

To: Legislative History

From: Emily Ostrander, Director, Conflict of Interest Office
Hailey Ritchie, Associate General Counsel

Policy Owner(s): Conflict of Interest Officer

Date: April 12, 2022

Subject: Policy 1-006 Revision 14 and Related Regulations

Introduction and Background

The University of Utah Conflict of Interest Office (“COI Office”) revised the following regulations, as outlined in more detail below:

- [Interim] Policy 1-006: Individual Financial Conflict of Interest Policy (“Policy 1-006”);
- [Interim] Rule 1-006C: Individual Financial Conflict of Interest in Research (“Rule 1-006C”);
- New Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research (“Procedure 1-006B”); and
- Guideline 1-006A: Determining “Relatedness” to Research (“Guideline 1-006A”).

This legislative history document includes redline versions of Policy 1-006, Rule 1-006C, and Guideline 1-006A showing the additions and deletions. Procedure 1-006B is new, so there is not redline version. This document also include the slides presented to the Academic Senate.

After consultation with the Academic Senate, former President Ruth Watkins approved the Revision 13 of Policy 1-006 and Rule R1-006C on an interim basis, effective February 25, 2021, with a recommendation that the interim regulations be reviewed and promulgated, with any changes, through the normal process within one year.

On December 20, 2021, the U.S. Department of Energy (“DOE”) released a new interim conflict of interest policy (“DOE COI Policy”) applicable to DOE funding opportunity announcements (except Office of Indian Energy and Phase I Small Business Innovation Research/Small Business Technology Transfer applications and awards), which requires entities applying for, or receiving, DOE funding to ensure their conflict of interest policies are consistent with the DOE’s COI Policy within 180 days of December 20, 2021. The DOE’s COI Policy is largely aligned with existing Public Health Service (“PHS”) requirements.

On January 4, 2022, the Biden Administration released guidance “directing federal research agencies to work together within the next 120 days to develop model grant application forms

and instructions that can be used (and adapted where required) by any federal research funding agency” regarding National Security Presidential Memorandum 33 (“[NSPM-33](#)”). In response to this guidance, we anticipate that other federal sponsors will shortly release new or updated COI policies, which may be substantially similar to PHS requirements.

Overview of Changes

1) Interim Changes effective February 25, 2021

Due to a request from the National Institutes of Health (“NIH”) that the University memorialize certain requirements from the NIH’s Policy Development Checklist in Policy 1-006 and related rules, the COI Office proposed interim changes to Policy 1-006 and associated regulations to timely respond to the NIH and avoid future enforcement action. After consultation with the Academic Senate Executive Committee, President Ruth Watkins enacted the interim policy and rules, effective February 25, 2021. Because the University had been complying with these regulatory requirements since the NIH adopted them in 2011, the interim policy changes did not affect the way the COI Office reviewed or managed conflicts of interest—the changes were consistent with the COI Office’s existing processes and practices.

- a) Key Changes to Policy 1-006: Individual Financial Conflict of Interest Policy (Revision 13)
 - i) Clarifications to confirm that Policy 1-006 complies with the NIH’s financial conflict of interest regulations and applies to subrecipients; that the BRR Disclosure Form must be updated no later than at the time of application for research funding; that certain travel disclosures are required for PHS-funded investigators; and that the University’s conflict of interest training addresses specific regulatory requirements regarding the content and timing of the training.
- b) Key Changes to Rule 1-006C: Individual Financial Conflicts of Interest in Research (Revision 1)
 - i) Clarifications to confirm that Rule 1-006C applies to Subrecipients; the process and timing by which the Individual Financial Conflict of Interest Committee (“COI Committee”) evaluates Financial Conflicts of Interest in Research; that the COI Committee monitors Investigator compliance; and the applicability of additional requirements (i.e., reporting, retrospective reviews/mitigation plans, public accessibility, and record retention) to Research funded by the PHS.
- c) New Guideline 1-006: Determining “Relatedness” to Research
 - i) Created Guideline 1-006 for the COI Committee to reference when determining whether an Investigator’s Significant Financial Interest is related to a Research project, and whether the Significant Financial Interest is a Financial Conflict of Interest.

2) Additional Proposed Changes

To ensure the University complies with the DOE's COI Policy, and in anticipation that federal agencies will soon adopt or modify their conflict of interest policies in response to the Biden Administration's request to federal agencies to standardize grant processes, the COI Office proposed additional policy changes described below.

- a) Key Changes to Policy 1-006: Individual Financial Conflict of Interest Policy (Revision 14)
 - i) Modification to the definition of "Investigator" to include Senior/Key Personnel, and, for research sponsored by the DOE, individuals who *participate* in the design, conduct, or reporting of Research;
 - ii) New definition for "Senior/Key Personnel" consistent with federal requirements; and
 - iii) Modifications to travel disclosure requirements for Investigators who participate in federally funded research, which (A) add requirements from the DOE COI Policy and (B) provide a general statement that other federal requirements may apply (in anticipation of future changes to federal policies).
- b) Key Changes to Rule 1-006C: Individual Financial Conflicts of Interest in Research (Revision 2)
 - i) Modification to exclusions from the definition of "Significant Financial Interest" to reflect new policy requirements from the DOE and the addition of a general statement that other federal requirements may apply (in anticipation of future changes to federal policies);
 - ii) Modification to expand PHS requirements as applicable when other federal sponsors have adopted requirements that are substantially similar to PHS requirements;
 - iii) Moved requirements specific to federally funded research (i.e., reporting, retrospective reviews/mitigation plans, public accessibility, record retention) performed by the COI Office to a new Procedure 1-006B; and
 - iv) Clarified requirements for Subrecipients that apply regardless of funding source.
- c) New Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research
 - i) Moved requirements specific to federally funded research (i.e., reporting, retrospective reviews/mitigation plans, public accessibility, record retention) performed by the COI Office from Rule 1-006C to a new Procedure 1-006B, and expanded the applicability of those requirements to other federal sponsors that have adopted requirements that are substantially similar to PHS requirements. Procedure 1-006B maintains the existing PHS requirements, but gives the Vice President for Research the flexibility to adjust Procedure 1-006B as federal sponsors modify their requirements in response to the Biden Administration's request. Requirements for individual Investigators, such as when Investigators must report a Significant Financial Interest and which financial interests constitute Financial Conflict of Interest, remain in Rule 1-006C.
- d) Key Changes to Guideline 1-006: Determining "Relatedness" to Research (Revision 1)
 - i) Added language required by the DOE COI Policy that the COI Committee consider a Significant Financial Interest to be related to Research when the Significant Financial Interest could affect the Research.

Regulation Development Process

The COI Office initiated interim policy changes in 2021 at the request of the NIH. Marc Rinehart (former Director of the COI Office) drafted those changes with the advice and collaboration of the COI Office, COI Committee, Office of General Counsel, Academic Senate Executive Committee, and Institutional Policy Committee. President Watkins put the interim policy into effect on February 25, 2021. It was enacted as an interim revision to timely comply with federal regulations and guidance from the PHS. The Academic Senate recommended the interim regulations be reviewed and promulgated, with any changes, through the normal process within one year.

