Reason(s) for the retrospective review; Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.); Findings of the review; and Conclusions of the review.

<sup>7</sup> The mitigation report must include, at a minimum, the key elements documented in the retrospective review, a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

# Policy 1-006: Individual Financial Conflict of Interest Policy

Revision 11. Effective date August 20, 2012.

## I. Purpose and Scope

The A 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, financial conflicts of interests may naturally arise that have the potential to impair the judgment of the individual in that work.

This Policy describes the process by which the University identifies, evaluates and manages financial conflicts of interest of individuals without violating its central missions. It uses disclosure as the key mechanism to bring potential financial conflicts of interest to light for evaluation and possible oversight. This Policy also identifies types of financial conflicts of interest in which individuals are not allowed to engage because they would be in violation of law or are judged by the University to be in violation of its central missions. This Policy establishes the Individual Conflict of Interest Committee and Officer to administer implementation of the Policy. This Policy is not intended to directly govern financial conflicts of interest of the University as an *institution*, a subject governed by other regulations. [See Policy ###.]

**{Drafting note: Work is underway on a University *Institutional* Conflict of Interest Policy. The citation to that Policy will be inserted here once approval is completed.}**

## 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. II. Definitions

- A. **Business entity 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. Business Entity does not include federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.
- 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. ~~**B. Compensation** means anything of economic value, however designated,~~

which is paid, loaned, granted, given, donated, or transferred to any person or ~~business entity~~ 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.~~
- C. **Disclosure Form** is the personal financial information provided to the Individual Conflict of Interest Committee by an Investigator or Employee which shall include a complete description, including dollar amounts or percentages of ownership, for all Significant Financial Interests related to their professional responsibilities to the University.
- ~~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.~~
- D. **Employee** means, for the limited purposes of this Policy, any individual who is employed by the University, whether full or part time, and includes but is not limited to staff, faculty, postdoctoral fellows, medical housestaff, educational trainees and students.
- ~~F.E. **Family Member** means, for the limited purposes of this policy Policy, spouse/domestic partner and/or dependent and/or minor children. (Domestic partner is further defined in University Rule 5-200A.)~~
- ~~G.F. **Gift** includes money, non-pecuniary gifts, excessive compensation or non-commercial loans. For the purpose of this policy 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 Act [Fn<sup>1</sup>], that would not tend to improperly influence an employee Employee in the discharge of his/her duties.~~
- G. **Human Subjects Research** is any research that has been designated "human subjects research" by the University's Institutional Review Board.
- H. **Intellectual property Property** means any ideas, inventions, technology, creative expression and embodiments thereof, in which a proprietary interest may be is 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.~~

- I. Investigator means an individual, regardless of whether or not an Employee of the University as defined in this Policy, who is the project director or the principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research or scholarly activities conducted in whole or in part under the auspices of the University, which may include for example, collaborators, consultants and/or subaward or subcontract recipients.
- J. **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). 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.~~
- K. Significant Financial Interest means a financial interest consisting of one or more of the following interests of the individual Investigator or Employee (and those of the Investigator's or Employee's Family Member as defined in this Policy) that reasonably appear to be related to the Investigator's or Employee's responsibilities to the University, as defined by an individual's department or job description [Fn<sup>2</sup>]:
1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received by the individual from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  2. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received by the individual from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3. Intellectual property rights and interests (e.g., patents, copyrights), when the patent application is filed or when the copyright is asserted or upon receipt of income related to such rights and interests, including royalty income from Intellectual Property owned by the University of Utah Research Foundation.

~~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.~~

L. ***However, Significant Financial Interest does NOT include:***

1. Salary, travel reimbursements or other non-royalty remuneration from the University if the Investigator is currently employed or otherwise appointed by the University;
2. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an

academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;

3. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
4. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

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

### III. Policy

A. General requirements (disclosure, prohibited activities). It is the duty of every individual member of the University community to disclose in a timely manner his or her personal or Family Member's involvement in activities listed as Activities Requiring Disclosure (Section III-B). Approval of the Individual Conflict of Interest Committee must be obtained before engaging in these activities. It is forbidden for individual University Employees or Investigators to engage in any Activities That Are Not Allowed (Section III-C).

