

Rule 1-006C: Individual Financial Conflict of Interest in Research.

Revision 0. Effective Date: July 1, 2020

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* 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 Regulations. [See [Policy 7-006](#): Institutional Financial Conflicts of Interest for Research Involving Human Subjects].

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. **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.

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 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:

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. 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. 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; or
3. 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 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 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 Conflicts of Interest in Research.

1. The Individual Conflict of Interest Committee will evaluate the information provided in an Investigator's BRR Disclosure Form to determine if the Investigator has any Significant Financial Interests that could create a financial conflict of interest [See [Procedure 1-006](#): Reviewing Individual Conflict of Interest BRR Disclosure Forms].
 - a. 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 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 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.

C. Management of Conflicts of Interests in Research.

The Individual Conflict of Interest Committee may manage conflicts of interest in Research by requiring:

1. Disclosure of financial conflicts of interest in publications and presentations;
2. Disclosure of financial conflicts of interest to students or subordinates working on the Research;
3. Disclosure of financial conflicts of interest to the Research team;
4. For Human Subjects Research, disclosure of financial conflicts of interest to potential participants;
5. Appointment of an independent monitor to evaluate the Research to protect against bias resulting from the conflict of interest;
6. Recusal from certain responsibilities in the Research;
7. Elimination of the Significant Financial interest; or
8. Any other management strategy the Committee determines is necessary to appropriately manage a conflict of interest.

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.

[<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.
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[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:

[Reserved]

V. References:

[Reserved]

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 0
Approved: Academic Senate: April 27, 2020
Approved: Board of Trustees: June 9, 2020, with designated effective date July 1, 2020.

[Legislative History](#) of Revision 0.