The COI Office proposed additional policy changes to comply with new and anticipated federal requirements. Emily Ostrander, Hailey Ritchie, and Allyson Hicks (Director of University Regulations) drafted the documents, with the advice and collaboration of the COI Committee. These revisions were reviewed by the stakeholders, presented for the information of the Academic Senate on April 4, 2022, and approved by the Board of Trustees on April 12, 2022.

Summary of Revisions to Individual Financial Conflict of Interest Policy 1-006 and Associated Regulations



Interim Policy 1-006 and Interim Rule 1-006C (Currently in Effect)

- The current policy version was approved in February 2021 on an interim basis and must be ratified now.
- The interim policy was applied at the request of NIH to memorialize certain NIH requirements, but did not change the COI Office's existing processes and practices because the University had been complying with the requirements since NIH adopted them in 2011.

Additional Proposed Revisions to Interim Policy 1-006, Interim Rule 1-006C, Guideline G1-006A, and New Procedure P1-006B

- Additional policy changes are also proposed to ensure compliance with new federal regulation. In December 2021, the U.S. Department of Energy released an updated conflict of interest policy. In January 2022, the Biden Administration put forth a call for federal agencies to standardize their grant applications (which may result in other federal sponsors releasing updated COI policies, as well).
- Changes primarily relate to the definition of an Investigator, travel reporting, subrecipient disclosures, and complying with additional federal requirements in the future.

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Proposed Revisions to the Individual Financial Conflict of Interest Policy 1-006 (and associated regulations)



Emily Ostrander, Director of the Conflict of Interest Office / COI Officer
Hailey Ritchie, Office of General Counsel

April 4, 2022 Presentation to University of Utah Academic Senate

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Introduction



The current policy version was approved in February 2021 on an interim basis and must be ratified now.

Additional policy changes are also proposed to ensure compliance with new federal regulation. In December 2021, the U.S. Department of Energy released an updated conflict of interest policy. In January 2022, the Biden Administration put forth a call for federal agencies to standardize their grant applications (which may result in other federal sponsors releasing updated COI policies, as well).

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The COI Office proposes revisions to:



- [Interim] Policy 1-006: Individual Financial Conflict of Interest Policy (“Policy 1-006”)
- [Interim] Rule 1-006C: Individual Financial Conflict of Interest in Research (“Rule 1-006C”)
- New Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research (“Procedure 1-006B”)
- Guideline 1-006A: Determining “Relatedness” to Research (“Guideline 1-006A”)

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Impact of Interim Revisions



The National Institutes of Health (“NIH”) requested that the University memorialize certain NIH requirements in our policy. These changes were made in the interim to timely respond to the NIH and avoid future enforcement action.

Other than compliance, there was no effect of these interim revisions, because the University had been complying with these regulatory requirements since the NIH adopted them in 2011 (the changes were consistent with the COI Office’s existing processes and practices).

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ADDITIONAL PROPOSED CHANGES

TO ENSURE COMPLIANCE WITH NEW FEDERAL REGULATIONS

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Individual Financial Conflict of Interest Policy 1-006



Key Changes to Policy 1-006: Individual Financial Conflict of Interest Policy (Revision 14)

- Modification to the definition of “Investigator” to include Senior/Key Personnel, and, for Research sponsored by the DOE, individuals who *participate* in the design, conduct, or reporting of Research;
- Modifications to travel disclosure requirements for Investigators who participate in federally funded Research, which (A) add requirements from the DOE COI Policy and (B) provide a general statement that other federal requirements may apply (in anticipation of future changes to federal policies).

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Rule 1-006C: Research



Key Changes to Rule 1-006C: Individual Financial Conflicts of Interest in Research (Revision 2)

- Modification to exclusions from the definition of “Significant Financial Interest” to reflect new policy requirements from the DOE and the addition of a general statement that other federal requirements may apply (in anticipation of future changes to federal policies);
- Modification to expand PHS requirements as applicable when other federal sponsors have adopted requirements that are substantially similar to PHS requirements;
- Restructuring to move requirements specific to federally funded Research (i.e., reporting, retrospective reviews/mitigation plans, public accessibility, record retention) performed by the COI Office to a new Procedure 1-006B; and
- Clarified requirements for Subrecipients that apply regardless of funding source.

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New Procedure 1-006B



New Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research

- Moved requirements specific to federally funded Research (i.e., reporting, retrospective reviews/mitigation plans, public accessibility, record retention) performed by the COI Office from Rule 1-006C to a new Procedure 1-006B, and expanded the applicability of those requirements to other federal sponsors that have adopted requirements that are substantially similar to PHS requirements.
- Procedure 1-006B maintains the existing PHS requirements, but gives the Vice President for Research the flexibility to adjust Procedure 1-006B as federal sponsors modify their requirements in response to the Biden Administration's request. Requirements for individual Investigators, such as when Investigators must report a Significant Financial Interest and which financial interests constitute Financial Conflict of Interest, remain in Rule 1-006C.

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Guideline 1-006

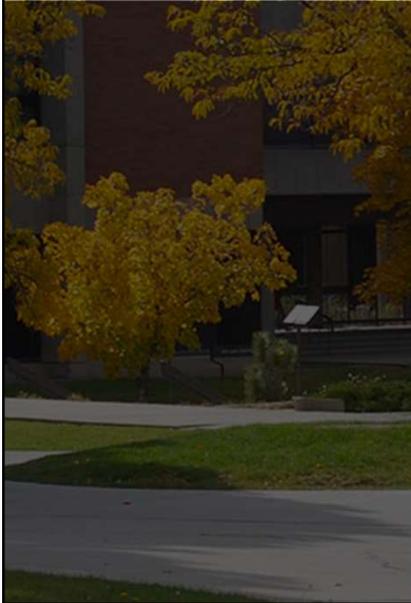


Key Changes to Guideline 1-006: Determining "Relatedness" to Research (Revision 1)

- Added language required by the DOE COI Policy that the COI Committee consider a Significant Financial Interest to be related to Research when the Significant Financial Interest could affect the Research.

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Impact of Additional Changes



- Compliance with DOE policy and flexibility to adapt to further federal regulation changes
- Revisions to the Business Relationship Reporting system to update training and expand travel disclosure requirements
- Retraining of University employees

**[INTERIM] POLICY 1-006: INDIVIDUAL FINANCIAL CONFLICT OF INTEREST
POLICY**

Revision ~~13~~14. Effective Date: ~~February 25, 2021~~

I. PURPOSE AND SCOPE

A. Purpose:

The University serves society 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 these institutional objectives with these shared institutional values, individual financial conflicts of interest may naturally arise that have the potential to impair the judgment of the individuals involved in that work.