#### ~~V.~~ B. Activities Requiring Disclosure

##### ~~A.~~ 1. 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.~~

- a. Investigators. Disclosure is required when an Investigator is responsible for the approval, design, conduct, or reporting of sponsored research conducted in whole or in part under the auspices of the University.
- b. Employees. Disclosure is required when an Employee or his/her Family Member has a Significant Financial Interest related to research or scholarly activities involving University subordinates or students and the Employee has responsibility for the subordinates' or students' employment and/or academic evaluations.
- c. Other individuals. Disclosure is required when a student or postdoctoral scholar or his/her Family Member has a Significant Financial Interest and submits an individual application for fellowship or other research support under the auspices of the University.

~~B. Clinical Research~~

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

2. Human Subjects Research

Disclosure is required when an Investigator is responsible for the design, conduct, or reporting of human subjects research conducted in whole or in part under the auspices of the University.

Research with human subjects must receive the highest level of protection from bias or appearance of bias created by an individual's conflict of interest. Consequently, the University shall apply a presumption against the conduct of research with human subjects in any circumstance where the individual has a conflict of interest relating to the research. The Individual Conflict of Interest Committee may approve conduct of the research by the individual only upon a finding of compelling circumstances and only when the Committee can craft an effective management plan to mitigate the conflict. Otherwise, the conflict must be eliminated or the research project shall not be conducted by the individual.

~~C. 3. 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.~~

Disclosure is required prior to the negotiation of any licensing agreements when an Employee is a named inventor on an invention disclosure and the Employee or his/her Family Member has a Significant Financial Interest in a Business Entity related to the Intellectual Property.

D. 4. Procurement

1. a. ~~Disclosure is required when a University employee, officer or a member of their family~~ an Employee or his/her Family Member has a significant financial or other interest Significant Financial Interest in a business entity Business Entity proposing to enter into a transaction with the University, and that ~~University employee, officer, or family member~~ Employee 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. b. ~~Disclosure is required when an employee or family member~~ an Employee or his/her Family Member has a significant financial or other interest Significant Financial Interest in a business entity Business Entity that provides goods or services, the University provides the same or similar goods and services, and the employee Employee is in a position to direct potential purchasers of the goods and services away from the University and to the business entity Business Entity. ~~This provision does not cover consulting by faculty or staff. This provision does not otherwise limit consulting by faculty or staff as defined under Policy 5-204.~~
3. c. 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. C. Activities That Are Not Allowed (Prohibited Activities)

The following activities present conflicts of interest ~~that~~ in which individuals are not allowed to engage because they ~~are a~~ would be in violation of law or ~~are~~ judged by the University to be a in violation of its central missions.

A. 1. Academic Freedom Restrictions

1. a. 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.~~

~~b. Investigators shall not permit a sponsor to compromise the integrity of the scientific analysis or the publication of research results or its conclusions.~~

~~3. c. Evaluation of faculty, ~~postdoctoral appointees~~, staff, medical housestaff, educational trainees or students is not allowed to be based, in whole or in part, on participation in (or refusal to participate in) ~~outside~~ non-University activities involving ~~business entities~~ Business Entities in which the evaluating employee Employee or Investigator has a significant financial or other interest Significant Financial Interest. The participation of faculty, staff, medical housestaff, educational trainees or students in non-University activities involving such Business Entities shall not be required or expected.~~

~~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.~~

~~2. Human Subjects Research~~

~~Individual Investigators or Employees participating in the design, conduct or reporting of a human subjects research study, or their Family Members, shall not, directly or indirectly, accept any incentives or gifts from a Business Entity that is sponsoring or providing support for the study. Payments to the University from Business Entities that are sponsoring or providing support for the study shall only be deposited into the investigators' restricted project account established for the study, unless otherwise approved by the Vice President for Research.~~

~~C. 3. Intellectual Property~~

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

~~D. 4. Solicitation or Receipt of Gifts [Fn<sup>1</sup>]~~

~~Solicitation or receipt of a gift by a University employee Employee, whether directly or indirectly through the institution, is not allowed, ~~where~~ when (1) (a) the purpose or effect of the gift is likely to~~

improperly influence the employee Employee in the discharge of his/her University responsibilities; (2) (b) the gift is given to reward the employee Employee for official action taken; or (3) (c) the gift is given in close proximity<sup>2</sup> [Fn<sup>3</sup>] to recent past, present or future transactions between the University and the giver of the gift.

