

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

REVISION 1. EFFECTIVE DATE: FEBRUARY 25, 2021

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. **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.
- 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 reasonably appear to be related to the Investigator's responsibilities to the University, as defined by an individual's department or job description [**<Endnote 1>**]:
1. With regard to any publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in the Business Entity as of the date of disclosure, when aggregated, exceed \$5,000.
 2. With regard to any non-publicly traded Business Entity, a Significant Financial Interest exists if the value of any Compensation received by the individual from the Business Entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual holds any Equity Interest; or
 3. Any instance where an Investigator (or a Family Member) has, or reasonably foresees having, the right to receive Compensation as a result of licensing or other commercialization of Intellectual Property created by that Investigator (or Family Member), including the right

to receive shares of revenue, royalties, or other payments generated by such commercialization (e.g., an inventor's share of royalty income under University policy).

However, Significant Financial Interest does NOT include:

- a. 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;
- b. 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:
 - 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; or
- c. Income received by the Investigator (or a Family Member) from investment vehicles, such as mutual funds and retirement accounts, provided that the Investigator (or Family Member) does not directly control the investment decisions made in these vehicles.

III. Rule.

A. Research Activities Requiring Disclosure.

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

1. Each Investigator is required to submit a BRR Disclosure Form to the University prior to approving, designing, conducting, or reporting on Research that is conducted in whole or in part under the auspices of the University. This includes, without limitation, Human Subjects Research and all other types of Research, including internally funded or unsponsored Research.
2. Each Investigator is required to submit a BRR Disclosure Form to the University prior to evaluating, supervising, or overseeing Research involving University subordinates or students.
3. The COI Office is responsible for identifying and managing Financial Conflicts of Interest related to sponsored Research and Human Subjects Research. It is the responsibility of each Employee to notify the Employee's supervisor and the Conflict of Interest Office of any perceived, potential, or actual 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.2., the Individual Conflict of Interest Committee will:
 - 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 1-006](#): 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.).

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. Otherwise, the individual will be required to eliminate the conflict or the Research project will be conducted without involvement by the Investigator who has the conflict.

2. In the case of a Research project funded by the Public Health Service, the Individual Conflict of Interest Committee will conduct the review and evaluation described in Section III.B.1. prior to the University's expenditure of funds for the project.
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, within sixty (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 such Financial Conflict of Interest going forward.

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 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. The Individual Conflict of Interest Committee will monitor each Investigator's compliance with the Investigator's management plan until completion of the Research project.

D. Prohibited Activities.

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

1. Any activity that benefits any Business Entity in which an Investigator has a Significant Financial Interest, and that compromises the integrity of the scientific analysis or the publication of Research results or its conclusions, is not allowed. Note that an Investigator has obligations under other University Regulations related to research integrity (e.g., Policy 7-001: Policy for Research Misconduct), and this Rule shall not be construed as limiting those obligations in any way.

2. An Investigator participating in the design, conduct, or reporting of any Human Subjects Research study shall not, directly or indirectly, accept any incentives or gifts from a Business Entity that is sponsoring or providing support for the Research. Any payments to the University from any Business Entity sponsoring or providing support for such Research shall only be deposited into the Investigator's restricted project account established for the Research, unless otherwise specifically approved in advance by the Vice President for Research.
3. Solicitation or receipt of a Gift by a University Employee, whether directly or indirectly through the institution, is not allowed, when (a) the purpose or effect of the Gift is likely to improperly influence the Employee in the discharge of the Employee's University responsibilities; (b) the Gift is given to reward the Employee for official action taken; or (c) the Gift is given in close proximity to recent past, present, or future transactions between the University and the giver of the Gift

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

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

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.);
 - 2. A description of the impact of the bias on the Research project; and
 - 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).
 - 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 require the Investigator involved to:

- i. Disclose the Financial Conflict of Interest in each public presentation of the results of the Research; and
- ii. Request an addendum to previously published presentations.

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:
 - i. The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel;
 - ii. The University determines the Significant Financial Interest is related to the PHS-funded Research; and
 - iii. The University determines the Significant Financial Interest is a Financial Conflict of Interest.
- b. The website by which the University ensures public accessibility under Section III.E.3.a. is required to:
 - i. Be updated at least annually;
 - ii. Be updated within sixty (60) calendar days of the University's receipt or identification of information concerning any additional Significant Financial Interest of the Senior/Key Personnel for the PHS-funded Research project that was not previously disclosed, or upon the disclosure of a Significant Financial Interest of Senior/Key Personnel who are new to the PHS-funded Research project, if the University determines that the Significant Financial Interest is related to the PHS-funded Research and is a Financial Conflict of Interest; and
 - iii. Note that the information provided is current as of the date listed 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.

- 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

1. 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

- a. With respect to a Research project that *is* funded by the PHS and that involves a Subrecipient, the Office of Sponsored Projects will require a written agreement with the Subrecipient that establishes whether Policy 1-006 and its associated University Regulations or another entity's equivalent policy (the Subrecipient's financial conflict of interest policy) will apply to the Subrecipient's Investigators.
 - i. If the Subrecipient's Investigators are required to comply with the Subrecipient's policy:
 - 1. The Subrecipient is required to certify that its financial conflict of interest policy is consistent with Policy 1-006 and its associated University

Regulations and complies with 42 C.F.R. pt. 50 and 45 C.F.R pt. 94. (Note: if the Subrecipient cannot provide such certification, the agreement will provide that 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 the Subrecipient's work for the University); and

2. The Subrecipient's agreement with the University will 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, 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).
- ii. If the Subrecipient's Investigators are required to comply with Policy 1-006 and its associated University Regulations, the Subrecipient's agreement with the University will 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 be sufficient to enable the University to timely comply with its review, management, and reporting obligations under Policy 1-006 and this Rule.

[<Endnote 1>]

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

[Note: Parts IV-VII of this Regulation (and all other University Regulations) are Regulations Resource Information – the contents of which are not approved by the Academic Senate or Board of

Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

IV. Procedures, Guidelines, Forms and other Related Resources:

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

VI. Contacts:

The designated contact officials for this Regulation are:

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

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

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

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

delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library... [and] bears the responsibility for determining – requirements of particular Policies....”

University Rule 1-001-III-B & E

VII. History:

Renumbering: [None]

Revision History:

A. Current version: Revision 1

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.

Legislative History of Revision 1.

B. Earlier Versions

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

[Legislative History](#) of Revision 0.