This ~~Policy~~policy establishes and describes the systems and processes through which the University identifies, evaluates, and manages financial conflicts of interest of individuals, without violating its institutional values. It uses disclosure as the key mechanism to bring potential financial conflicts of interest to light for evaluation and possible oversight. This ~~Policy~~policy also identifies types of financial conflicts of interest that are not allowed because they are a violation of law or are judged by the University to be a violation of its institutional values.

This ~~Policy~~policy establishes the Individual Conflict of Interest Committee and the position of Individual Conflict of Interest Officer to implement the ~~Policy~~policy. It is intended that the ~~Policy~~policy will be further implemented through adoption of various associated University ~~Regulations~~regulations, including ~~Rules~~rules and ~~Procedures~~procedures.

This ~~Policy~~policy and its associated University ~~Regulations~~regulations are intended to comply with, and implement, the requirements of applicable federal

regulations (particularly 42 C.F.R. pt. 50 and 45 C.F.R. pt. 94) for research for federally funded Research, including Research funded through the Public Health Service, and shall be construed in accordance with such federal regulations and shall be deemed to include any requirements imposed by such federal regulations that are not otherwise expressly set forth in this Policy and its associated University Regulations.

Commented [AH1]: This paragraph was added in the Interim Policy

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 other University 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, which are governed by other Regulations (see Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects).

Regarding subrecipients of research who are investigators (as defined by this Policy), this Policy includes the University's commitment to take reasonable steps to ensure that such subrecipients comply with applicable federal regulations (see Section III.G.). As more fully described in Rule 1-006C, by specific agreement,

such ~~subrecipients~~Subrecipients may become obligated to comply with this ~~Policy~~policy and associated University ~~Regulations~~regulations.

Commented [AH2]: This paragraph was added in the Interim Policy

II. Definitions

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

- A. ~~“BRR Disclosure Form—is”~~means 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.
- 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.
- C. ~~“Compensation—”~~means anything of economic value, however designated, which is paid, loaned, granted, given, donated, transferred, or promised to any person or Business Entity. 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 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. ~~An~~

~~“Employee” includes an~~ unpaid faculty member ~~is also considered an~~.

~~“Employee for purposes of the requirements of this Policy.”~~

~~An~~ includes 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~~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 a spouse or domestic partner or a dependent or minor child (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~~employment, consulting, or any other activity resulting in payment or other Compensation;
 - b. ~~Any~~any Equity Interest, excluding ownership in mutual funds or pension funds described in Section II.G.2.b;
 - c. ~~Any~~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~~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~~ [regulations](#)).

2. "Financial Relationship" does not include:

- a. ~~Salary~~ [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~~ [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~~" [means](#) money, non-pecuniary gifts, excessive compensation, or non-commercial loans. ~~However, "Gift" does not include~~ occasional non-pecuniary gifts that have an insignificant monetary value, as defined by the Utah Public Officers' and Employees' Ethics Act, that would not tend to improperly influence an Employee in the discharge of 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, 2021, 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~~" [means](#) 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, 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, who is the project director ~~or~~ the ~~Principal Investigator~~principal investigator, or Senior/Key Personnel for a Research project, 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.

For Research sponsored by the United States Department of Energy, or if required by a Research sponsor, “Investigator” also includes a person who participates in the design, conduct, or reporting of Research conducted in whole or in part under the auspices of the University

L. “Public Health Services” or “PHS—” means the United States Public Health Service, which is a division of the United States Department of Health and Human Services.

M. “Research—” means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. ~~The term~~“Research” 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~~“Research” also includes Research that is internally funded or unsponsored. Human Subjects Research is a specific subcategory of Research.

N. “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.

Commented [AH3]: This definition was added in the Interim policy

Examples of Educational Activity include, but are not limited to, the supervision, training, or mentoring of students, graduate students, trainees, or fellows.

“Senior/Key Personnel” means the project director, principal investigator, and any other individual identified as Senior/Key personnel by the University in the grant application, approved budget, progress report, or any other report submitted to the PHS or other federal sponsor.

~~O.~~ “Subrecipient” means an individual or entity that acts as a subcontractor, subgrantee, or subawardee for Research, including Research funded by the Public Health Service.

Commented [AH4]: This definition was added in the Interim Policy

~~P.~~ “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 “Transaction” includes, but are is 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. Disclosure and Training Requirements.

The system and processes established under this ~~Policy~~ 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;
- ii. ~~Within thirty~~ (within 30) calendar days of generating, discovering, or acquiring (e.g., through purchase, marriage, inheritance, or any other mechanism) a new Financial Relationship; and
- iii. ~~No~~ later than at the time of application for Research funding (including Research funded by the Public Health Service).

~~2.~~ BRR Disclosure Form Contents (Relevant Information).

Commented [AH5]: This requirement was added in the Interim policy

- 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 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 Public Health Service [or the United States Department of Energy](#) 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 ~~[-Endnote 1-]; provided, however, that this disclosure requirement does not apply to~~[\(or to the Investigator's responsibility to the Investigator's employer or profession if the Investigator is not an employee of the University\).](#)

[An investigator who participates in Research funded by the Public Health Service shall disclose reimbursed or sponsored](#) travel ~~that~~[unless the travel](#) 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.

An investigator who participates in Research funded by the Department of Energy shall disclose reimbursed or sponsored travel unless the travel is reimbursed or sponsored by the following entities within the United States:

a federal, state, or local government agency;

an institution of higher education as defined at 20 U.S.C. § 1000 (a); or

a domestic research institute that is affiliated with an institution of higher education within the United States.

An Investigator who participates in Research funded by a federal sponsor other than the Public Health Service or the Department of Energy shall disclose reimbursed or sponsored travel as required by the federal sponsor.

Each Investigator who is required to disclose reimbursed or sponsored travel under this section, Section III.A.2.b., ~~is required to~~ shall disclose, at a minimum, the purpose of the travel, the identity of the sponsor/organizer, the destination, and the duration.

Commented [AH6]: This requirement was added in the Interim Policy

- c. State or federal law or other University ~~Regulations~~ regulations may require individuals to disclose certain financial and other relationships that are not covered by this ~~Policy~~ policy. It is the responsibility of each Investigator and each Employee to comply with all such laws or ~~Regulations~~ regulations.

~~3.~~ Training.

- a. 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.

Such training will address the requirements of this Policy and associated University Regulations, and the requirements of federal PHS' regulations ~~for~~ regarding conflicts of interest and promoting objectivity in Research ~~(42 C.F.R. pt. 50 and 45 C.F.R. pt. 94)~~. Note that each Investigator has obligations under other University Regulations and federal regulations related to Research that are not addressed by the financial conflict of interest training, and each Investigator ~~is expected to~~ shall be familiar with and comply with those obligations.

Commented [AH7]: Added in the Interim Policy

- b. ~~Once~~ An Investigator or an ~~individual completes~~ Employee is required to complete the training described in Section III.A.34.a., ~~the individual is required to repeat the training:~~

immediately upon hire by the University;

~~i.~~ at least every four ~~(4)~~ years thereafter; and

~~ii.~~ immediately if:

1. the University revises this Policy or its associated Regulations in any manner that materially affects the requirements of Investigators;
- ~~2. an Investigator is new to the University;~~ or
- ~~3.~~ the Individual Conflict of Interest Committee determines that an Investigator or Employee is not in compliance with this Policy (or its associated Regulations) or the Investigator's or Employee's management plan.

