

University of Utah

**Legislative History
Policy 1-006 Revision 12,
Rules 1-006C Rev0, 1-006D Rev 0, 1-006E Rev 0.
Procedure 1-006 Rev 1.**

As all approved by the Academic Senate April 27, 2020,
With Policy 1-006 Rev. 12 approved by the Board of Trustees June 9, 2020,
All with designated effective date of July 1, 2020.

Prepared by Bob Flores, Senate Policy Liaison, for the Institutional Policy Committee

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MEMORANDUM

TO: Andrew S. Weyrich, Vice President for Research

FROM: Marc Rinehart, PhD, Director/Officer, Conflict of Interest Office

SUBJECT: Proposed Changes to Individual Financial Conflict of Interest Policy 1-006

DATE: March 16, 2020

I. Overview

This is a proposal to make various important changes to the Individual Financial Conflict of Interest Policy 1-006 (Policy 1-006) and Procedures 1-006: Reviewing Individual Conflict of Interest Disclosure Forms (Procedure 1-006). The current version of the main Policy 1-006, Revision 11, has been in place since 2012. See <https://regulations.utah.edu/general/1-006.php>. Currently, Policy 1-006 addresses conflicts of interest in four areas: Research and Scholarly Activity, Human Subjects Research, Intellectual Property, and Procurement. This proposed revision would reorder and redefine these areas and would create a set of new University Rules, associated with the main Policy, for each new area to clarify the review process for each type of conflict of interest. These changes will help clarify existing policy requirements and help ensure that University of Utah (University) employees comply with Utah state law concerning conflicts of interest and provide complete and accurate disclosures of relevant outside interests and relationships to the University.

II. Background

In December 2016, the Office of Legislative Auditor General of the State of Utah (Legislative Auditor) conducted an audit of the relationship between Utah State University's (USU's) anthropology program and Utah State University Archaeological Services (USUAS), a private corporation owned by USU anthropology faculty. In that audit, the Legislative Auditor found that, on several occasions, USU anthropology faculty with an ownership interest in USUAS selected USUAS for sub-awards in grant applications, and that USU failed to provide adequate oversight over those sub-award decisions. To address this issue and help ensure compliance with the Utah Public Officers' and Employees' Ethics Act (Ethics Act), the Legislative Auditor recommended that USU develop controls for identifying and managing potential conflicts of interest before faculty apply for grants.

Following the USU audit, here at the University of Utah, the University's Vice President for Research directed the University's Conflict of Interest (COI) Office to work with the

University's Office of Sponsored Projects (OSP), the University's Purchasing Department, the University's Center for Technology and Venture Commercialization, and other offices to review the University's conflict of interest policies and processes and, if appropriate, recommend ways to strengthen those policies and processes so that conflicts of interest related to sub-awards are appropriately identified and managed, as required by the Ethics Act.

The COI Office completed that review and now recommends that Policy 1-006 and Procedure 1-006 be revised in several substantive ways. These recommended changes will not only strengthen the COI Office's ability to identify and appropriately manage conflicts of interest related to sub-awards, in particular, but they will also strengthen the COI Office's ability to timely identify and manage conflicts of interest related to transactions more broadly (e.g., subcontracts, sub-awards, purchases, licensing agreements, lease agreements, etc.). In addition, the proposed changes will help the University respond to recent requests by federal agencies, such as the National Institutes of Health and the National Science Foundation (NSF), that institutions take a more proactive approach in identifying and managing conflicts of interest related to foreign entities. Full disclosure of relationships is central to that effort and, as a recent report commissioned by the NSF concluded, is the United States' "most effective" response to, and "main defense against," foreign influence.¹

The changes now proposed are limited in scope, as dictated by the need to enact the changes and begin implementation expeditiously. Given continuing trends at the national and international levels, it is anticipated that further adjustments to University practices, and possibly further revisions of University Regulations in these areas, will be needed. One such change may be to further enlarge the scope of categories of University employees of whom disclosures are routinely required. And so the Conflict of Interest Office anticipates reviewing the effectiveness of these revised Regulations after two years of experience with them, and possibly then returning with further proposed changes.

For the present proposal, the proposed changes to existing Policy 1-006 and new Rules 1-006C to 1-006E can be grouped into three broad areas of focus:

1. adding a requirement that the following categories of University employees submit an annual disclosure of relevant outside interests and relationships: (a) faculty members (excluding emeritus, visiting, and adjunct faculty); (b) staff employed at the manager level or above; and (c) staff with purchasing authority or delegated purchasing authority;

¹ JASON, FUNDAMENTAL RESEARCH SECURITY 31 (Dec. 2019).

2. clarifying disclosure and process strategies by redefining activities that are subject to conflict of interest review and oversight and reorganizing descriptions of these activities into new Rules for more specific, activity-based guidance; and
3. broadening the types of interests and relationships that (a) individuals must disclose to help ensure that employees appropriately disclose all of the interests and relationships listed in the Ethics Act and (b) are necessary to protect against foreign influence.

III. Summary of Major Changes

A. Changes to Policy 1-006

Section II – Changes to Definitions.

The proposed revisions of definitions will make the following changes.

- Definition of “Business Entity”
 - The current definition of “Business Entity” excludes federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with institutions of higher education. The Utah Ethics Act does not carve out these entities from its definition of “Business Entity.” Also, federal agencies expect institutions to require individuals to disclose relationships with these entities so that institutions can address potential issues related to foreign influence. The limited scope of the existing definition in Policy 1-006 results in University Employees not being clearly required to disclose relationships and interests with such agencies and organizations of importance for the Utah Act and federal agencies. To help ensure Employees will disclose relevant interests in and relationships with all Business Entities, the expanded definition will include those previously excluded types of agencies and organizations.
 - Significantly, however, when the COI Committee evaluates Research for conflicts of interest, the COI Committee will not consider an individual’s disclosed relationships with, or interests in, such federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education. This is consistent with the NIH conflict of interest policy and reflects the COI Committee’s current practice.

- Definition of “Compensation”
 - The revised definition of “Compensation” will cover future payments and other beneficial interests that may create a conflict of interest. For example, if an individual sold her company, and the contract of sale had an “earn out” clause that enabled her to earn money over future years depending on the company meeting certain earning thresholds, that interest would be considered Compensation. Similarly, if an employee’s friend held an Equity Interest in a Business Entity on behalf of the employee, that Equity Interest would be considered Compensation.
- Definition of “Disclosure Form”
 - Renamed to “BRR Disclosure Form” to specify which form is required to be submitted in compliance with Policy 1-006.
 - The revised definition no longer references the BRR Disclosure Form's contents--details that are better addressed in the body of the policy or relevant rule.
- Definition of “Employee” and sub-categories
 - The revised definition of “Employee” will clarify that the sub-category of “faculty” includes paid and unpaid faculty. It also clarifies that an individual who is a student, but also employed by the University, is considered an Employee for purposes of this Policy. Similarly, it clarifies that an individual who meets the definition of an Investigator and also the definition of an Employee is subject to the requirements established under this Policy for both such categories of personnel.
- Definition of “Equity Interest”
 - The current Policy has definitions of “equity interest” repeated throughout the Policy. The addition of “Equity Interest” in Section II as a defined term will eliminate this redundancy.
- Definition of “Financial Relationships”
 - The current Policy requires individuals involved in certain University activities to disclose their “Significant Financial Interests,” a term that originates from the NIH conflict of interest policy. Because the Utah

Ethics Act and federal guidance on foreign influence require public employees who are engaged in business transactions on behalf of the University to disclose additional relationships and interests that may not always fall within the definition of Significant Financial Interest (e.g., serving as an unpaid officer, an agent, an employee who earns less than \$5,000 a year, etc.), the proposal includes creating a new term, “Financial Relationships,” and broadening the types of interests and relationships that individuals must disclose, so that it is consistent with NIH policy, the Ethics Act, and federal guidance on foreign influence. This will help ensure that Employees make appropriate disclosures as required by law.

- Under the current Policy, individuals must disclose if they have Intellectual Property rights and interests when the patent application is filed or when the copyright is asserted or upon receipt of income related to such rights and interests. The revised Policy will narrow that disclosure obligation so that individuals need only disclose Intellectual Property if it is imminent of commercialization or if it has been commercialized. This change reflects the COI Committee’s practice of only considering conflicts related to Intellectual Property if that Intellectual Property has been, or will soon be, commercialized.
- Although the disclosure of a Financial Relationship that is reasonably related to certain University activities will generate a conflict of interest review, the COI Committee will not consider a Financial Relationship to create a conflict of interest related to Research or Scholarly or Educational Activity unless that Financial Relationship also meets the definition of *Significant* Financial Interest. In other words, the new requirement to disclose *Financial Relationships*, as opposed to *Significant* Financial Interests, will not change the way the COI Committee reviews conflicts of interest related to Research or Scholarly or Educational Activity. The COI Committee will only evaluate Research or Scholarly or Educational Activity for conflicts of interest if the COI Committee determines the individual has a Significant Financial Interest related to the Research or Scholarly or Educational Activity. This nuance will be captured in the proposed new Rules 1-006C: Individual Financial Conflicts of Interest in Research and 1-006D: Individual Financial Conflicts of Interest in Scholarly and Educational Activity.
- In terms of a conflict of interest related to a Transaction, the COI Committee will not consider a Financial Relationship relevant, unless that Financial Relationship also meets the definition of Substantial

Interest. In other words, the new requirement to disclose Financial Relationships, as opposed to Substantial Interests, will not change the way the COI Committee reviews conflicts of interest related to Transactions. The COI Committee will only evaluate Transactions for conflicts of interest if the COI Committee determines the individual has a Substantial Interest related to the Transaction. This nuance will be captured in the proposed new Rule 1-006E: Individual Financial Conflicts of Interest in Transactions.