## VII.—~~Conflict of Interest Committee~~

**{Drafting note: The general requirements of the Individual Conflict of Interest Committee have been relocated to Section III-E below. Additional details about the Committee have been removed from this Policy and are included in the draft of supplemental Rule 1-006A.}**

- 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

**{Drafting note: The general responsibilities of individual Investigators and Employees have been relocated to Section III-D below. Additional details about the Committee have been removed from this Policy and are included in the draft of supplemental Procedures.}**

~~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.~~

D. Investigator and Employee Disclosure Responsibilities

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

1. Each Investigator or Employee engaged in any activities specified in Section III-B is required to complete financial conflict of interest training offered by the University.
2. Each Investigator or Employee must personally complete and submit a Disclosure Form prior to engaging in any activities specified in Section III-B.
  - a. The Investigator or Employee must provide complete and accurate information about all Significant Financial Interests

that reasonably appear related to his/her professional responsibilities to the University.

b. The Investigator or Employee will not engage in any activities specified in Section III-B until the Individual Conflict of Interest Committee determines whether a Significant Financial Interest creates a financial conflict of interest for the Investigator or Employee and approves a plan to manage, reduce or eliminate any such conflicts.

3. Once a Disclosure Form has been required by the University, each Investigator or Employee must update his/her Disclosure Form at least annually and within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest that is related to his/her professional responsibilities to the University [Fn<sup>2</sup>].

4. Investigators participating in research funded by the Public Health Service (PHS) must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their responsibilities to the University [Fn<sup>4</sup>]; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

#### E. Individual Conflict of Interest Committee

1. The Individual Conflict of Interest Committee is hereby established as a University standing committee. The voting members shall be nominated by the Personnel and Elections Committee of the Academic Senate and appointed by the President of the University to serve for three year terms. A majority of the voting members shall be University faculty. The Committee shall be a campus-wide committee with broad representation from across campus. The President shall also appoint non-voting ex-officio participants from relevant administrative offices. Further details of the membership structure may be specified in a University Rule associated with this Policy, to be approved as per Policy 1-001. **{Drafting note: Because the further details of the membership structure are to be specified in a University Rule, and the process for approval of University Rules requires that they be submitted to the Senate these details will effectively be subject to Senate review and approval.}**

2. The Committee is charged with:

- a. providing education and training to members of the University community about financial conflicts of interest and how they can be effectively managed, reduced or eliminated;
  - b. reviewing Disclosure Forms submitted by Investigators and Employees;
  - c. determining whether a disclosed Significant Financial Interest is a financial conflict of interest; and, if so,
  - d. determining how a financial conflict of interest can be managed, reduced, or eliminated to protect the Investigator or Employee, the interests of the University, research participants and the public.
3. A Conflict of Interest Officer and other staff as needed shall be employed by the University and adequate resources allocated to support the duties of the Individual Conflict of Interest Committee.
  4. The Committee and its members shall act without bias in administering this Policy.

F. Conflict of Interest Office and Committee Responsibilities

1. The Conflict of Interest Office, on behalf of the Individual Conflict of Interest Committee, will determine, for each individual's Disclosure Form, whether a Significant Financial Interest exists that requires the review of the Conflict of Interest Committee. The individual Investigator or Employee and his/her department chair or supervisor will be notified when the Conflict of Interest Office refers a potential conflict of interest to the Conflict of Interest Committee for review.
2. The Conflict of Interest Committee will consult with the individual Investigator or Employee as appropriate and determine whether a Significant Financial Interest creates a financial conflict of interest. If it is determined that a financial conflict of interest exists, then the Conflict of Interest Committee will determine how it can be managed, reduced, or eliminated.
3. The Conflict of Interest Office will transmit the decision of the Conflict of Interest Committee to the Investigator or Employee, his/her University superiors, and the appropriate offices within the University.
4. The Committee is primarily responsible for monitoring and ensuring compliance with approved plans to manage, reduce or eliminate financial conflicts of interest. In most circumstances, this will include requiring the Investigator or Employee to submit compliance reports at intervals specified by the Committee in the management plans. When plans require specific expertise, the Committee may enlist peers to assist with monitoring compliance as needed.