Commented [AH8]: Added in the Interim Policy

B. Individual Conflict of Interest Committee.

1. The Individual Conflict of Interest Committee (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 an institution-wide committee with broad representation 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~~rule associated with this ~~Policy~~policy (see Rule 1-006A: Individual Conflict of Interest Committee Membership Rule).

2. The Committee ~~is charged with~~shall:
 - a. ~~Providing~~provide 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~~Review the information submitted by Investigators and Employees as required under this ~~Policy~~policy, including completed BRR Disclosure Forms; and
 - c. ~~Determining~~determine whether a ~~disclosed~~-Financial Relationship of an individual that has been (or should have been) disclosed is a financial conflict of interest; and, if so,
 - d. ~~Determining~~ determine 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, Research participants, and the public.
3. The University shall establish a Conflict of Interest Office (Office), employ a Conflict of Interest Officer and such other staff as needed, and allocate adequate resources to support the duties of the Individual Conflict of Interest Committee and the implementation of this ~~Policy~~policy.
4. The Committee and ~~its~~Committee members shall act without bias in administering this ~~Policy~~policy and associated regulations.

C. Conflict of Interest Office and Committee Responsibilities.

1. The Conflict of Interest Office, on behalf of the Individual Conflict of Interest Committee, ~~will~~shall initially screen each individual case (as presented through a submitted BRR Disclosure Form) to determine whether a Financial Relationship exists that requires the review of the Committee. The Office ~~will~~shall notify the Investigator or Employee, as well as the Investigator's or Employee's department chair or supervisor, when the ~~Conflict of Interest~~ Office refers a potential conflict of interest to the Committee for review.
2. For each case referred to it, the Individual Conflict of Interest Committee ~~will~~shall consult with the Investigator or Employee as appropriate and determine whether a Financial Relationship creates a financial conflict of interest. If ~~it is determined~~the Committee determines that a financial conflict of interest exists, the Committee ~~will~~shall determine how ~~it~~the financial conflict of interest can be managed, reduced, or eliminated.
3. The Conflict of Interest Office ~~will~~shall transmit the decision of the Individual Conflict of Interest Committee to the Investigator or Employee, the Investigator's or Employee's 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 plan to manage, reduce, or eliminate a financial conflict 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 plan. When a plan requires specific expertise beyond that of the Office or the Committee members, the Committee may enlist qualified experts to assist with monitoring compliance as needed.
5. The University ~~will~~shall adhere to 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) calendar 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~~is final.

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

1. This ~~Policy~~policy and its associated University ~~Regulations~~regulations will be publicly available on the University's website (currently at <https://regulations.utah.edu/>).
2. The information disclosed for a case under this ~~Policy~~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 following offices (or equivalents): Office of the Vice President for Research; Office of General Counsel; Internal Audit; Institutional Review Board; Office of Sponsored Projects; Partners for Innovation, Ventures, Outreach & Technology; Procurement & Contracting Services; Graduate School; and
 - c. ~~Other~~other Employees whose responsibilities to the University are directly affected by the conflict of interest.

Commented [AH9]: Added in the Interim Policy

3. The University ~~will~~shall adhere to Research sponsor requirements and state and federal law for reporting of disclosures.
4. In certain circumstances, federal or state law may require public dissemination of information relating to an identified conflict of interest.
5. In ~~other~~certain circumstances, including, but not limited to, conflicts regarding Human Subjects Research, the University may require public dissemination of information as part of a conflict of interest management plan.
6. Except for the ~~foregoing categories allowing for~~ dissemination of information ~~contemplated~~described in this ~~Policy~~policy and related regulations, the Individual Conflict of Interest Committee and other individuals within the University who have direct responsibility for reviewing potential conflicts or investigating potential violations of this ~~Policy~~policy, including non-compliance with conflict of interest management plans, shall treat the information received and considered during these processes as confidential information.
7. Any information disclosed by an Investigator or Employee as required by this ~~Policy~~policy shall be used solely for the purpose of administering this ~~Policy~~policy and ~~shall~~may not be used for any other purpose unless required by law.
8. An Employee who violates Section III.E.56 or Section III.E.67 shall be deemed to have engaged in unethical behavior, which is punishable under pertinent University ~~Regulations~~regulations, including Policy 5-111: Corrective Action and Termination Policy for Staff Employees or Policy 6-316: Code of Faculty Rights and Responsibilities.

F. Violations/Non-Compliance.

1. Reporting Violations or Management Plan Non-Compliance.

A potential violation of this ~~Policy~~policy, including a potential failure to comply with any approved conflict of interest management plan 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 violation of this [Policy](#), including any potential failure to comply with an approved conflict of interest management plan.

3. Protection of Affected Parties.

To the extent permitted by law and University [Regulations](#), the University will protect the identity and privacy of any individual who, in good faith, 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 is prohibited, and the retaliator may be subject to discipline under pertinent University [Regulations](#).

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

- a. For a violation 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 Research 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 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 final.
 - c. In a situation involving the health or safety of any person or the potential loss of significant University resources, the Committee may implement any restrictions listed in 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 violation 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 violation 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~~withholding payment owed under a procurement contract relating to the conflict;

~~ii. Legal~~legal action to rescind or revise University contracts entered into or found to be in violation of this ~~Policy~~policy or of federal or state law;

~~iii. Legal~~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 violation of this ~~Policy~~policy; or

~~iv.~~ Other similar and appropriate actions.

6. Violations of ~~the~~Utah Code Title 67, Chapter 16, 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 the Associate Vice President for Research Integrity and Compliance shall report incidents of violations of ~~f/~~or non-compliance with this ~~Policy~~policy to external agencies and sponsors as required by state and federal law.

G. Applicability to Subrecipients

1. With respect to a Research project that involves Subrecipients, the University will take reasonable steps to ensure that each Subrecipient complies with applicable federal regulations ~~(particularly 42 C.F.R. pt. 50 and 45 C.F.R. pt. 94) and with this Policy and associated University Regulations.~~

~~As further described in Rule 1-006C: Individual Financial Conflict of Interest in Research, the University may accomplish this by ensuring that a Subrecipient complies with another entity's, and with the relevant portions of this policy that is equivalent to this Policy and associated University~~

~~Regulations, or by an agreement that makes the Subrecipient directly subject to this Policy and associated University Regulations~~regulations.