- Definition of “Gift”
 - The revised definition of “Gift” will include content that was previously placed in a footnote (and therefore perhaps easily overlooked), and the footnote [Fn1] will be deleted.
- Definition of “Intellectual Property”
 - The revised definition of “Intellectual Property” will provide additional information on what Intellectual Property means. More specifically, the revised definition will include tangible property, physical materials, artistic works, data, algorithms, software, including its component coding, designs, databases, and media.
- Definition of “Investigator”
 - The revised definition of “Investigator” will include “visiting scientist” as an example.
- Definition of “Scholarly or Educational Activity”
 - The current Policy does not define “Scholarly Activity.” The revised Policy will replace references to “Scholarly Activity” with “Scholarly or Educational Activity;” it will also add a definition to clarify the type of scholarly or educational activities that individuals might engage in and that, if reasonably related to an individual’s “Financial Relationships,” must be disclosed.
- Definition of “Significant Financial Interest”
 - As noted above, to ensure the Policy language is consistent with the Ethics Act and guidance related to foreign influence, the revised Policy will require individuals to disclose their Financial Relationships instead of their Significant Financial Interests. Whether an interest or

relationship is a Significant Financial Interest is only relevant when the COI Committee evaluates Research for conflicts of interest. In those cases, the COI Committee will determine if a Financial Relationship is a Significant Financial Interest, as defined by the NIH conflict of interest policy and further clarified by University Procedure 1-006. To avoid confusion about what individuals must disclose, the proposal includes removing the existing definition of Significant Financial Interest from Policy 1-006 and moving it to new Rules 1-006C and 1-006D where it will be better understood in context.

- Definition of “Transaction”
 - The revised definition of “Transaction” will simply add a reference to the University of Utah Research Foundation (UURF) and provide various examples of Transactions for clarity. Specifically, Transaction will be defined to include purchases (including the purchase of supplies, equipment, or services), subcontracts, sub-awards, material transfer agreements, term sheets (whether binding or non-binding), option agreements, licensing agreements, agreements for sponsored research, grants, lease agreements, etc.

Section III – Policy, Subsection A

- The proposal is to delete “General Requirements (disclosure, prohibited activities)” and replace it with “Disclosure and Training Requirements.” Some of this language comes from Sections III.B. (“Activities Requiring Disclosure”) and III.D. (“Investigator and Employee Disclosure Responsibilities”) of the current Policy. It is proposed to combine those sections in Section III.A of the revised Policy, so that training and disclosure responsibilities are listed up front.

Section III – Policy, Subsection A.1

- A new subsection is added, titled “Disclosure Schedule,” which has the following requirements:
 - Each (1) faculty member (with the exception of those in the categories of emeritus faculty, visiting faculty, or adjunct faculty), (2) Employee at a manager level and above, and (3) Employee with purchasing authority or delegated purchasing authority is required to submit a BRR Disclosure Form upon hire and at the start of each academic year; and

- Each Employee in a category not identified above is required to submit a BRR Disclosure Form prior to engaging in Research, Scholarly or Educational Activity, or Transactions; and
- Each Investigator and Employee is required to submit an updated BRR Disclosure Form within 30 days of any changes (note that this is an existing requirement).

Section III – Policy, Subsection A.2

- A new subsection will be added, titled "BRR Disclosure Form Contents (Relevant Information)."
- Will include a new description of the relevant information to be disclosed in the BRR Disclosure Form. This includes guidance on disclosure of Financial Relationships and sponsored travel.
- As noted above, the revised Policy will refer to Financial Relationships, instead of Significant Financial Interests – again, to help ensure Employees make appropriate disclosures, as required by state law.

Section III – Policy, Subsection A.3

- Will add a new subsection, titled "Training."
- Will update the training language to clarify when and where the training must be completed. Specifically, an individual must complete a training through the University's Business Relationship Reporting system (1) when the individual initially submits a BRR Disclosure Form and (2) at least every four years thereafter. The four-year requirement comes from the NIH conflict of interest policy.

Section III – Policy, Subsection B

- The existing section entitled "Activities That Are Not Allowed (Prohibited Activities)" will be removed from the main Policy, and the provisions detailing the prohibited activities will be moved into the respective new Rules to which they are applicable.
- "Individual Conflict of Interest Committee," which used to be Subsection C, will be renumbered as Subsection B.

Section III – Policy, Subsection B.1

- It will be clarified that faculty members serving on the Individual Conflict of Interest Committee must be tenure-line or career-line.
- A reference will be added to existing University Rule 1-006A: Individual Conflict of Interest Committee Membership Rule.

Section III – Policy, Subsection B.2.

- As explained above, the existing reference to “Significant Financial Interest” will be replaced with “Financial Relationship.”

Section III – Policy, Subsection C

- “Conflict of Interest Office and Committee Responsibilities,” which used to be Subsection D, will be renumbered to Subsection C.

Section III – Policy, Subsection C.1

- As explained above, references to “Significant Financial Interest” will be replaced with “Financial Relationship.”

Section III – Policy, Subsection D

- The existing language from Section III.H (“Appeals”) will be moved to this subsection.

Section III – Policy, Subsection E

- The title of this section will be revised to “Confidentiality and Internal and External Dissemination of Information Regarding Conflicts.”
- The language in Section III.E.7. will be updated to clarify that confidential information available only to certain University offices and employees as described in Sections III.E.5 and III.E.6. cannot be disclosed or used for any purpose unrelated to Policy 1-006, unless required by law.

Section III – Policy, Subsection F

- The title of this subsection will be revised to “Violations/Non-Compliance.” Throughout this section language will be added describing an individual’s failure to comply with an approved conflict of interest

management plan as a policy violation, which is consistent with the COI Committee's current practice.

Section III – Policy, Subsection G.1

- A duplicate paragraph in the current Policy will be deleted.
- To ensure this Policy is consistent with Policy 7-006 (Institutional Financial Conflicts of Interest for Research Involving Human Subjects), the revision will clarify that the COI Committee and the University's ICOI Officer (as opposed to the ICOI Committee) will consult on cases on institutional COIs.

B. Changes of Three University Rules

The proposal is to create three new University Rules, and to make minor changes to one University Procedure associated with Policy 1-006.

The new University Rules are intended to address the conflict of interest review process for Research, Scholarly or Educational Activity, and Transactions. As explained above, much of the contents of these new Rules will be existing contents of the existing main Policy, being moved into the new Rules and then appropriately modified. The Rules are:

- Rule 1-006C: Individual Financial Conflict of Interest in Research
- Rule 1-006D: Individual Financial Conflict of Interest in Scholarly or Educational Activity
- Rule 1-006E: Individual Financial Conflict of Interest in Transactions

Note that the proposal does not contemplate any changes to the two existing University Rules associated with Policy 1-006, which are:

- Rule 1-006A: Individual Conflict of Interest Committee Membership Rule, and
- Rule 1-006B Individual Financial Conflict of Interest Non-Compliance.

Nor is any change now being proposed to Supplemental Rule SR1-006: Health Sciences Industry Relations Policy.

All are viewable at <https://regulations.utah.edu/info/policyList.php>

1. New Rule 1-006C: Individual Financial Conflict of Interest in Research

- This new Rule will provide clarity and guidance regarding the COI Committee's evaluation and management of conflicts of interest related to Research and Human Subjects Research.
- The definition of Significant Financial Interest will be moved from the main Policy to this Rule.

Section III.A.

- Will provide a description of activities related to Research that require an individual to submit a BRR Disclosure Form.

Section III.B.

- Will provide a description of the evaluation process for determining if a Financial Relationship meets the threshold of Significant Financial Interest and is, therefore, subject to the review of the COI Committee.

Section III.C.

- Will provide a list of potential management strategies for identified conflicts of interest in Research.

Section III.D.

- Will provide a list of prohibited activities related to Research. This language is moved from Section III.C. of the Policy.

2. New Rule 1-006D: Individual Financial Conflict of Interest in Scholarly and Educational Activity

- This Rule will provide clarity and guidance regarding the COI Committee's evaluation and management of conflicts of interest related to Scholarly and Educational Activity.
- The definition of Significant Financial Interest is moved to this Rule from the main Policy.

Section III.A.

- Will provide a description of activities related to Scholarly and Educational Activity that require an individual to submit a BRR Disclosure Form.

Section III.B.

- Will describe the evaluation process for determining if a Financial Relationship meets the threshold of Significant Financial Interest and is, therefore, subject to the review of the COI Committee.

Section III.C.

- Will list potential management strategies for identified conflicts of interest in Scholarly and Educational Activity.

Section III.D.

- Will provide a list of prohibited activities related to Research. This language is moved from Section III.C. of the main Policy.

3. New Rule 1-006E: Individual Financial Conflict of Interest in Transactions

- This Rule will provide clarity and guidance regarding the COI Committee's evaluation and management of conflicts of interest related to Transactions.
- Will provide a definition of Substantial Interest based on thresholds defined in the Ethics Act.

Section III.A.

- Will describe activities related to Transactions that require an individual to submit a BRR Disclosure Form.

