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

Revision 13. 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 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 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 establishes the Individual Conflict of Interest Committee and the position of Individual Conflict of Interest Officer to implement the Policy. It is intended that the Policy will be further implemented through adoption of various associated University Regulations, including Rules and Procedures.

This Policy and its associated University 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 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.

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 1-006E). 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 may become obligated to comply with this Policy and associated University Regulations.

II. Definitions

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

- A. **BRR Disclosure Form** -- is the form through which an individual Investigator or Employee provides personal financial information provided to the University (to be reviewed by the Individual Conflict of Interest Committee). The BRR Disclosure Form is submitted through the University's online Business Relationship Reporting ("BRR") system.
- 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 unpaid faculty member is also considered an Employee for purposes of the requirements of this Policy.

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

- E. **Equity Interest** -- means any stock, stock option, or other ownership interest in a Business Entity.
- F. **Family Member** -- means 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, consulting, or any other activity resulting in payment or other Compensation:
 - b. Any Equity Interest, excluding ownership in mutual funds or pension funds described in Section II.G.2.b;
 - c. Any paid or unpaid leadership position in a Business Entity such as director, officer, partner, trustee, agent, or any position of management; and
 - d. Any instance in which an Investigator or Employee (or a Family Member) has, or reasonably foresees having, the

right to receive Compensation as a result of licensing or other commercialization of Intellectual Property created by that Investigator or Employee (or Family Member), including the right to receive shares of revenue, royalties, or other payments generated by such commercialization (e.g., an inventor's share of royalty income under University policy).

- 2. Financial Relationship does *not include:*
 - Salary, travel reimbursements, or other non-royalty Compensation from the University if that Investigator or Employee (or Family Member) is currently employed by, appointed at, or otherwise affiliated with the University; or
 - b. Income from investment vehicles, such as mutual funds and retirement accounts, provided that an Investigator or Employee (or a Family Member) does not directly control the investment decisions made in those vehicles.
- H. Gift -- includes money, non-pecuniary gifts, excessive compensation, or non-commercial loans. However, 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, <u>Utah Code Ann. § 67-16-1</u> et seq., permitted occasional, nonpecuniary gifts that do not exceed \$50.00.
- Human Subjects Research -- is any Research that has been designated as "human subjects research" by the University's Institutional Review Board.
- J. **Intellectual Property** -- means any ideas, inventions, technology, tangible property, creative expression, or embodiments thereof, in which a proprietary interest is claimed, including, but not limited to, patents, copyrights, trademarks, know-how, 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 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.
- 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 includes, but is not limited to, basic and applied research (e.g., a published article, book or book chapter) or product development (e.g., a diagnostic test or drug). This term also includes Research that is internally funded or unsponsored. Human Subjects Research is a specific subcategory of Research.
- 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. Examples of Educational Activity include, but are not limited to, the supervision, training, or mentoring of students, graduate students, trainees, or fellows.
- 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.
- 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, but are not limited to, purchases (including the purchase of supplies, equipment, or services), subcontracts, sub-awards, material transfer agreements, term sheets (whether binding or non- binding), option agreements, licensing agreements, agreements for sponsored research, grants, lease agreements, etc.

III. POLICY

A. Disclosure and Training Requirements.

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

- 1. Disclosure Schedule.
 - a. Annual Disclosure Requirement for Certain Employees.

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

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

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

- i. Research;
- ii. Scholarly or Educational Activity; or
- iii. Transactions.
- c. Requirement to update BRR Disclosure Form.

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

- i. At least annually;
- ii. Within thirty (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).
 - 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 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 travel that is reimbursed or sponsored by the following entities within the United States:
 - i. a federal, state, or local government agency;
 - ii. an institution of higher education as defined at 20 U.S.C. § 1001(a);
 - iii. an academic teaching hospital;
 - iv. a medical center; or

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

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

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

3. Training.

- 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 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 be familiar with and comply with those obligations.
- b. Once an individual completes the training described in Section III.A.3.a., the individual is required to repeat the training:
 - i. at least every four (4) years thereafter; and
 - ii. immediately if:
 - 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 is not in compliance with this Policy or its associated Regulations or the Investigator's management plan.

