

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

REVISION 2. EFFECTIVE DATE: APRIL 12, 2022

I. Purpose and Scope.

A. Purpose.

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

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

B. Scope.

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

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

This rule is not intended to directly govern other conflicts of interest that might arise during an Investigator's University duties, which are governed by other regulations (see *e.g.*, Policy 5-204: Remunerative Consultation and Other Employment Activities, Supplemental Rule 1-006: Health Sciences Industry Relations Policy). Similarly, this rule is not intended to directly govern financial conflicts of interest of the University as an *institution*, which are governed by other University 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 Policy 1-006), this rule includes the University's commitment to take reasonable steps to ensure that such 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.

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.
- B. "Significant Financial Interest" means a financial interest consisting of one or more of the following interests of the individual Investigator (or those of the Investigator's Family Member) that for a University Employee, reasonably appear to be related to the Investigator's responsibilities to the University, as defined by their department or job description, 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 months preceding the disclosure and the value of any Equity Interest in the Business Entity as of the date of disclosure, when aggregated, exceeds \$5,000.
 - 2. 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 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 regulations).

However, "Significant Financial Interest" does not include:

1. salary, travel reimbursements, or other non-royalty Compensation received by the Investigator (or a Family Member) from the University if the Investigator (or a Family Member) is currently employed or otherwise appointed by the University;
2. 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. a federal, state, or local government agency;
 - b. an institution of higher education as defined at 20 U.S.C. Sec.1001(a);
 - c. 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. Income received by the Investigator (or 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. This rule implements the policy with the following requirements.
 - a. Each Investigator 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, including Human Subjects Research and all other types of Research, including internally funded or unsponsored Research.
 - b. Each Investigator shall submit a BRR Disclosure Form to the University prior to evaluating, supervising, or overseeing Research involving University subordinates or students.
 - c. The Conflict of Interest Office is responsible for identifying and managing Financial Conflicts of Interest related to sponsored Research and Human Subjects Research. Each Employee 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.3., the Individual Conflict of Interest Committee shall:
 - a. review the information provided in an Investigator's BRR Disclosure Form; and
 - b. determine if an Investigator has any Significant Financial Interest related to the Research; and, if so,
 - c. 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: 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.).
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 Financial Conflict of Interest. Otherwise, the individual will be required to eliminate the Financial Conflict of Interest or the Research will be conducted without involvement by the Investigator who has the conflict.
3. If required by the federal sponsor of a Research project (e.g. the 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'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. 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 shall, within 60 calendar days:
 - a. review the Significant Financial Interest;
 - b. determine whether the Significant Financial Interest is related to the Research; and, if so,
 - c. determine whether a Financial Conflict of Interest exists; and, if so,
 - d. implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the Financial Conflict of Interest going forward.

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 of Financial Conflicts of Interest in publications and presentations;

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

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. Any activity that benefits a Business Entity in which an Investigator has a Significant Financial Interest and that compromises the integrity of the scientific analysis or the publication of Research results or its conclusions, is not allowed. Note that an Investigator has obligations under other University regulations related to research integrity (e.g.,

Policy 7-001: Policy for Research Misconduct), and this rule does not limit those obligations in any way.

- b. An Investigator participating in the design, conduct, or reporting of any Human Subjects Research study may not, directly or indirectly, accept any incentives or Gifts from a Business Entity that is sponsoring or providing support for the Research. Any payments to the University from any Business Entity sponsoring or providing support for such Research 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. 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 and this provision shall be interpreted to be in conformity with that Act.

E. Additional Requirements for Research Funded by Federal Sponsors

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. For federally funded research, the Conflict of Interest Office shall complete retrospective reviews of Financial Conflicts of Interest that are not identified or managed in a timely manner. Procedure 1-1006B describes the timing, content, and reporting on outcomes of retrospective reviews.
3. 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 shall require the Investigator with the Financial Conflict of Interest to:
 - a. disclose the Financial Conflict of Interest in each public presentation of the results of the Research; and
 - b. request an addendum to previously published presentations.
4. The University shall comply with requirements for public accessibility to Financial Conflict of Interest information established by the PHS and other federal sponsors. Procedure 1-1006B describes the University's responsibilities related to public accessibility of this information.

F. Applicability to Subrecipients

1. For Research that involves a Subrecipient, the Office of Sponsored Projects shall require a written agreement with the Subrecipient that establishes whether Policy 1-006 and associated University regulations or another entity's equivalent policy (the Subrecipient's financial conflict of interest policy) apply to the Subrecipient's Investigators.
 - a. If the Subrecipient's Investigators are required to comply with the Subrecipient's financial conflict of interest policy:

- i. the Subrecipient shall certify that the Subrecipient's financial conflict of interest policy is consistent with Policy 1-006 and associated University regulations and complies with the requirements of the sponsor of the Research project;
 - ii. the Subrecipient shall make the Subrecipient's 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 written policy; and
 - iii. the Subrecipient's agreement with the University 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 required, to the sponsor of the Research.
- b. 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, the Subrecipient's agreement with the University 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) shall be sufficient to enable the University to timely comply with its review, management, and reporting obligations under Policy 1-006 and this rule.

[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. 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

See University Rule 1-001 for information about the roles and authority of policy owners and policy officers.

VII. History:

A. Renumbering: [None]

B. Revision History:

1. Current version: Revision 2 Approved by the Academic Senate April 4, 2022 and the Board of Trustees, April 12, 2022.

- a. Legislative History of Revision 2.

C. Earlier Versions

1. Revision 1 Effective February 25, 2021

- a. Legislative History of Revision 1

2. Revision 0: Effective dates – July 1, 2020 to February 24, 2021

- a. Legislative History of Revision 0.