Section III.B.

- Will describe the evaluation process for determining if a Financial Relationship meets the threshold of Substantial Interest and is, therefore, subject to the review of the COI Committee.

Section III.C.

- Will provide a list of potential management strategies for identified conflicts of interest in Transactions.

Section III.D.

- Will provide a list of prohibited activities related to Research. Most of this language is moved from Section III.C. of the main Policy.

C. Changes to University Procedure 1-006

- Will change the title to “Procedure 1-006: Reviewing Individual Conflict of Interest BRR Disclosure Forms.”
- Will update the name of the Center for Technology & Venture Commercialization.

IV. Proposal Development Process - Consultation

The proposal was developed by a revision team consisting of:

Marc Rinehart, Director/Officer, Conflict of Interest Office
 Emily Ostrander, Associate Director, Conflict of Interest Office
 Hailey Ritchie, Associate General Counsel, Office of General Counsel

The proposal was presented to the Individual Conflict of Interest Committee on May 21, 2019. The policy draft was also discussed with the following individuals:

- Dr. Harriet Hopf (Interim AVP for Academic Affairs)
- Dr. Sarah Projansky (AVP for Academic Affairs)
- Dr. Robert Fujinami (AVP for Education and Faculty Development)
- Dr. Erin Rothwell (AVP for Research Integrity and Compliance)
- Dr. Caren Frost (Director of Compliance in Research Integrity and Compliance Office)
- Glendon Mitchell (Director of Purchasing and ex officio member of the COI Committee)
- Keith Marmer (Executive Director of the Center for Technology and Venture Commercialization)
- Brent Brown (Director of the Office of Sponsored Projects and ex officio member of the COI Committee)
- Jahn Barlow (former University COI Officer)

The proposal was presented to the Academic Senate Institutional Policy Committee on August 9, 2019, and September 13, 2019.

The proposal was presented to the Academic Senate Executive Committee on September 16, 2019, and October 14, 2019.

Revisions to the proposal were presented to Academic Senate officers (Julio Facelli, Thomas Richmond, Randy Dryer, and Bob Flores) on March 6, 2020.

The proposal was presented to the School of Medicine Executive Committee on March 12, 2020.

The proposal is scheduled to be presented to the Health Sciences Research Forum on March 17, 2020, the Council of Academic Deans on March 19, 2020, the President's Cabinet on March 25, 2020, and the Research Leadership Luncheon on April 1, 2020.

If you approve of this proposal, it should be presented next to the Executive Committee of the Academic Senate, the Academic Senate, and the Board of Trustees for their approval.

Questions about the proposal may be directed to Marc Rinehart (Director/Officer, Conflict of Interest Office).

V. Proposal Contents

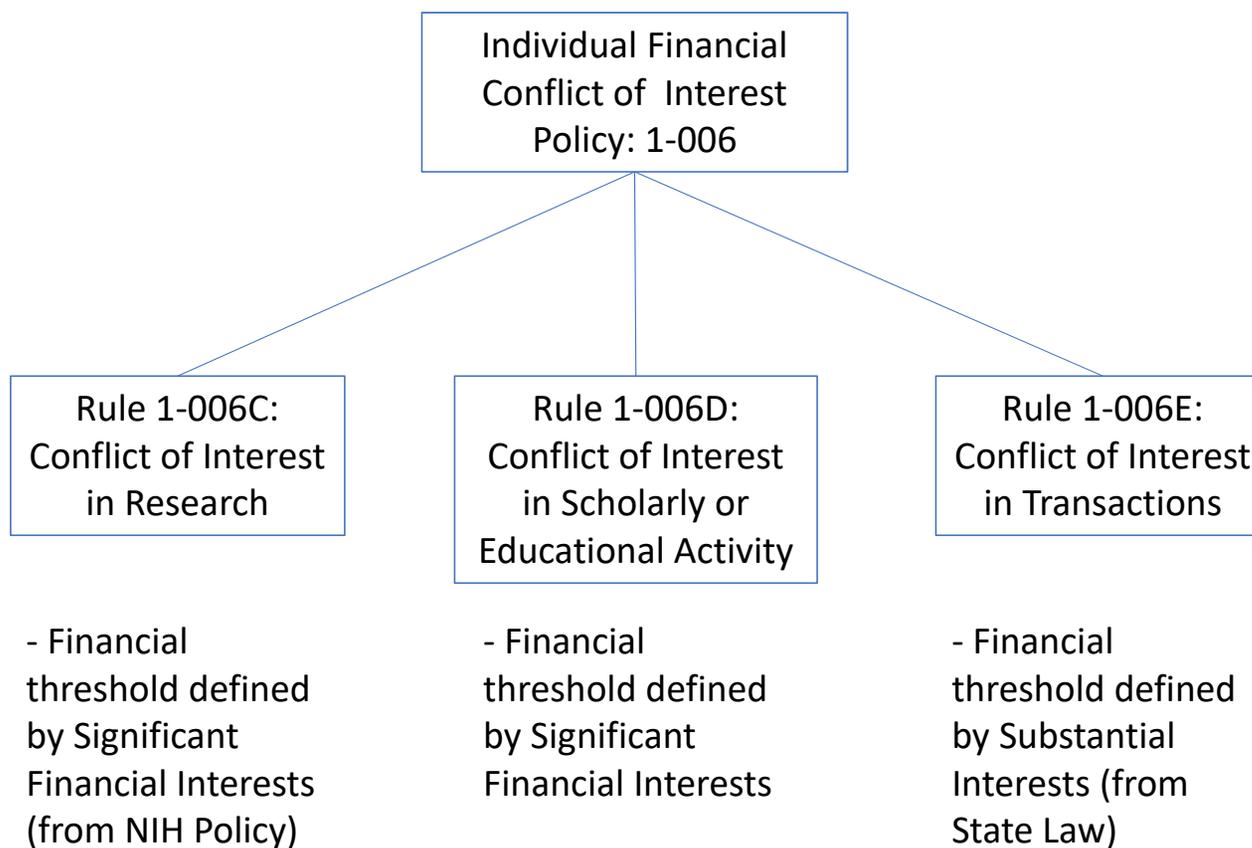
The proposal materials consist of (A) this Memorandum, (B) a "clean" version of the revised Policy 1-006, (C) a redlined version of the revised Policy 1-006, (D) a redlined version of new Rule 1-006C: Individual Financial Conflict of Interest in Research, (E) a redlined version of new Rule 1-006D: Individual Financial Conflict of Interest in Scholarly and Educational Activity, (F) a redlined version of new Rule 1-006E: Individual Financial Conflict of Interest in Transactions (for those Rules, the redlined versions show the existing contents moved from the current main Policy, and then modifications made afterward.), and (G) a redlined version of the revised Procedure 1-006.

Proposed Revisions to Conflict of Interest Regulations

- Three key revisions:
 1. Add an annual disclosure process for certain employees
 2. Simplify the disclosure threshold for all employees
 3. Clarify and simplify the event-based disclosure and review process

- Most of the proposed changes:
 - Are not substantive
 - Are consistent with existing requirements

Restructured COI Policy Format



Draft 3/16/2020

Policy 1-006: Individual Financial Conflict of Interest Policy Revision 12.

Effective Date: ~~????~~, 2020

I. Purpose and Scope

A. Purpose

~~A central mission of the~~ The University ~~is to educate the~~ serves society ~~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 individual members of the University community work to accomplish ~~this mission~~ these institutional objectives with these shared institutional values, individual financial conflicts of interests may naturally arise that have the potential to impair the judgment of the individuals involved in that work.

This Policy establishes and describes the systems and processes through by which the University identifies, evaluates, and manages financial conflicts of interest of individuals, without violating its institutional values ~~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 that in which individuals are not allowed ~~to engage~~ because they ~~would be in~~ are a violation of law or are judged by the University to be in a violation of its ~~central missions~~ institutional values.

This Policy establishes the Individual Conflict of Interest Committee and the position of Individual Conflict of Interest Officer to ~~administer~~ implementation ~~of~~ the Policy. It is intended that the Policy will be further implemented through adoption of various associated Rules and Procedures.

B. Scope

This Policy applies to all individuals affiliated with the University who meet the definitions of Investigator or Employee, as defined here.

This Policy addresses individual conflicts of interest related to the following activities in which an Investigator or Employee may participate: Research (see Rule 1-006C), Scholarly or Educational Activity (see Rule 1-006D), and Transactions (see Rule 1-006E). More detailed direction may be further specified through Rules and Regulations associated with this Policy.

This Policy is not intended to directly govern other conflicts of interest that might arise during an Employee's University duties, which are governed by other Regulations. [See e.g., Policy 5-204: Remunerative Consultation and Other Employment Activities, Supplemental Rule 1-006: Health Sciences Industry Relations Policy]. Similarly, this Policy is not intended to directly govern financial conflicts of interest of the University as an *institution*, a *subject* which are governed by other Regulations. [See Policy 7-006 Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects].

II. Definitions

These definitions apply for the limited purpose of this Policy and any Rules or other University Regulations associated with this Policy.