B. Individual Conflict of Interest Committee.

1. The Individual Conflict of Interest Committee is hereby established as a University standing committee. The voting members shall be nominated by the Personnel and Elections Committee of the Academic Senate and appointed by the President of the University to serve for three (3) year terms. A majority of the voting members shall be University tenure-line or career-line faculty members. The Committee shall be 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 associated with this Policy (see Rule 1-006A: Individual Conflict of Interest Committee Membership Rule).

2. The Committee is charged with:

- a. Providing education and training to members of the University community about financial conflicts of interest and how they can be effectively managed, reduced, or eliminated;
- b. Reviewing the information submitted by Investigators and Employees as required under this Policy, including completed BRR Disclosure Forms:
- c. Determining 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 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, 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.

- 4. The Committee and its members shall act without bias in administering this Policy.
- C. Conflict of Interest Office and Committee Responsibilities.
 - 1. The Conflict of Interest Office, on behalf of the Individual Conflict of Interest Committee, will 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 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 consult with the Investigator or Employee as appropriate and determine whether a Financial Relationship creates a financial conflict of interest. If it is determined that a financial conflict of interest exists, the Committee will determine how it can be managed, reduced, or eliminated.
 - 3. The Conflict of Interest Office will transmit the decision of the Individual Conflict of Interest Committee to the Investigator or Employee, the Investigator's or Employee's 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 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 final.

- E. Confidentiality and Internal and External Dissemination of Information Regarding Conflicts.
 - 1. This Policy and its associated University 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 (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 Investigator's or Employee's University superiors;
 - b. 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 Employees whose responsibilities to the University are directly affected by the conflict of interest.
 - 3. The University will 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 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 in this Policy, 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, 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 shall be used solely for the purpose of administering this Policy and shall not be used for any other purpose unless required by law.
- 8. An Employee who violates Section III.E.5. or Section III.E.6. shall be deemed to have engaged in unethical behavior, which is punishable under pertinent University Regulations, including Policy 5-111: Corrective Action and Termination Policy for Staff Employees or Policy 6-316: Code of Faculty Rights and Responsibilities.
- F. Violations/Non-Compliance.
 - 1. Reporting Violations or Management Plan Non-Compliance.
 - A potential violation of this 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:
 - Freeze Research funds, or otherwise suspend, a project or projects related to the policy violation/noncompliance;
 - 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.
- 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 payment owed under a procurement contract relating to the conflict;
- Legal action to rescind or revise University contracts entered into or found to be in violation of this Policy or of federal or state law;
- Legal action to recover the amount of financial benefit received by an Investigator or Employee as a result of the Investigator's or Employee's violation of this Policy; or
- iv. Other similar and appropriate actions.
- 6. Violations of the Utah Public Officers' and Employees' Ethics Act, <u>Utah Code</u> Ann. § 67-16-1, et seq., may result in prosecution and criminal penalties pursuant to that Act.
- 7. The remedies provided or referenced above are cumulative and may include any other remedies required or provided by applicable state or federal law.
- 8. The Office of Associate Vice President for Research Integrity and Compliance shall report incidents of violations of/non-compliance with this 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 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.

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

[<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

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

C. Guidelines

- 1. Guideline G1-006A: Determining "Relatedness" to Research
- D. Forms [reserved]
- E. Other related resource materials.
 - Supplemental Rule 1-006: Health Sciences Industry Relations Policy

V. REFERENCES

- A. Utah Public Officers' and Employees' Ethics Act, <u>Utah Code Ann.</u> § 67-16-1 et seq.
- B. Utah Code Ann. § 76-8-105(1).
- 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. <u>Policy 5-111</u>, 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. <u>Policy 6-400</u>, 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. <u>Policy 1-020</u>, Required Professional Boundaries in Relationships.
- 3. <u>Policy 5-105</u>, Employment or Supervision of Immediate Family.
- 4. <u>Policy 7-004</u>, University Faculty Profit-Making Corporations, discusses conflicts of commitment.
- 5. <u>Policy 7-002</u>, Patents and Inventions, discusses requirements for transfer of University technology and other intellectual property.
- 6. <u>Policy 6-316</u>, Code of Faculty Rights and Responsibilities, discusses use of the University's name or property.
- 7. <u>Policy 7-006</u>, 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 University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provide in University Rule 1-001:

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

"The Policy Officer will identify an 'Owner' for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to who the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... [and] bears the responsibility for determining – requirements of particular Policies...." University Rule 1-001-III-B & E

VII. HISTORY

Renumbering:

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

Revision History:

A. Current version: 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