**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

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1. **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.

1. **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]](#footnote-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;
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.
4. **Summary of Major Changes**
5. ***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.
1. ***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.
1. ***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.

1. **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 or 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).

1. **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.

1. JASON, Fundamental Research Security 31 (Dec. 2019). [↑](#footnote-ref-1)