- A. **BRR Disclosure Form** is the form through which an individual Investigator or Employee provides personal financial information provided to the University (to be reviewed by the Individual Conflict of Interest Committee). The BRR Disclosure Form is submitted through the University's online Business Relationship Reporting ("BRR") system. ~~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.~~
- B. **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. Business Entity includes local, state, federal, or international entities. ~~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.~~
- C. **Compensation** means anything of economic value, however designated, which is paid, loaned, granted, given, donated, ~~or~~ transferred, or promised to any person or Business Entity ~~for or in consideration of personal services, materials, property, or the like.~~ Compensation includes a beneficial interest held by an individual on behalf of an Investigator or Employee, even if the Investigator or Employee does not receive the Compensation directly (e.g., an Employee's or an Investigator's friend holds an Equity Interest in a Business Entity on behalf of the Employee or Investigator).
- 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, all of the following categories of individuals when they are employed by the University: staff, faculty members, postdoctoral fellows, medical housestaff, and educational trainees ~~and students.~~ An unpaid faculty member is also considered an Employee for purposes of the requirements of this Policy.

An individual who is a student, but also employed by the University, is considered to be an Employee for purposes of the requirements this Policy establishes for Employees. An individual who meets the definition of an Investigator and also the definition of an Employee is subject to the requirements established under this Policy for both such categories of personnel.

- E. **Equity Interest** means any stock, stock option, or other ownership interest in a Business Entity.
- F. **Family Member** means, ~~for the limited purposes of this Policy,~~ a spouse or domestic partner ~~and/or~~ a dependent or minor child~~ren~~. (Domestic partner is further defined in University Rule 5-200A).
- G. **Financial Relationship** means any financial interest or relationship of an Investigator or Employee (or those of an Investigator's or Employee's Family Member), whether or not the value is readily ascertainable, that reasonably appears to be related to an Investigator's or Employee's responsibilities to the University, as those responsibilities are defined by the Investigator's or Employee's department or job description.
1. Financial Relationship includes:
 - a. Employment, consulting, or any other activity resulting in payment or other Compensation;
 - b. Any Equity Interest, excluding ownership in mutual funds or pension funds described in Section II.G.2.b;
 - c. Any paid or unpaid leadership position in a Business Entity such as director, officer, partner, trustee, agent, or any position of management; and
 - d. Any instance in which an Investigator or Employee (or a Family Member) has, or reasonably foresees having, the right to receive Compensation as a result of licensing or other commercialization of Intellectual Property created by that Investigator or Employee (or Family Member), including the right to receive shares of revenue, royalties, or other payments generated by such commercialization (e.g., an inventor's share of royalty income under University policy).
 2. Financial Relationship does not include:
 - a. Salary, travel reimbursements, or other non-royalty Compensation from the University if that Investigator or Employee (or Family Member) is currently employed by, appointed at, or otherwise affiliated with the University; or
 - b. Income from investment vehicles, such as mutual funds and retirement accounts, provided that an Investigator or Employee (or a

Family Member) does not directly control the investment decisions made in those vehicles.

- H. **Gift** includes money, non-pecuniary gifts, excessive compensation, or non-commercial loans. ~~For the purpose of this Policy a gift does not apply to~~ However, occasional non-pecuniary gifts that have an insignificant monetary value, as defined by the Utah Public Officers' and Employees' Ethics Act ~~[Fn1]~~, that would *not* tend to improperly influence an Employee in the discharge of ~~his/her~~ the Employee's duties are not considered to be a Gift for purposes of the requirements of this Policy. Note that as of January 1, 2020, the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq., permitted occasional, nonpecuniary gifts that do not exceed \$50.00.
- I. **Human Subjects Research** is any Research that has been designated as "human subjects research" by the University's Institutional Review Board.
- J. **Intellectual Property** means any ideas, inventions, technology, tangible property, creative expression, or embodiments thereof, in which a proprietary interest is claimed, including, but not limited to, patents, copyrights, trademarks, know-how, ~~and~~ biological or physical materials, artistic works, data, algorithms, software (including its component coding), designs, databases, or media.
- K. **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 pPrincipal Investigator ~~and or~~ 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, visiting scientists, collaborators, consultants, or sub-award or subcontract recipients.
- L. **Research** means a systematic investigation, study, or experiment designed to develop or contribute to generalizeable generalizable knowledge. The term includes, but is not limited to, basic and applied research (e.g., a published article, book or book chapter) or product development (e.g., a diagnostic test or drug). This term also includes Research that is internally funded or unsponsored. Human Subjects Research is a specific subcategory of Research.

~~**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 [Fn2]:~~

- ~~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.~~

~~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;~~
- ~~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. Scholarly or Educational Activity means any activity involving the creation, discovery, dissemination, integration, or application of knowledge, ideas, or concepts, as well as any teaching, mentoring, or other scholarly work that promotes, facilitates, or contributes to the intellectual advancement of students or other individuals. Examples of Scholarly Activity include, but are not limited to, academic presentations and publications; creative endeavors, performances, or literary or artistic works; significant study in pursuit of scholarly expertise; or the design or improvement of a method, application, device, computer program, therapy, treatment approach, or

teaching/educational model or curriculum. Examples of *Educational Activity* include, but are not limited to, the supervision, training, or mentoring of students, graduate students, trainees, or fellows.

- N. **Transaction** means a formal or informal contract or agreement, express or implied, to which the University or the University of Utah Research Foundation (“UURF”) is a party. Transactions include, but are not limited to, purchases (including the purchase of supplies, equipment, or services), subcontracts, sub-awards, material transfer agreements, term sheets (whether binding or non-binding), option agreements, licensing agreements, agreements for sponsored research, grants, lease agreements, etc.

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).~~

A. Disclosure and Training Requirements

The system and processes established under this Policy use disclosure by individuals as the key mechanism for identifying, evaluating, and, when necessary, managing individual financial conflicts of interest. To ensure such disclosure occurs appropriately, individuals are required to periodically undergo training, including training regarding disclosure procedures.

1. Disclosure Schedule

a. Annual Disclosure Requirement for Certain Employees

The following Employees are required to submit a BRR Disclosure Form upon hire and at the start of each academic year:

- i. All faculty members, excluding emeritus faculty, visiting faculty, and adjunct faculty;
- ii. All staff employed at the manager level or above; and
- iii. All staff with purchasing authority or delegated purchasing authority, including account executives and their delegates, staff authorized to use an institutional credit card (e.g., Purchasing Card or PCard), and staff authorized to make purchases through UShop.

b. Event-Based Disclosure Requirement for Employees Who Participate in Certain Activities

Each Investigator and each Employee is required to submit a BRR Disclosure Form and receive approval from the Individual Conflict of Interest Committee prior to engaging in the following activities:

- i. Research;
- ii. Scholarly or Educational Activity; or
- iii. Transactions

c. Requirement to Update BRR Disclosure Form

Once an Investigator or Employee submits a BRR Disclosure Form as required in this section, Section III.A., the individual is required to update that BRR Disclosure Form:

- i. At least annually; or
- ii. Within thirty (30) days of generating, discovering, or acquiring (e.g., through purchase, marriage, inheritance, or any other mechanism) a new Financial Relationship.

2. BRR Disclosure Form Contents (Relevant Information)

- a. As provided for in the University's approved BRR Disclosure Form instructions, when an Investigator or Employee submits a BRR Disclosure Form as required by this section, Section III.A.1., the individual is required to disclose all Financial Relationships that are reasonably related to the individual's responsibilities to the University, as those responsibilities are defined by the individual's department or job description. If the Investigator or Employee has no such Financial Relationships, the Investigator or Employee is required to submit a BRR Disclosure Form and certify that the individual has nothing to disclose.
- b. In addition to disclosing Financial Relationships, each Investigator who participates in Research funded by the United States Public Health Services is required to 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) that is related to the Investigator's responsibilities to the University [Fn1]; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by the following entities within the United States:
 - i. a federal, state, or local government agency;

- ii. an institution of higher education as defined at 20 U.S.C. § 1001(a);
 - iii. an academic teaching hospital;
 - iv. a medical center; or
 - v. a research institute that is affiliated with an institution of higher education within the United States.
- c. State or federal law or other University Regulations may require individuals to disclose certain financial and other relationships that are not covered by this Policy. It is the responsibility of each Investigator and each Employee to comply with all such laws or Regulations.
3. Training

Each Investigator and each Employee who is required to submit a BRR Disclosure Form under Section III.A.1. is also required to complete a financial conflict of interest training that is provided by the University. Once an individual completes such training, the individual is required to repeat the training at least every four (4) years thereafter.

~~Activities Requiring Disclosure~~

~~a.—Research and Scholarly Activity~~

- ~~1.—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~~
- ~~2.—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.~~
- ~~3.—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.~~

~~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.~~

~~3. 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.~~

~~4. Procurement~~

- ~~1. Disclosure is required when an Employee or his/her Family Member has a Significant Financial Interest in a Business Entity proposing to enter into a transaction with the University, and that Employee or Family Member is in a position to influence the outcome of the University's decision on that transaction.~~
- ~~2. Disclosure is required when an Employee or his/her Family Member has a Significant Financial 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 otherwise limit consulting by faculty or staff as defined under Policy 5-204.~~
- ~~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.~~

~~B. Activities That Are Not Allowed (Prohibited Activities)~~

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

~~1. Academic Freedom Restrictions~~

- ~~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).~~
- ~~b. Investigators shall not permit a sponsor to compromise the integrity of the scientific analysis or the publication of research results or its conclusions.~~
- ~~c. Evaluation of faculty, staff, postdoctoral fellows, 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) non-University activities involving Business Entities in which the evaluating Employee or Investigator has a 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.~~

~~2. Human Subjects Research~~

~~Individual Investigators or Employees participating in the design, conduct, or reporting of 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.~~

~~3. 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 or his/her Family Member has a Significant Financial Interest is not allowed.~~

~~4. Solicitation or Receipt of Gifts [Fn1]~~

~~Solicitation or receipt of a gift by a University Employee, whether directly or indirectly through the institution, is not allowed, when (a) the purpose or effect of the gift is likely to improperly influence the Employee in the discharge of his/her University responsibilities; (b) the gift is given to reward the Employee for official action taken; or (c) the gift is given in close proximity [Fn3] to recent past, present, or future transactions between the University and the giver of the gift.~~

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.