Commented [AH10]: This was added in the Interim Policy

H. Other Conflict of Interest Policies and Procedures.

1. University Institutional Conflict of Interest Policy.

In situations in which both an individual and an institutional conflict of interest may exist, Investigators and Employees are required to comply with the requirements of this ~~Policy~~policy and also with the requirements of ~~Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects Policy.~~

The Individual Conflict of Interest Committee and the University Institutional Conflict of Interest Officer 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"~~supplemental rule (as described in Policy 1-001) applicable for conflicts of interest arising within that unit. Any ~~such Supplemental Rules~~supplemental rule shall operate in conjunction with this ~~Policy~~policy, provided that such ~~Supplemental Rule must~~supplemental rule shall aid in the implementation of and ~~not be in~~may conflict with the terms of this ~~Policy. Any such Supplemental Rule~~policy. A supplemental rule proposed by any unit of the University shall be submitted for the approval of the Individual Conflict of Interest Committee.

~~【<Endnote 1>~~

~~(1) An Investigator who is not a University Employee, as defined in this Policy, and who participates in the design, conduct, or reporting of Research that is conducted under the auspices of the University and is funded by the Public Health Service, 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:~~

- ~~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.~~

[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 1-006A](#): Individual Conflict of Interest Committee Membership Rule
2. [Rule 1-006B](#): 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 1-006A](#): Reviewing Individual Conflict of Interest BRR Disclosure Forms

[Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research](#)

C. Guidelines

1. Guideline G1-006A: Determining “Relatedness” to Research

D. Forms [reserved]

E. Other related resource materials.

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

V. REFERENCES

- A. Utah [Code Title 67, Chapter 16, Utah](#) Public Officers' and Employees' Ethics Act, ~~Utah Code Ann. § 67-16-1 et seq.~~
- B. ~~Utah Code Ann. § 76-8-105(1)~~ [Utah Code Section 76-8-105](#)
- C. National Science Foundation Grant Policy Manual, Chapter V, Grantee Management Standard 510, Conflict of Interest Policies-
- D. U.S. Department of Health and Human Services, Promoting Objectivity in Research, 42 C.F.R. pt. 50, Subpart F (for NIH Contracts, 45 C.F.R. pt. 94, Responsible Prospective Contractors)-
- E. U.S. Department of Health and Human Services, Financial Disclosure by Clinical Investigators, 21 C.F.R. pt. 54-

- F. Anti-Kickback Act of 1986, 41 U.S.C. § 8701 *et seq.*, 48 C.F.R. § 3.502-1 *et seq.*, and OMB Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 2 C.F.R. pt. 200-
- G. [Policy 5-111](#); Corrective Action and Termination Policy for Staff Employees-
- H. [Policy 1-012](#); University Non-discrimination Policy-
- I. [Rule 3-100E](#); Restricted Purchases and Special Procurement-
- J. [Policy 7-001](#); Policy for Research Misconduct-
- K. [Policy 7-003](#); Ownership of Copyrightable Works and Related Works.
- L. [Policy 6-400](#); Code of Student Rights and Responsibilities (“Student Code”).
- M. [Policy 6-316](#); Code of Faculty Rights and Responsibilities.

~~N. Regulations Addressing Related Topics Not Directly Addressed by this Policy:~~

- ~~1. [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.~~
 - ~~2. [Policy 1-020](#), Required Professional Boundaries in Relationships.~~
 - ~~3. [Policy 5-105](#), Employment or Supervision of Immediate Family.~~
 - ~~4. [Policy 7-004](#), University Faculty Profit-Making Corporations, discusses conflicts of commitment.~~
 - ~~5. [Policy 7-002](#), Patents and Inventions, discusses requirements for transfer of University technology and other intellectual property.~~
 - ~~6. [Policy 6-316](#), Code of Faculty Rights and Responsibilities, discusses use of the University’s name or property.~~
- ~~7. [Policy 7-006](#), [Policy 7-006](#): Institutional Financial Conflicts of Interest for Research Involving Human Subjects-~~
- ~~8. [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~~[See](#) University President or delegee, with assistance of the Institutional Policy Committee, to have the following [Rule 1-001 for information about the](#) roles and authority, ~~as provide in University Rule 1-001:~~ [of policy owners and policy officers.](#)

~~“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

Renumbering: Renumbered as Policy 1-006 effective 09/15/2008, formerly known as PPM 2-30.

Revision History:

~~A.~~ Current version: Revision [14](#)

[Legislative History of Revision 14](#)

Past versions:

Revision 13

~~This Interim Policy was put into effect on February 25, 2021, by President Ruth Watkins, after consultation with the Academic Senate Executive Committee on January 25, 2021. It was enacted as an Interim revision (in accord with Policy 1-001) in order to timely comply with federal regulations and guidance from the Public Health Service. The Interim Policy will remain in effect until a permanent version is adopted, which is anticipated to occur in one year, after review by appropriate internal University groups.~~

Legislative History of Revision 13

~~B. Past versions:~~

Revision 12: Effective dates – July 1, 2020 to February 24, 2021

Legislative History of Revision 12

Revision 11: Effective dates – August 20, 2012 to June 30, 2020

Legislative History of Revision 11

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

[INTERIM] RULE 1-006C: INDIVIDUAL FINANCIAL CONFLICT OF INTEREST IN RESEARCH.

REVISION 12. EFFECTIVE DATE: **FEBRUARY 25, 2021**

I. Purpose and Scope.

A. Purpose.

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

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

This ~~Rule~~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~~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~~rule is not intended to directly govern financial conflicts of interest of the University as an *institution*, which are governed by other University ~~Regulations~~regulations (see Policy 7-006: Institutional Financial Conflicts of Interest for Research Involving Human Subjects).

Regarding ~~subrecipients~~Subrecipients of ~~research~~Research who are ~~investigators~~Investigators (as defined by Policy 1-006), this ~~Rule~~rule includes the

University's commitment to take reasonable steps to ensure that such ~~subrecipients~~ Subrecipients comply with applicable federal regulations. As more fully described in Section III.F., by specific agreement, such subrecipients may become obligated to comply with this Rule.

Commented [AH1]: Added in Interim Rule

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. ~~“Financial Conflict of Interest—”~~ means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

Commented [AH2]: Added in Interim Rule

~~B. **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.~~

~~C. **Public Health Service or PHS**—means the United States Public Health Service, which is a division of the United States Department of Health and Human Services.~~

~~D. **Senior/Key Personnel**—means the project director, Principal Investigator, and any other individual identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the Public Health Service related to Research funding from the PHS.~~

- B. E. ~~“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 for a University Employee, reasonably appear to be related to the Investigator's responsibilities to the University, as defined by an individual's their department or job description ~~[<Endnote 1>],~~ or for an Investigator who is not a University Employee, reasonably appear to be related to their employer or profession:

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~~exceeds \$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~~regulations).

However, "Significant Financial Interest" does ~~NOT~~not include:

1. ~~a. Salary~~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. ~~b. Income~~unless required to be considered a Significant Financial Interest by the Research sponsor, 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. ~~i.~~ a federal, state, or local government agency;
 - b. ~~ii.~~ an institution of higher education as defined at 20 U.S.C. [Sec. 1001\(a\)](#);
 - ~~iii.~~ ~~an academic teaching hospital;~~
 - ~~iv.~~ ~~a medical center; or~~
 - c. ~~v.~~ a research institute that is affiliated with an institution of higher education within the United States;
 - d. [for Research other than Research funded by the United State Department of Energy:](#)
 - i. [an academic teaching hospital;](#) or
 - ii. [a medical center; and](#)
 - e. [any other entity excluded by the federal sponsor.](#)
3. ~~e.~~ 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.