5. The University will adhere to research sponsor requirements and state and federal law for reporting of disclosure and management, reduction or elimination of conflicts of interest.

## 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**~~

### G. Confidentiality

1. Conflict of interest disclosures and Committee determinations concerning conflicts and violations shall be available to:
  - a. the Investigator or Employee's University superiors;
  - b. the appropriate University offices, including but not limited to, the Office of the Vice President for Research, the Office of General Counsel, Internal Audit, Institutional Review Board, Office of Sponsored Projects, Technology Commercialization Office, Procurement and Supply Management, Graduate School; and
  - c. other Employees whose responsibilities to the University are directly affected by the conflict of interest.
2. In certain circumstances, federal and state law may require public disclosure of information relating to identified conflicts of interest.
3. In other circumstances, including but not limited to conflicts regarding human subjects research, the University may require public disclosure as part of a conflict management plan.
4. Except for the foregoing disclosures contemplated in this Policy, the Individual Conflict of Interest Committee and those within the University who have direct responsibility for reviewing potential conflicts or investigating potential violations of this Policy shall treat the information received and considered during these processes as confidential information.
5. Any information disclosed by an Investigator or Employee as required by this Policy shall be used solely for the purpose of administering this Policy and shall not be used for any other purpose unless required by law.

6. Unauthorized disclosure of any such information by an Employee shall be deemed to be unethical behavior and shall be punishable under pertinent University Regulations including **Policy 5-111 (Corrective Action and Termination Policy for Staff Employees)** or **Policy 6-316, Sections 4 & 5 (Faculty Code)**.

H. Appeals

Any decision of the Individual Conflict of Interest Committee concerning the existence of a conflict of interest or the appropriateness of a plan to manage, reduce, or eliminate a conflict may be appealed within thirty (30) days to a panel which shall include the Senior Vice President for Academic Affairs, the Senior Vice President for Health Sciences and the Vice President for Research. The decision of the panel shall be final.

X. — Violations and Sanctions

{**Drafting note:** The general requirements of this Policy for non-compliance have been relocated to Section III-I below. Additional details about the procedures for non-compliance have been removed from this Policy and are included in the draft of Rule 1-006B.}

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 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.~~

I. Non-Compliance

1. Reports of Non-Compliance

Potential violations of this Policy or any conflict of interest management plans must be reported to the University's Conflict of Interest Officer.

2. Investigation of Non-Compliance

The Individual Conflict of Interest Committee shall investigate all potential non-compliance with this Policy, including potential non-compliance with prescribed management plans.

3. Protection of Affected Parties

To the extent permitted by law and University policies, the University will protect the identity and privacy of those individuals who, in good faith, report apparent non-compliance with this Policy or furnish information regarding such non-compliance. Retaliation of any kind against any individual, who, in good faith, alleges non-compliance or cooperates with the investigation, is prohibited and the retaliator may be subject to discipline under pertinent University policies.

4. Restrictions That May Be Imposed by the Individual Conflict of Interest Committee

a. For violations of this Policy, the Committee may impose one or more of the following restrictions on an individual:

Freeze research funds, or otherwise suspend, a project or projects related to the policy violation;

Remove the individual found to be in violation from a role as Principal Investigator or Investigator on a project or projects related to the policy violation;

Prohibit submission of new applications to the Institutional Review Board and/or the Office of Sponsored Projects until resolution of the relevant conflict of interest issues or for a specified period of time;

Other restrictions as may be deemed appropriate by the Committee.

- b. The individual Investigator or Employee may appeal the restrictions imposed by the Committee to a panel which shall include the Senior Vice President for Academic Affairs, the Senior Vice President for Health Sciences, and the Vice President for Research. The decision of the panel shall be final.
- c. In situations involving the health or safety of any person or the potential loss of significant University resources, the Committee may implement any restrictions listed in paragraph 4(a) that are necessary to protect these persons and resources pending the outcome of the investigation. Otherwise, no restrictions, disciplinary or administrative action shall occur until the conclusion of the violation evaluation process set forth in this Policy.