5. 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.
6. 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.
7. 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 [Fn2].
8. 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 [Fn4]; 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.

B. 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 (3) year terms. A majority of the voting members shall be University tenure-line or career-line faculty members. The Committee shall be ~~a campus-wide~~ an institution-wide committee with broad representation ~~from across campus~~ throughout the University. 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 [See Rule 1-006A: Individual Conflict of Interest Committee Membership Rule], ~~to be approved as per Policy 1-004.~~

2. The Committee is charged with:
 - a. ~~providing~~ 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~~ Reviewing ~~Disclosure Forms~~ the information submitted by Investigators and Employees as required under this Policy, including completed BRR Disclosure Forms;
 - c. ~~determining~~ Determining whether a disclosed ~~Significant Financial Interest~~ Financial Relationship of an individual that has been (or should have been) disclosed is a financial conflict of interest; and, if so,
 - d. ~~determining~~ Determining if and how a financial conflict of interest can be managed, reduced, or eliminated to protect the Investigator or Employee, the interests of the University, University subordinates, ~~R~~Research participants, and the public.
 3. ~~A~~ The University shall establish a Conflict of Interest Office, employ a Conflict of Interest Officer and such other staff as needed, ~~shall be employed by the University~~ and allocate adequate resources ~~allocated~~ to support the duties of the Individual Conflict of Interest Committee and the implementation of this Policy.
 4. The Committee and its members shall act without bias in administering this Policy.
- C. 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,~~ initially screen each individual case (as presented through a submitted Disclosure Form) to determine whether a Financial Relationship ~~Significant Financial Interest~~ exists that requires the review of the ~~Conflict of Interest~~ Committee. The Office will notify the Investigator or Employee, as well as the Investigator's or Employee's ~~his/her~~ department chair or supervisor, when the Conflict of Interest Office refers a potential conflict of interest to the ~~Conflict of Interest~~ Committee for review.
 2. For each case referred to it, ~~the~~ Individual Conflict of Interest Committee will consult with the Investigator or Employee as appropriate and determine whether a Financial Relationship creates a financial conflict of interest. If it is determined

- that a financial conflict of interest exists, 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 Individual Conflict of Interest Committee to the Investigator or Employee, the Investigator's or Employee's ~~his/her~~ University superiors, and appropriate offices within the University.
 4. The Individual Conflict of Interest Committee is primarily responsible for monitoring and ensuring compliance with an approved plans to manage, reduce, or eliminate a 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 a plans requires specific expertise beyond that of the Office or the Committee members, the Committee may enlist ~~peers~~ qualified experts to assist with monitoring compliance as needed.
 5. The University will adhere to ~~R~~Research sponsor requirements and state and federal law for reporting of disclosure and management, reduction, or elimination of conflicts of interest.

D. 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 that includes 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 will be the University's final decision.

E. Confidentiality and Internal and External Dissemination of Information Regarding Conflicts

- ~~1. Conflict of interest disclosures and Committee determinations concerning conflicts and violations shall be available to:~~
 1. The information disclosed for a case under this Policy (including contents of any BRR Disclosure Form), the written descriptions of the Individual Conflict of Interest Committee's determinations in a case concerning any conflicts or any violations/non-compliance, and the final report of a decision on an appeal to the panel (described in Section III.D.) of a decision regarding a policy violation/non-compliance (described in Section III.F.) shall be disseminated (or as appropriate, made available) internally within the University to:
 - a. ~~the~~ The Investigator's or Employee's University superiors;
 - b. ~~the~~ 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, Center for Technology & Venture Commercialization ~~Technology Commercialization Office~~, Procurement & Contracting Services, Graduate School; and

- c. ~~other~~ Other Employees whose responsibilities to the University are directly affected by the conflict of interest.
2. The University will adhere to Research sponsor requirements and state and federal law for reporting of disclosures.
 3. In certain circumstances, federal ~~and~~ or state law may require public ~~disclosure~~ dissemination of information relating to an identified conflicts of interest.
 4. In other circumstances, including, but not limited to, conflicts regarding ~~h~~Human ~~s~~Subjects ~~r~~Research, the University may require public ~~disclosure~~ dissemination of information as part of a conflict of interest management plan.
 5. Except for the foregoing ~~disclosures~~ categories allowing for dissemination of information contemplated in this Policy, the Individual Conflict of Interest Committee and ~~those~~ other individuals within the University who have direct responsibility for reviewing potential conflicts or investigating potential violations of this Policy, including non-compliance with conflict of interest management plans, shall treat the information received and considered during these processes as confidential information.
 6. 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.
 7. An Employee who violates Section III.E.5. or Section III.E.6. Unauthorized of any such information by an Employee shall be deemed to have engaged in ~~be~~ unethical behavior, ~~which is and shall be~~ punishable under pertinent University Regulations, including Policy 5-111: (Corrective Action and Termination Policy for Staff Employees) or Policy 6-316: Code of Faculty Rights and Responsibilities. ~~Policy 6-316, Sections 4 & 5 (Faculty Code).~~

~~B. 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.~~

F. Violations/Non-Compliance

1. ~~Reports~~ Reporting Violations or Management Plan ~~of~~ Non-Compliance
~~Potential violations~~ A potential violation of this Policy, including a potential failure to comply with any approved ~~or any~~ conflict of interest management plans adopted under the authority of this Policy, must be reported to the University's Conflict of Interest Officer.

2. Investigation of [Violations or Management Plan](#) Non-Compliance

The Individual Conflict of Interest Committee shall investigate [any](#) potential ~~non-compliance with violation of~~ this Policy, including [any](#) potential ~~non-compliance with prescribed~~ [failure to comply with an approved conflict of interest](#) management plans.

3. Protection of Affected Parties

To the extent permitted by law and University ~~policies~~ [Regulations](#), the University will protect the identity and privacy of ~~these~~ [any](#) individuals who, in good faith, ~~report apparent non-compliance with this Policy or furnish information regarding such non-compliance~~ [reports or furnishes relevant information for an investigation of a potential violation of this Policy, including potential non-compliance with a conflict of interest management plan.](#)

Retaliation of any kind against any [such](#) 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~~ [Regulations](#).

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

a. For [a](#) violations of this Policy, [including failure to comply with an approved conflict of interest management plan](#), the [Individual Conflict of Interest Committee](#) may impose one or more of the following restrictions on an individual:

- i. Freeze ~~r~~[R](#)esearch funds, or otherwise suspend, a project or projects related to the policy violation/[non-compliance](#);
- ii. Remove the individual found to be in violation from a role as ~~Principal Investigator or~~ [Investigator](#) on a project([s](#)) related to the policy violation/[non-compliance](#);
- iii. Prohibit submission of new applications to the Institutional Review Board or to the Office of Sponsored Projects until resolution of the relevant conflict of interest issues or for a specified period of time; [or](#)
- iv. 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 that 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 the University's final decision.

c. In [a](#) 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)~~ [Section III.F.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 a violations of this Policy, including failure to comply with an approved conflict of interest management plan, the Individual Conflict of Interest 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 a violations of this Policy, including failure to comply with an approved conflict of interest management plan, the Individual Conflict of Interest Committee may recommend to the cognizant vice president(s) that one or more of the following administrative actions be taken:

- i. Withholding payment owed under a procurement contract relating to the conflict;
- ii. 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;
- iii. Legal action to recover the amount of financial benefit received by an Investigator or Employee as a result of the Investigator's or Employee's ~~his or her~~ violation of this ~~p~~Policy; or
- iv. Other similar and appropriate actions.

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

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 and Compliance shall report incidents of violations/non-compliance of with this Policy to external agencies and sponsors as required by state and federal law.

G. Other Conflict of Interest Policies and Procedures

1. University Institutional Conflict of Interest Policy

In situations ~~where~~ in which both an individual and an institutional conflict of interest may exist, Investigators and Employees ~~will be~~ are required to comply with the requirements of this Policy and also with the requirements of [Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects Policy](#) [~~Policy XXX – (new University Institutional Conflict of Interest policy currently being written)~~]. ~~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 Officer ~~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, provided 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.

[Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information – the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

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

A. Rules

1. Rule ~~R1-006A~~: Individual Conflict of Interest Committee Membership Rule
2. Rule ~~R1-006B~~: Individual Financial Conflict of Interest Non-Compliance
3. [Rule 1-006C: Individual Financial Conflict of Interest in Research](#)
4. [Rule 1-006D: Individual Financial Conflict of Interest in Scholarly or Educational Activity](#)
5. [Rule 1-006E: Individual Financial Conflict of Interest in Transactions](#)

B. Procedures

1. Procedure [P1-006](#): Reviewing Individual Conflict of Interest BRR Disclosure Forms

C. Guidelines [\[reserved\]](#)

D. Forms [\[reserved\]](#)

E. Other related resource materials.

1. [Supplemental Rule 1-006](#): Health Sciences Industry Relations Policy [SR1-006](#)

V. References

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

B. [Utah Code Ann. § 76-8-105\(1\).](#)

C. National Science Foundation ~~Policy~~; Grant Policy Manual, [Chapter V, Grantee Management Standard](#) 510, [Conflict of Interest Investigator Disclosure Policy](#), ~~60 F.R. 132, pp. 35810-823 (July 11, 1995).~~

D. 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 C.F.R. ~~pt. Part~~ 50, Subpart F (for NIH Contracts, 45 C.F.R. ~~pt. Part~~ 94, Responsible Prospective Contractors).