1. [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~~[instructions](#). This ~~Rule~~[rule](#) implements the ~~Policy~~[policy](#) with the following requirements.
 - a. ~~4.~~ Each Investigator ~~is required~~[shall](#) 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, including~~ Human Subjects Research and all other types of Research, including internally funded or unsponsored Research.

~~b. 2.~~ Each Investigator ~~is required to~~ shall submit a BRR Disclosure Form to the University prior to evaluating, supervising, or overseeing Research involving University subordinates or students.

~~c. 3.~~ The ~~COI~~ Conflict of Interest Office is responsible for identifying and managing Financial Conflicts of Interest related to sponsored Research and Human Subjects Research. ~~It is the responsibility of each~~ Each Employee ~~to~~ shall notify the Employee's supervisor and the Conflict of Interest Office of any perceived, potential, or actual Financial 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 Financial Conflicts of Interest in Research.

1. Subject to Section III.B. ~~23.~~, the Individual Conflict of Interest Committee

~~will~~ shall:

- a. ~~Review~~ review the information provided in an Investigator's BRR Disclosure Form; and
- b. ~~Determine~~ determine if an Investigator has any Significant Financial Interest related to the Research; and, if so,
- c. ~~Determine~~ determine if the Investigator's Significant Financial Interest could create a Financial Conflict of Interest (see Procedure 1-006A: Reviewing Individual Conflict of Interest BRR Disclosure Forms; ~~Guideline G1-006A~~ Guideline G1-006A: Determining "Relatedness" to Research); and, if so,

- d. Develop and implement a management plan that specifies the actions that have been, and shall be, taken to manage the Financial Conflict of Interest (see Section III.C.).

Commented [AH3]: Added in the Interim Rule

2. 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 Financial 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 Financial 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~~ Financial Conflict of Interest. Otherwise, the individual will be required to eliminate the ~~conflict~~ Financial Conflict of Interest or the Research ~~project~~ will be conducted without involvement by the Investigator who has the conflict.
3. ~~2. In~~ lf required by the ~~case~~ federal sponsor of a Research project ~~funded by (e.g. the ~~Public Health Service~~ PHS or another federal sponsor that has adopted requirements that are substantially similar to PHS requirements, such as the Department of Energy)~~, the Individual Conflict of Interest Committee ~~will conduct the~~ 's review and evaluation described in Section III.B.1. shall occur prior to the University's expenditure of funds for the project and within 60 calendar days of any subsequently identified Financial Conflict of Interest.
4. ~~3.~~ If, during an ongoing Research project, an Investigator who is new to participating in the Research project discloses a Significant Financial Interest; an existing Investigator discloses a new Significant Financial Interest; or the Individual Conflict of Interest Committee identifies a Significant Financial Interest that an Investigator did not disclose in a timely

manner or that the Individual Conflict of Interest Committee did not previously review, the Individual Conflict of Interest Committee ~~will~~shall, within ~~sixty (60)~~ calendar days:

- a. ~~Review~~review the Significant Financial Interest;
- b. ~~Determine~~determine whether the Significant Financial Interest is related to the Research; and, if so,
- c. ~~Determine~~determine whether a Financial Conflict of Interest exists; and, if so,
- d. ~~Implement~~implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage ~~such~~the Financial Conflict of Interest going forward.

Commented [AH4]: Added in the Interim Rule

~~See Section III.E.2. for additional requirements that apply when a Financial Conflict of Interest related to a Research project funded by the Public Health Service is not identified or managed in a timely manner.~~

C. Management of Financial Conflicts of Interests in Research-

1. The Individual Conflict of Interest Committee may manage Financial Conflicts of Interest in Research by requiring:
 - a. ~~Disclosure~~disclosure of Financial Conflicts of Interest in publications and presentations;
 - b. ~~Disclosure~~disclosure of Financial Conflicts of Interest to students or subordinates working on the Research;
 - c. ~~Disclosure~~disclosure of Financial Conflicts of Interest to the Research team;

- d. ~~For~~for Human Subjects Research, disclosure of Financial Conflicts of Interest to potential participants;
 - e. ~~Appointment~~appointment of an independent monitor to evaluate the Research to protect against bias resulting from the Financial Conflict of Interest;
 - f. ~~Recusal~~recusal from certain responsibilities in the Research;
 - g. ~~Elimination~~elimination of the Significant Financial interest; or
 - h. ~~Any~~any other management strategy the Committee determines is necessary to appropriately manage a Financial Conflict of Interest.
2. ~~The~~For each Investigator who has a management plan, the Individual Conflict of Interest Committee ~~will~~shall monitor ~~each~~the Investigator's compliance with the Investigator's management plan until completion of the Research project.

Commented [AH5]: Added in the Interim Rule

D. Prohibited Activities.

1. 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.
- a. ~~1.~~ Any activity that benefits ~~any~~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~~regulations related to research integrity (e.g., Policy 7-001: Policy for Research Misconduct), and this ~~Rule~~rule does not ~~be construed as limiting~~limit those obligations in any way.

~~b. 2.~~ An Investigator participating in the design, conduct, or reporting of any Human Subjects Research study ~~shall~~may not, directly or indirectly, accept any incentives or ~~gifts~~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~~may 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.

~~c. 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

1. This provision is intended to help ensure Employees comply with the Utah Code Title 67, Chapter 16, 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.

E. Additional Requirements for Research Funded by ~~the Public Health Service~~
Federal Sponsors

~~1. Reporting on PHS-Funded Research Projects~~

~~a. For Research funded by the PHS, the Conflict of Interest Office will send financial conflict of interest reports, as described in Section III.E.1.b., to the PHS Awarding Component:~~

- i. ~~Prior to the institution's expenditure of funds under a Research project funded by the PHS;~~
 - ii. ~~Within sixty (60) calendar days of the institution identifying a Financial Conflict of Interest for an Investigator who is new to the project;~~
 - iii. ~~Within sixty (60) calendar days of a new Financial Conflict of Interest, or a newly identified Financial Conflict of Interest for existing Investigators;~~
 - iv. ~~At least annually (at the same time the Conflict of Interest Office submits the annual progress report; multi-year progress report, if applicable; or at the time of extension); and~~
 - v. ~~Following a retrospective review to update a previously submitted report, if appropriate.~~
- b. ~~Financial conflict of interest reports submitted to the PHS will include, at a minimum, all of the following:~~
- i. ~~Project number;~~
 - ii. ~~Project director/Principal Investigator or contact project director/Principal Investigator if a multiple project director/Principal Investigator model is used;~~
 - iii. ~~Name of the Investigator with the Financial Conflict of Interest;~~
 - iv. ~~Name of the Business Entity with which the Investigator has a Financial Conflict of Interest;~~

v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

vi. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

vii. A description of how the financial interest relates to the PHS-funded Research and the basis for the institution's determination that the financial interest conflicts with such Research; and

viii. A description of the management plan, including the role and principal duties of the conflicted Investigator in the Research project, conditions of the management plan, how the management plan is designed to safeguard objectivity in the Research, confirmation of the Investigator's agreement of the management plan, and how the management plan will be monitored to ensure Investigator compliance.