5. Disciplinary and Other Administrative Actions

- a. For violations of this Policy, the Committee may recommend to the cognizant vice president(s) that disciplinary action be taken against the individual (including but not restricted to: reprimands, fines, probation, suspension, or dismissal). The Committee may proceed with a complaint against the Investigator or Employee before the appropriate University hearing body.

b. Other Administrative Actions

For violations of this Policy, the Committee may recommend to the cognizant vice president(s) that one or more of the following administrative actions be taken:

Withholding payment owed under a procurement contract relating to the conflict;

Legal action to rescind or revise University contracts entered into or found to be in violation of this Conflict of Interest Policy or of federal or state law;

Legal action to recover the amount of financial benefit received by an Investigator or Employee as a result of his or her violation of this policy;

Other similar and appropriate actions.

6. Violations of the Utah Public Officers' and Employees' Ethics Act may result in prosecution and criminal penalties pursuant to that Act. (Utah Code Ann. § 67-16-1, et seq.)

7. The remedies provided or referenced above are cumulative and may include any other remedies required or provided by applicable state or federal law.
8. The Office of Associate Vice President for Research Integrity shall report incidents of non-compliance of with this Policy to external agencies and sponsors as required by state and federal law.

J. Other Conflict of Interest Policies and Procedures

1. University Institutional Conflict of Interest Policy

In situations where both an individual and an institutional conflict of interest may exist, Investigators and Employees will be required to comply with the requirements of this Policy and also with the requirements of [[Policy XXX – the University Institutional Conflict of Interest Policy]]. **{Drafting note: work is underway on the companion University Institutional Conflict Policy, and this bracketed information will be filled in when that other Policy is approved.}**The Individual Conflict of Interest Committee and the University Institutional Conflict of Interest Committee shall consult on cases of overlapping oversight to determine the appropriate plan to manage, reduce, or eliminate both the individual and the institutional conflicts.

The Individual Conflict of Interest Committee and the University Institutional Conflict of Interest Committee shall consult on cases of overlapping oversight to determine the appropriate plan to manage, reduce, or eliminate both the individual and the institutional conflicts.

2. Supplemental Rules Regarding Conflicts of Interest

Any unit within the University may elect to adopt a “Supplemental Rule” (as described in Policy 1-001) applicable for conflicts of interest arising within that unit. Any such Supplemental Rule shall operate in conjunction with this Policy, providing that such Supplemental Rule must aid in the implementation of and not be in conflict with the terms of this Policy. Any such Supplemental Rule proposed by any unit of the University shall be submitted for the approval of the Individual Conflict of Interest Committee.

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

A. Rules

1.

**{Drafting note: The University Rule (Rule 1-006A & B) providing details of the membership structure of the Individual Conflict of Interest Committee and the Procedures for Non-compliance will be listed and linked here upon approval, as will any other Rules, Procedures, etc that may be developed pertinent to this Policy.}**

- B. Procedures [reserved]
- C. Guidelines [reserved]
- D. Forms [reserved]
- E. Other related resource materials

School of Medicine Industry Relations: Supplemental Rule **SOM-001**

V. 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.

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.~~

~~School of Medicine Industry Relations: Supplemental Rule **SOM-001**~~

~~XIII.VI. 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.~~

~~Policy Officer: Vice President/General Counsel, 801-585-7002~~

~~Policy Owner: Office of General Counsel, 801-585-7002~~

VII. History.

Renumbering: Renumbered as Policy 1-006 effective 9/15/2008, formerly known as PPM 2-30.

Revision History:

A. Current version: Revision 11

Effective date *[upon final approval]*

Approved: Academic Senate [\_\_\_\_\_]

Approved: Board of Trustees [\_\_\_\_\_]

Legislative History of Revision 11 {link to copy of the entire proposal packet as approved by Senate}

B. Earlier versions:

Revision 10: Effective dates March 8, 2004 to [ ]

Approved Academic Senate: 2/02/04

Approved Board of Trustees: 3/08/04

Footnotes:

(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) For Investigators who are not University Employees, as defined in this Policy, Significant Financial Interest shall include those financial interests that reasonably appear to be related to the Investigator's responsibilities to his/her employer and/or profession.

~~(2)~~ (3) In conformity with the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-5 et seq.

(4) For Investigators who are not University Employees, as defined in this Policy, disclosure of travel shall include the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the Investigator's responsibilities to his/her employer and/or profession provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.