E. U.S. Department of Health and Human Services, Financial Disclosure by Clinical Investigators, 21 C.F.R. ~~pt. Part~~ 54.

F. Anti-Kickback Act of 1986 ~~(41 U.S.C. § 8701 et seq., 51-58)~~ [48 C.F.R. § 3.502-1 et seq.](#) and OMB ~~Uniform Guidance~~ [Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards](#) ~~Guidance~~, (2 C.F.R. ~~pt. 200~~).

G. [Policy 5-111](#), [Corrective Action and Termination Policy for Disciplinary Actions and Dismissal of](#) Staff Employees.

H. [Policy 1-0125-210](#), [University Non-discrimination Policy](#) ~~Employee Relations Procedures for Alleging Discrimination or Harassment and for Initiating Staff Employment Grievances.~~

I. [Rule 3-100E](#) ~~Policy 3-192~~, Restricted Purchases and Special Procurement.

J. [Policy 7-001](#), Policy for Research Misconduct.

K. [Policy 7-003](#), [Ownership of Copyrightable Works and Related Works](#) ~~Policy: Ownership Purpose and Scope.~~

L. [Policy 6-400](#), Code of Student Rights and Responsibilities (["Student Code"](#)).

M. [Policy 6-316](#), Code of Faculty Rights and Responsibilities.

[Regulations Addressing](#) Related Topics Not [Directly](#) Addressed by this Policy

- A. [Policy 5-204](#), Remunerative Consultation and Other Employment Activities, and [Policy 5-403](#), Additional Compensation and Overload Policy, discuss conflicts of commitment of time and use of the University's name, property, facilities, or resources.
~~Policy 4-005, Use and Security of Property, discusses use of property, supplies and services purchased with University funds.~~
- B. [Policy 1-020, Required Professional Boundaries in Relationships.](#)
- C. [Policy 5-105, Employment or Supervision of Immediate Family.](#)
- D. [Policy 7-004](#), University Faculty Profit-Making Corporations, discusses conflicts of commitment.
- E. [Policy 7-002](#)~~043~~, Patents and Inventions, discusses requirements for transfer of University technology and other intellectual property.
- F. [Policy 6-316](#), Code of Faculty Rights and Responsibilities, discusses use of the University's name or property.
- G. [Policy 7-006](#): Institutional [Financial](#) Conflicts of Interest [for Research Involving Human Subjects](#)~~are not covered by this policy.~~
- H. [Policy 8-001, Medical Practice Plan for the University of Utah School of Medicine Full-Time Faculty.](#)

VI. Contacts:

The designated contact officials for this Policy are:

- A. Policy Owner (primary contact person for questions and advice): Conflict of Interest Officer
- B. Policy Officers: Vice President and General Counsel, Vice President for Research

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provided in University Rule 1-001:

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

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

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

VII. History Renumbering:

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

Revision History:

A. Current version: Revision 12

Effective date: XXXXX

Approved: Academic Senate: May 7, 2012

Approved: Board of Trustees: June 12, 2012

Legislative History of Revision 12

B. Earlier versions:

Revision 11: Effective dates – August 20, 2012 to XXXXX

Revision 10: Effective dates - March 8, 2004 to August 19, 2012

Revision 9: Effective dates - February 9, 2004 to March 7, 2004

Revision 8: Effective dates - July 15, 2003 to February 8, 2004

Revision 7: Effective dates - April 15, 2002 to July 14, 2003

Revision 6: Effective dates - September 22, 2000 to April 14, 2002

Revision 5: Effective dates - July 18, 1994 to September 21, 2000

~~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.~~

~~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.~~

- (1) An Investigator who is not University Employees, as defined in this Policy, is required to 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) that is related to the Investigator's responsibilities to the Investigator's employer or profession; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by the following entities within the United States:
1. a federal, state, or local government agency;
 2. an institution of higher education as defined at 20 U.S.C. 1001(a);
 3. an academic teaching hospital;
 4. a medical center; or
 5. a research institute that is affiliated with an institution of higher education within the United States.

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

~~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.~~

Draft 3/16/2020

Rule 1-006C: Individual Financial Conflict of Interest in Research. Revision 0.

Effective Date: ????, 2020

I. Purpose and Scope

A. Purpose

This Rule implements Policy 1-006: Individual Financial Conflict of Interest Policy by clarifying how the University identifies, evaluates, and manages individual financial conflicts of interest in Research activities.

The University is committed to ensuring that Investigators conduct Research with the utmost integrity, free from bias or prejudice that may arise from financial conflicts of interest.

B. Scope

This Rule applies to each individual who meets the definition of Investigator.

This Rule addresses *individual* conflicts of interest related to Research.

This Rule is not intended to directly govern other conflicts of interest that might arise during an Investigator's University duties, which are governed by other Regulations. [See e.g., Policy 5-204: Remunerative Consultation and Other Employment Activities, Supplemental Rule 1-006: Health Sciences Industry Relations Policy]. Similarly, this Rule is not intended to directly govern financial conflicts of interest of the University as an *institution*, which are governed by other Regulations. [See Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects].

II. Definitions

The definitions provided in Policy 1-006 apply for purposes of this Rule. Additionally, the following definitions apply for the limited purposes of this Rule.

- A. **Investigator** -- means an individual, regardless of whether or not an Employee, who is the project director or the Principal Investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research conducted in whole or in part under the auspices of the University, which may include, for example, visiting scientists, collaborators, consultants, or sub-award or subcontract recipients.

- B. **Significant Financial Interest** -- means a financial interest consisting of one or more of the following interests of the individual Investigator (or those of the Investigator's Family Member) that reasonably appear to be related to the Investigator's responsibilities to the University, as defined by an individual's department or job description [Fn1]:
1. With regard to any publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in the Business Entity as of the date of disclosure, when aggregated, exceed \$5,000.
 2. With regard to any non-publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual holds any Equity Interest; or
 3. Any instance where an Investigator (or a Family Member) has, or reasonably foresees having, the right to receive Compensation as a result of licensing or other commercialization of Intellectual Property created by that Investigator (or Family Member), including the right to receive shares of revenue, royalties, or other payments generated by such commercialization (e.g., an inventor's share of royalty income under University policy).

However, Significant Financial Interest does NOT include:

1. Salary, travel reimbursements, or other non-royalty Compensation received by the Investigator (or a Family Member) from the University if the Investigator (or a Family Member) is currently employed or otherwise appointed by the University;
2. Income received by the Investigator (or a Family Member) from seminars, lectures, or teaching engagements sponsored by, or income received by the Investigator (or Family Member) from service on advisory committees or review panels for the following entities within the United States:
 - a. a federal, state, or local government agency;
 - b. an institution of higher education as defined at 20 U.S.C. 1001(a);
 - c. an academic teaching hospital;
 - d. a medical center; or
 - e. a research institute that is affiliated with an institution of higher education within the United States; or
3. Income received by the Investigator (or a Family Member) from investment vehicles, such as mutual funds and retirement accounts, provided that the

Investigator (or Family Member) does not directly control the investment decisions made in these vehicles.

III. Rule

A. Research Activities Requiring Disclosure

Policy 1-006 requires Investigators to disclose certain types of information using an approved BRR Disclosure Form in accord with the University's approved BRR Disclosure Form Instructions. This Rule implements the Policy with the following requirements.

1. Each Investigator is required to submit a BRR Disclosure Form to the University prior to approving, designing, conducting, or reporting on Research that is conducted in whole or in part under the auspices of the University. This includes, without limitation, Human Subjects Research and all other types of Research, including internally funded or unsponsored Research.
2. Each Investigator is required to submit a BRR Disclosure Form to the University prior to evaluating, supervising, or overseeing Research involving University subordinates or students.
3. The COI Office is responsible for identifying and managing conflicts of interest related to sponsored Research and Human Subjects Research. It is the responsibility of each Employee to notify the Employee's supervisor and the Conflict of Interest Office of any perceived, potential, or actual conflict of interest that may arise as a result of the Employee's involvement in Research, including internally funded or unsponsored research.

B. Evaluation of Conflicts of Interest in Research

1. The Individual Conflict of Interest Committee will evaluate the information provided in an Investigator's BRR Disclosure Form to determine if the Investigator has any Significant Financial Interests that could create a financial conflict of interest [See Procedure 1-006: Reviewing Individual Conflict of Interest BRR Disclosure Forms].
 - a. Consistent with the University's institutional values, Human Subjects Research shall receive the highest level of protection from bias or the appearance of bias created by an individual's conflict of interest. Consequently, the University will apply a presumption against the conduct of Human Subjects Research in any circumstance in which an individual has a conflict of interest relating to the Research. The Individual Conflict of Interest Committee may allow such an individual to conduct the Research only upon a finding of compelling circumstances and only when the Committee can craft an effective management plan to mitigate the conflict. Otherwise, the individual will be required to eliminate the conflict or the Research project will be conducted without involvement by the Investigator who has the conflict.