2. Retrospective Reviews of, Mitigation Plans for, Bias in PHS-Funded Research

a. Whenever a Financial Conflict of Interest related to PHS-funded Research is not identified or managed in a timely manner (including, for example, failure by an Investigator to disclose a Significant Financial Interest that the institution determines to be a Financial Conflict of Interest; failure by the Individual Conflict of Interest Committee to review or manage such a Financial Conflict of Interest; or failure by an Investigator to comply with the Investigator's management plan), the Conflict of Interest Office shall, within one hundred and twenty (120) calendar days from the date of the institution's determination of noncompliance, complete a

retrospective review of the Investigator's activities and the PHS-funded Research project to determine if there was any bias in the design, conduct, or reporting of the PHS-funded Research conducted during the time period of noncompliance;

b. The Conflict of Interest Office will document all retrospective reviews of PHS-funded Research projects, and such documentation will include, at a minimum, all of the following:

i. Project number;

ii. Project title;

iii. Project director/Principal Investigator or contact project director/Principal Investigator if a multiple project director/Principal Investigator model is used;

iv. Name of the Investigator with the Financial Conflict of Interest;

v. Name of the Business Entity with which the Investigator has a Financial Conflict of Interest;

vi. Reason(s) for the retrospective review;

vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

viii. Findings of the review; and

~~ix. Conclusions of the review.~~

~~c. Based on the results of the retrospective review, if appropriate, the Conflict of Interest Office will update any previously submitted financial conflict of interest report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.~~

~~d. Following the retrospective review, if the Conflict of Interest Office determines there was bias in the design, conduct, or reporting of the PHS-funded Research conducted during the time period of noncompliance, the Conflict of Interest Office will:~~

~~i. Promptly notify the PHS Awarding Component; and~~

~~ii. Submit a mitigation report to the PHS Awarding Component that includes, at a minimum, all of the following:~~

~~1. The elements documented as part of the retrospective review (see Section III.E.2.b.);~~

1. The Conflict of Interest Office shall submit reports to a federal sponsor on Financial Conflicts of Interest related to Research funded by the federal sponsor at the intervals required by the federal sponsor and including the information required by the federal sponsor. Procedure 1-1006B describes the timing and content of these reports.
2. A description of the impact of the bias on the Research project; and For federally funded research, the Conflict of Interest Office shall complete retrospective reviews of Financial Conflicts of Interest that are not identified

Commented [AH6]: The provisions, new in the Interim Rule, are now being moved to Procedure P1-006B

or managed in a timely manner. Procedure 1-1006B describes the timing, content, and reporting on outcomes of retrospective reviews.

~~3.—A description of the institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact of the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable).~~

3. ~~e.~~ If the U.S. Department of Health and Human Services determines that a PHS-funded Research project of clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported as required by this Rule, the University ~~will~~ shall require the Investigator ~~involved~~ with the Financial Conflict of Interest to:

a. ~~i. Disclose~~ disclose the Financial Conflict of Interest in each public presentation of the results of the Research; and

b. ~~ii. Request~~ request an addendum to previously published presentations.

Commented [AH7]: Added in the Interim Rule

~~3.—Public Accessibility~~

~~a.—Prior to the University’s expenditure of any funds under a PHS-funded Research project, the University will ensure public accessibility, via a publicly accessible website or written response to any request within five (5) business days of a request, of information concerning any Significant Financial Interest disclosed to the University that meets the following criteria:~~

c. The information that the University makes available under Section III.E.3.a. is required to include, at a minimum, all of the following:

i. The Investigator's name;

ii. The Investigator's title and role with respect to the Research project;

iii. The name of the Business Entity in which the Significant Financial Interest is held;

iv. The nature of the Significant Financial Interest; and

v. The approximate dollar value of the Significant Financial Interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

d. If the University responds to a written request submitted under Section III.E.3.a., the University is required to note in its written response that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within sixty (60) calendar days of the University's identification of a new Financial Conflict of Interest which should be requested subsequently by the requestor.

e. Information concerning a Significant Financial Interest of an individual under Section III.E.3.a. will remain available for responses to written requests or for posting via the University's publicly accessible website for at least three (3) years from the date that the information was most recently updated.

4. Record Retention for PHS-Funded Research Projects

a. Unless state or federal law requires a longer period of retention, the Conflict of Interest Office will retain records related to the following for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 C.F.R. §§ 74.53(b) and 92.42(b):

i. Investigator disclosures of financial interests;

ii. The institution's review of, and response to, Investigator disclosures of financial interests, regardless of whether a disclosure resulted in the institution's determination of a Financial Conflict of Interest;

iii. All actions under a retrospective review; and

iv. All actions under Policy 1-006 and its associated University Regulations.

F. Applicability to Subrecipients

Commented [AH8]: This provision, new in the Interim Rule, is being moved to Procedure P1-006B

Commented [AH9]: This section, regarding applicability to subrecipients, was new in the Interim rule. It is now being revised to remove the different process for PHS-funded research and Non-PHS-funded research

4. Research That is Not Funded by the Public Health Service

a. With respect to a Research project that is *not* funded by the PHS and that involves a Subrecipient, the Subrecipient shall provide appropriate assurances to the Office of Sponsored Projects that the Subrecipient will, in connection with the execution of the Subrecipient's work on the Research project, comply with and enforce another entity's policy on conflicts of interest (the Subrecipient's financial conflict of interest policy) that is no less stringent than this Rule and its associated University Regulations.