C. Management of Conflicts of Interests in Research

The Individual Conflict of Interest Committee may manage conflicts of interest in Research by requiring:

1. Disclosure of financial conflicts of interest in publications and presentations;
2. Disclosure of financial conflicts of interest to students or subordinates working on the Research;
3. Disclosure of financial conflicts of interest to the Research team;
4. For Human Subjects Research, disclosure of financial conflicts of interest to potential participants;
5. Appointment of an independent monitor to evaluate the Research to protect against bias resulting from the conflict of interest;
6. Recusal from certain responsibilities in the Research;
7. Elimination of the Significant Financial interest; or
8. Any other management strategy the Committee determines is necessary to appropriately manage a conflict of interest.

D. Prohibited Activities

The following types of activities present conflicts of interest in which an Investigator who has a Significant Financial Interest is not allowed to participate because such an activity would be a violation of law or is judged by the University to be a violation of its institutional values.

1. Any activity that benefits any Business Entity in which an Investigator has a Significant Financial Interest, and that compromises the integrity of the scientific analysis or the publication of Research results or its conclusions, is not allowed. Note that an Investigator has obligations under other University Regulations related to research integrity (e.g., Policy 7-001: Policy for Research Misconduct), and this Rule shall not be construed as limiting those obligations in any way.
2. An Investigator participating in the design, conduct, or reporting of any Human Subjects Research study shall not, directly or indirectly, accept any incentives or gifts from a Business Entity that is sponsoring or providing support for the Research. Any payments to the University from any Business Entity sponsoring or providing support for such Research shall only be deposited into the Investigator's restricted project account established for the Research, unless otherwise specifically approved in advance by the Vice President for Research.
3. Solicitation or receipt of a Gift by a University Employee, whether directly or indirectly through the institution, is not allowed, when (a) the purpose or effect of

the Gift is likely to improperly influence the Employee in the discharge of the Employee's University responsibilities; (b) the Gift is given to reward the Employee for official action taken; or (c) the Gift is given in close proximity to recent past, present, or future transactions between the University and the giver of the Gift

This provision is intended to help ensure Employees comply with the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq., and this provision shall be interpreted to be in conformity with that Act.

- (1) For an Investigator who is not a University Employee, as defined in Policy 1-006, "Significant Financial Interest" includes those financial interests that reasonably appear to be related to that Investigator's responsibilities to the Investigator's employer or profession.

[Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information – the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

IV. Procedures, Guidelines, Forms and other Related Resources

[Reserved]

V. References

[Reserved]

VI. Contacts

The designated contact officials for this Regulation are:

- A. Policy Owner (primary contact person for questions and advice): Conflict of Interest Officer
- B. Policy Officers: Vice President for Research and Vice President and General Counsel

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provide in University Rule 1-001:

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

“The Policy Officer will identify an ‘Owner’ for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to who the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... [and] bears the responsibility for determining – requirements of particular Policies...”

University Rule 1-001-III-B & E

VII. History

Current version____Revision 0. Approved by +++ date +++.

Legislative History. [link]

DRAFT

Draft 3/16/2020

Rule 1-006D: Individual Financial Conflict of Interest in Scholarly or Educational Activity. Revision 0.

Effective Date: ????, 2020

I. Purpose and Scope

A. Purpose

This Rule implements Policy 1-006: Individual Financial Conflict of Interest Policy by clarifying how the University identifies, evaluates, and manages conflicts of interest in Scholarly or Educational Activity.

The University is committed to ensuring that Employees engage in Scholarly or Educational Activity with the utmost integrity, free from bias or prejudice that may arise from financial conflicts of interest.

B. Scope

This Rule applies to each Employee who engages in Scholarly or Educational Activity.

This Rule addresses *individual* conflicts of interest related to Scholarly or Educational Activity.

This Rule is not intended to directly govern other conflicts of interest that might arise during an Employee's University duties, which are governed by other Regulations. [See e.g., Policy 5-204: Remunerative Consultation and Other Employment Activities, Supplemental Rule 1-006: Health Sciences Industry Relations Policy]. Similarly, this Rule is not intended to directly govern financial conflicts of interest of the University as an *institution*, which are governed by other Regulations. [See Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects].

II. Definitions

The definitions provided in Policy 1-006 apply for purposes of this Rule. Additionally, the following definitions apply for the limited purposes of this Rule.

- A. **Scholarly or Educational Activity** means any activity involving the creation, discovery, dissemination, integration, or application of knowledge, ideas, or concepts, as well as any teaching, mentoring, or other scholarly work that promotes, facilitates, or contributes to the intellectual advancement of students or other individuals. Examples of *Scholarly Activity* include, but are not limited to, academic presentations and publications; creative endeavors, performances, or literary or artistic works; significant study in pursuit of scholarly expertise; or the design or

improvement of a method, application, device, computer program, therapy, treatment approach, or teaching/educational model or curriculum. Examples of *Educational Activity* include, but are not limited to, the supervision, training, or mentoring of students, graduate students, trainees, or fellows.

- B. **Significant Financial Interest** -- means a financial interest consisting of one or more of the following interests of the individual Employee (or those of the Employee's Family Member) that reasonably appear to be related to the Employee's responsibilities to the University, as defined by an individual's department or job description:
1. With regard to any publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in the Business Entity as of the date of disclosure, when aggregated, exceed \$5,000;
 2. With regard to any non-publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual holds any Equity Interest; or
 3. Any instance where an Employee (or a Family Member) has, or reasonably foresees having, the right to receive Compensation as a result of licensing or other commercialization of Intellectual Property created by that Employee (or Family Member), including the right to receive shares of revenue, royalties, or other payments generated by such commercialization (e.g., an inventor's share of royalty income under University policy).

However, Significant Financial Interest does NOT include:

1. Salary, travel reimbursements, or other non-royalty Compensation from the University if the individual is currently employed or otherwise appointed by the University;
2. Income received by the Employee (or a Family Member) from seminars, lectures, or teaching engagements sponsored by, or income received by the Employee (or Family Member) from service on advisory committees or review panels for the following entities within the United States:
 - a. a federal, state, or local government agency;
 - b. an institution of higher education as defined at 20 U.S.C. 1001(a);
 - c. an academic teaching hospital;
 - d. a medical center; or

- e. a research institute that is affiliated with an institution of higher education within the United States; or
3. 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.

III. Rule

A. Scholarly or Educational Activities Requiring Disclosure

Policy 1-006 requires Employees to disclose certain types of information using an approved BRR Disclosure Form in accord with the University's approved BRR Disclosure Form Instructions. This Rule implements the Policy with the following requirements.

1. Each Employee is required to submit a BRR Disclosure Form to the University prior to engaging in Scholarly or Educational Activity.
2. Each Employee is required to submit a BRR Disclosure Form to the University prior to evaluating, supervising, or overseeing Scholarly or Educational Activity involving University subordinates or students.
3. Each Employee is required to notify the Employee's supervisor and the Conflict of Interest Office of any perceived, potential, or actual conflict of interest that may arise as a result of the Employee's involvement in Scholarly or Educational Activity.

B. Evaluation of Conflicts of Interest in Scholarly or Educational Activity

1. The Individual Conflict of Interest Committee will evaluate the information provided in an Employee's BRR Disclosure Form to determine whether or not a Significant Financial Interest(s) exists that could potentially create a financial conflict of interest [See Procedure 1-006: Reviewing Individual Conflict of Interest BRR Disclosure Forms].

C. Management of Conflicts of Interest in Scholarly or Educational Activity

The Individual Conflict of Interest Committee may manage conflicts of interest in Scholarly or Educational Activity by requiring any of the following:

1. Disclosure of financial conflicts of interest to Supervisor(s);
2. Disclosure of financial conflicts of interest to students or subordinates involved in the Scholarly or Educational Activity;
3. Recusal from certain roles or responsibilities related to the Scholarly or Educational Activity;

4. Elimination of the Significant Financial interest; or
5. Any other management strategy the Committee determines is necessary to appropriately manage a conflict of interest.

D. Prohibited Activities

The following types of activities present conflicts of interest in which an Employee who has a Significant Financial Interest is not allowed to participate because such an activity would be a violation of law or is judged by the University to be a violation of its institutional values.

1. An Employee is not allowed to participate in any secrecy or confidentiality obligation benefitting a Business Entity in which the Employee has a Significant Financial Interest if that obligation affects evaluation of any University student, faculty member, or other Employee, or if it delays fulfillment of a student's degree requirements by more than the time contractually allowed for publication or protection of Intellectual Property rights (up to six (6) months).
2. No Employee who has a Significant Financial Interest in any Business Entity shall, on behalf of the University, take any employment action or exercise any evaluation regarding any individual University faculty member, staff, postdoctoral fellow, medical housestaff member, educational trainee, or student that is based, in whole or in part, on that individual's refusal to participate in, agreement to participate in, or level of performance while participating in, any non-University activities involving that Business Entity. No faculty member, staff, medical housestaff member, educational trainee, or student shall be required or expected to participate in any non-University activity involving any such Business Entity.
3. If an Employee acts on behalf of a Business Entity to supervise an individual who is conducting non-University work for that Business Entity, that Employee is not allowed to also act on the University's behalf as that individual's supervisor or otherwise evaluate that individual for purposes of University employment or Scholarly or Educational Activity. For example, if an Employee supervises a graduate student's non-University work for a Business Entity, that Employee is not allowed to participate on that student's dissertation committee at the University.
4. Solicitation or receipt of a Gift by a University Employee, whether directly or indirectly through the institution, is not allowed, when (a) the purpose or effect of the Gift is likely to improperly influence the Employee in the discharge of the Employee's University responsibilities; (b) the Gift is given to reward the Employee for official action taken; or (c) the Gift is given in close proximity to recent past, present, or future transactions between the University and the giver of the Gift.