- ~~2. Research That is Funded by the Public Health Service~~
1. ~~a.~~ For Research ~~project that is funded by the PHS and~~ that involves a Subrecipient, the Office of Sponsored Projects ~~will~~shall require a written agreement with the Subrecipient that establishes whether Policy 1-006 and ~~its~~ associated University ~~Regulations~~regulations or another entity's equivalent policy (the Subrecipient's financial conflict of interest policy) ~~will~~ apply to the Subrecipient's Investigators.
- a. ~~i.~~ If the Subrecipient's Investigators are required to comply with the Subrecipient's financial conflict of interest policy:
- i. ~~1. The~~the Subrecipient ~~is required to~~shall certify that ~~its~~the Subrecipient's financial conflict of interest policy is consistent with Policy 1-006 and ~~its~~ associated University ~~Regulations~~regulations and complies with ~~42 C.F.R. pt. 50 and 45 C.F.R pt. 94. (Note: if the~~ requirements of the sponsor of the Research project;
- ii. ~~the Subrecipient cannot provide such certification, the agreement will provide that~~shall make the Subrecipient's ~~Investigators are subject to Policy 1-006 and its associated University Regulations for disclosing Significant Financial Interests that are directly related to~~financial conflict of interest policy available via a publicly accessible website, unless the Subrecipient does not have such a website, in which case the Subrecipient shall make its written policy available to any requester within five business days of a request for the Subrecipient's ~~work for the University~~written policy; and
- iii. ~~2. The~~the Subrecipient's agreement with the University ~~will~~shall specify time period(s) for the Subrecipient to report all identified Financial Conflicts of Interest to the University so that the University can provide timely financial conflict of interest reports, as ~~necessary~~required, to the

~~PHS (i.e., prior to the expenditure of funds and within sixty (60) calendar days of any subsequently identified Financial Conflict of Interest) sponsor of the Research.~~

b. ~~ii~~ If the Subrecipient cannot provide the certification described in Section III. F.1.a.i or the Subrecipient's Investigators are otherwise required to comply with Policy 1-006 and its associated University ~~Regulations~~regulations, the Subrecipient's agreement with the University ~~will~~shall specify the time period(s) for the Subrecipient to submit all Investigator disclosures of Significant Financial Interests to the University. Such time period(s) ~~will~~shall be sufficient to enable the University to timely comply with its review, management, and reporting obligations under Policy 1-006 and this ~~Rule~~rule.

~~{<Endnote 1>~~

~~(1) For an Investigator who is not a University Employee, as defined in Policy 1-006, "Significant Financial Interest" includes these 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:

A. Procedure 1-006A: Reviewing Individual Conflict of Interest BRR Disclosure Forms

[B. Procedure P1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research](#)

[C. ~~B.~~ Guideline G1-006A: Determining "Relatedness" to Research](#)

V. References:

A. National Science Foundation Grant Policy Manual, Chapter V, Grantee Management Standard 510, Conflict of Interest Policies.

B. U.S. Department of Health and Human Services, Promoting Objectivity in Research, 42 C.F.R. pt. 50, Subpart F (for NIH Contracts, 45 C.F.R. pt. 94, Responsible Prospective Contractors).

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

[D. U.S. Department of Energy, Appendix 1 Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance, FAL 2022-02 \(12/20/2021\).](#)

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~~[See](#) University President or delegee, with assistance of the Institutional Policy Committee, to have the following [Rule 1-001](#)

for information about the roles and authority, ~~as provide in University Rule 1-001:~~
of policy owners and policy officers.

~~“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:

A. Renumbering: [None]

B. Revision History:

1. A. Current version: Revision 42

~~This Interim Rule was put into effect on February 25, 2021, by President Ruth Watkins, after consultation with the Academic Senate Executive Committee on January 25, 2021. It was enacted as an Interim revision (in accord with Policy 1-001) in order to timely comply with federal regulations and guidance. The Interim Rule will remain in effect until a permanent version is adopted, which is anticipated to occur within one year, after review by appropriate internal University groups.~~

a. Legislative History of Revision 42.

C. ~~B.~~ Earlier Versions

1. Revision 1

[a. Legislative History of Revision 1](#)

[2.](#) Revision 0: Effective dates – July 1, 2020 to February 24, 2021

[a. Legislative History](#) of Revision 0.

Guideline G1-006A: Determining “Relatedness” to Research

I. Purpose and Scope

To provide guidelines for the Individual Conflict of Interest Committee (“Committee”) to determine whether an Investigator’s Significant Financial Interest is related to Research conducted in whole or in part under the auspices of the University, including Research funded by the Public Health Service, and, if so related, whether the Significant Financial Interest is a Financial Conflict of Interest.

II. Definitions

The definitions provided in Policy 1-006 and Rule 1-006C apply for purposes of this Guideline.

III. Guideline

- A. To determine whether an Investigator’s Significant Financial Interest is related to Research, and if so, whether the Significant Financial Interest is a Financial Conflict of Interest, the Committee shall consider:
 1. The role of the Investigator and the Investigator’s opportunity, if any, to bias the results of the Research;
 2. The nature of the Research being proposed; and
 3. The value of the Significant Financial Interest in relation to the size and value of the Business Entity.
- B. In making the determination in Section III.A., the Committee may also consider the following factors:
 1. Whether the Business Entity in which the Investigator has a Significant Financial Interest is also the sponsor of the Research;
 2. Whether the Business Entity in which the Investigator has a Significant Financial Interest is the manufacturer of a drug, device, or product being used or evaluated in the Research;

3. Whether the outcomes of the Research could have a financial impact on the Business Entity in which the Investigator has a Significant Financial Interest;
4. Whether the Research is of a basic or fundamental nature directed at understanding basic scientific processes;
5. Whether the degree of replication and verification of Research results is such that immediate commercialization or clinical application is not likely;
6. Whether the goal of the Research is to evaluate an invention linked to the Significant Financial Interest (such as where the Significant Financial Interest is a patent, or an interest in a company that has licensed the invention);
7. In the case of Human Subjects Research, whether there are double blind conditions or the involvement of a data and safety monitoring board;
8. Where the Significant Financial Interest is in a privately held company, whether the researcher's Significant Financial Interest could result in the Investigator having influence over company decisions, or whether the Research could have a significant impact on the Business Entity's business or financial outlook;
9. The magnitude of the Significant Financial Interest (e.g., the amount of consulting, or the percentage or value of equity);
10. Where the Significant Financial Interest is in the sponsor of the Research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future;
11. The number and nature of relationships an Investigator has with a Business Entity (multiple relationships can create a relationship with a Business Entity that is stronger than the sum of the parts);
12. Whether the goal of the Research is to validate or invalidate a particular approach or methodology that could affect the value of the Significant Financial Interest;

13. Whether other scientific groups are independently pursuing similar questions;
14. Whether sufficient external review of the Research conducted and the reporting of Research results exist to mitigate undue bias;
15. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a Significant Financial Interest; or
16. Whether the project involves a sub-award to a Business Entity in which the Investigator has a Significant Financial Interest.

C. The Committee will consider an Investigator's Significant Financial Interest to be related to the Research when the Committee reasonably determines that the Significant Financial Interest:

1. Could [affect or](#) be affected by the Research; or
2. Is in a Business Entity whose financial interest could [affect or](#) be affected by the Research.

IV. References

A. University of Utah Policy 1-006: Individual Financial Conflict of Interest Policy

[B. University of Utah Rule 1-006C: Individual Financial Conflict of Interest in Research](#)

[B.C. University of Utah Procedure 1-006B: Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research](#)

~~C. U.S. Department of Health and Human Services, Promoting Objectivity in Research, 42 C.F.R. pt. 50, Subpart F (for NIH Contracts, 45 C.F.R. pt. 94, Responsible Prospective Contractors)~~

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

V. Contacts

Policy Owner: Questions about Policy 1-006 and any related Rules, Procedures, and Guidelines should be directed to the Conflict of Interest Officer.