This provision is intended to help ensure Employees comply with the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq., and this provision shall be interpreted to be in conformity with that Act.

[Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information – the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

IV. Procedures, Guidelines, Forms and other Related Resources

[Reserved]

V. References

[Reserved]

VI. Contacts

The designated contact officials for this Regulation are:

- A. Policy Owner (primary contact person for questions and advice): Conflict of Interest Officer
- B. Policy Officers: Vice President for Research and Vice President and General Counsel

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provide in University Rule 1-001:

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

“The Policy Officer will identify an ‘Owner’ for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to who the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... [and] bears the responsibility for determining – requirements of particular Policies....”

University Rule 1-001-III-B & E

VII. History

Current version____Revision 0. Approved by +++ date +++.

Legislative History. [[link](#)]

DRAFT

Draft 3/16/2020

R1-006E: Individual Financial Conflict of Interest in Transactions. Revision 0.

Effective Date: ????, 2020

I. Purpose and Scope

A. Purpose

This Rule implements Policy 1-006: Individual Financial Conflict of Interest Policy by clarifying how the University identifies, evaluates, and manages conflicts of interest of Employees in certain Transactions. The University is committed to ensuring that Employees engage in such Transactions with the utmost integrity, free from bias or prejudice that may arise from financial conflicts of interest.

B. Scope

This Rule applies to each Employee who engages in any “Transaction” (as that is specifically defined in Policy 1-006, encompassing various agreements to which the University or the University of Utah Research Foundation is a party).

This Rule addresses *individual* conflicts of interest related to such Transactions.

This Rule is not intended to directly govern other conflicts of interest that might arise during an Employee’s University duties, which are governed by other Regulations. [See e.g., Policy 5-204: Remunerative Consultation and Other Employment Activities, Supplemental Rule 1-006: Health Sciences Industry Relations Policy]. Similarly, this Rule is not intended to directly govern financial conflicts of interest of the University as an *institution*, which are governed by other Regulations. [See Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects].

II. Definitions

The definitions provided in Policy 1-006 apply for purposes of this Rule. Additionally, the following definitions apply for the limited purposes of this Rule.

- A. **Substantial Interest** means the ownership, either legally or equitably, by an Employee (or the Employee’s spouse or minor children) of at least 10% of the outstanding capital stock of a corporation, or at least a 10% interest in any other type of Business Entity. However, an Employee is NOT deemed to have a Substantial Interest in a Business Entity, if the total value of the Equity Interest of the Employee (or the Employee’s spouse or minor children) does not exceed \$2,000. A life insurance policy or an annuity may not be considered when determining the value of a Substantial Interest.

An Employee also has a Substantial Interest if the Employee serves as an officer, director, agent, or employee of a Business Entity.

- B. Transaction means a formal or informal contract or agreement, express or implied, to which the University or the University of Utah Research Foundation (“UURF”) is a party. Transactions include, but are not limited to, purchases (including the purchase of supplies, equipment, or services), subcontracts, sub-awards, material transfer agreements, term sheets (whether binding or non-binding), option agreements, licensing agreements, agreements for sponsored research, grants, lease agreements, etc.

III. Rule

A. Transactions Requiring Disclosure

Policy 1-006 requires Employees to disclose certain types of information using an approved BRR Disclosure Form in accord with the University’s approved BRR Disclosure Form Instructions. This Rule implements the Policy with the following requirements.

1. If an Employee has a Substantial Interest in a Business Entity, and the Business Entity commences negotiations with the University of Utah Research Foundation (UURF) or the University regarding a Transaction to secure Intellectual Property, the Employee is required to submit a BRR Disclosure Form to the University upon becoming aware of such negotiations.
2. If an Employee has a Substantial Interest in a Business Entity that is proposing to enter into another type of Transaction with UURF or the University, and the Employee is in a position to influence the decision of the UURF or the University’s decision on that Transaction, the Employee is required to submit a BRR Disclosure Form to the University upon becoming aware of that proposed Transaction.
3. If an Employee has a Substantial 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, the Employee is required to submit a BRR Disclosure Form to the University upon becoming aware of these circumstances.
4. Each Employee is required to notify the Employee’s supervisor and the Conflict of Interest Office of any perceived, potential, or actual conflict of interest that may arise as a result of the Employee’s involvement in a Transaction on behalf of the University.

B. Evaluation of Conflicts of Interest in Transactions

1. The Individual Conflict of Interest Committee will evaluate the information provided in an Employee’s BRR Disclosure Form, or information otherwise

provided, to determine whether or not a Substantial Interest in a Business Entity exists that could create a conflict of interest [See Procedure 1-006: Reviewing Individual Conflict of Interest BRR Disclosure Forms].

C. Management of Conflicts of Interest in Transactions

The Individual Conflict of Interest Committee may manage conflicts of interest of any Employee in any Transaction by requiring any of the following:

1. Disclosure of an Employee's financial conflict of interest to a Supervisor;
2. Recusal of an Employee from participating on behalf of the University in the Transaction process (e.g., preparation of specifications, evaluations, bids, or contracts, or committee deliberations/voting);
3. If an Employee's University responsibilities otherwise require input into the selection of products or services from a Business Entity in which the Employee has a Substantial Interest, at the time of the Employee providing such input, require written disclosure of an Employee's financial conflict of interest to all University decision-makers involved in the Transaction;
4. Require elimination of an Employee's Substantial Interest in the Business Entity;
or
5. Any other management strategy the Committee determines is necessary to appropriately manage a conflict of interest.

D. Prohibited Activities

The following types of activities present conflicts of interest in which an Employee who has a Substantial Interest in a Business Entity is not allowed to participate because such an activity would be a violation of law or is judged by the University to be a violation of its institutional values.

1. An Employee is not allowed to negotiate for the University or UURF or act as a University decision maker or a UURF decision maker regarding any Transaction with a Business Entity in which the Employee has (or will likely have) a Substantial Interest.
2. An Employee is not allowed to disclose or use any of the University's controlled, private, or protected business information (1) to further the Employee's or another's business interests or (2) to secure special privileges or exemptions for the Employee or others.
3. Solicitation or receipt of a Gift by a University Employee, whether directly or indirectly through the institution, is not allowed, when (a) the purpose or effect of the Gift is likely to improperly influence the Employee in the discharge of the Employee's University responsibilities; (b) the Gift is given to reward the Employee for official action taken; or (c) the Gift is given in close proximity to

recent past, present, or future transactions between the University and the giver of the [Gift](#).

[This provision is intended to help ensure Employees comply with the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq., and this provision shall be interpreted to be in conformity with that Act.](#)

[Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information – the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

IV. Procedures, Guidelines, Forms and other Related Resources

[Reserved]

V. References

[Reserved]

VI. Contacts

The designated contact officials for this Regulation are:

- A. Policy Owner (primary contact person for questions and advice): Conflict of Interest Officer
- B. Policy Officers: Vice President for Research and Vice President and General Counsel

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provide in University Rule 1-001:

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

“The Policy Officer will identify an ‘Owner’ for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to who the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant

portions of the Regulations Library... [and] bears the responsibility for determining – requirements of particular Policies....”

University Rule 1-001-III-B & E

VII. History

Current version____Revision 0. Approved by +++ date +++.

Legislative History. [[link](#)]

DRAFT

Procedures 1-006: Reviewing Individual Conflict of Interest BRR Disclosure Forms

1. The Individual Conflict of Interest Committee (“Committee”) shall review potential conflicts of interest and recommendations forwarded by the Conflict of Interest Office.
2. If the Committee determines that a financial conflict of interest exists, and the Investigator or Employee proposed a plan to manage, reduce, or eliminate the conflict, the Committee shall determine whether the proposed plan is acceptable. The Committee will give the individual an opportunity to provide the Committee with additional information pertaining to the potential conflict or the proposed plan.
3. If the Committee determines that the proposed plan is acceptable, the Conflict of Interest Officer shall transmit the Committee's decision to the individual, ~~his/her~~the individual's department chair or supervisor, and appropriate University offices (e.g., Institutional Review Board, Office of Sponsored Projects, Center for Technology & Venture Commercialization ~~Office~~, Procurement & Contracting Services, Graduate School).
4. If the Committee determines that the proposed plan is not acceptable, or if the individual does not propose a plan, the Committee shall draft an appropriate plan to manage, reduce, or eliminate the conflict. The Committee will give the individual an opportunity to provide any additional information pertaining to the potential conflict of interest. The Conflict of Interest Officer will transmit the Committee's decision and the plan to the individual, ~~his/her~~the individual's department chair or supervisor, and appropriate University offices (e.g., Institutional Review Board, Office of Sponsored Projects, Center for Technology & Venture Commercialization ~~Office~~, Procurement & Contracting Services, Graduate School).
5. If the individual does not agree with the decision or plan approved by the Committee, the Committee will give ~~he/she~~the individual opportunity to resolve any differences with the Committee directly.