

## **Procedure P1-006B. Conflict of Interest Office Procedures Related to Requirements for Federally Funded Research**

**Revision #0.** Effective date: April 12, 2022

### **I. Purpose and Scope**

#### **A. Purpose**

This procedure establishes procedures for the Conflict of Interest Office to comply with federal regulations related to Financial Conflicts of Interest in Research.

#### **B. Scope**

This procedure applies to the Conflict of Interest Office's management of Conflict of Interest requirements for federally funded Research.

### **II. Definitions**

The definitions provided in Policy 1-006 and Rule R1-006C apply for this procedure.

### **III. Procedure**

#### **A. Reporting to Federal Agencies on Federally Funded Research**

1. For Research sponsored by PHS or another federal sponsor that has adopted requirements that are substantially similar to PHS requirements, such as the United States Department of Energy, the Conflict of Interest Office shall submit Financial Conflict of Interest Reports to the sponsor at the following times:
  - a. Prior to the University's expenditure of funds under the Research project;
  - b. Within 60 calendar days of the University identifying a Financial Conflict of Interest for an Investigator who is new to the Research project;

- c. Within 60 calendar days of a new Financial Conflict of Interest, or a newly identified Financial Conflict of Interest for existing Investigators;
  - d. 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
  - e. Following a retrospective review to update a previously submitted report if appropriate.
2. Financial Conflict of Interest Reports submitted to the PHS (or another federal sponsor that has adopted substantially similar requirements) shall include:
  - a. Project number;
  - b. Name of the project director/ principal investigator or contact project director/principal investigator if a multiple project director/ principles investigator model is used;
  - c. Name of the Investigator with the Financial Conflict of Interest;
  - d. Name of the Business Entity with which the Investigator has a Financial Conflict of Interest;
  - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - f. 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;
  - g. A description of how the financial interest relates to the Research and the basis for the institution's determination that the financial interest conflicts with such Research; and

- h. A description of the management plan, including the role and principal duties of the Investigator who has the Financial Conflict of Interest 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.
3. If a federal sponsor establishes reporting requirements related to Financial Conflicts of Interest that differ from the PHS reporting requirements, the Conflict of Interest Office shall comply with the federal sponsor's requirements for Research funded by the federal sponsor.

**B. Retrospective Reviews and Mitigation Plans Related to Bias in Federally Funded Research**

1. If a Financial Conflict of Interest related to Research funded by the PHS (or another federal sponsor that has adopted substantially similar requirements, such as the United States Department of Energy) is not identified or managed in a timely manner (including, for example, failure by an Investigator to disclose a Significant Financial Interest that the University 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 120 calendar days from the date of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the Research project to determine if there was any bias in the design, conduct, or reporting of the Research conducted during the time period of noncompliance.

2. The Conflict of Interest Office shall document all retrospective reviews of Research projects funded by the PHS (or federal sponsor that has adopted substantially similar requirements) and such documentation shall include:
  - a. Project number;
  - b. Project title;
  - c. Name of the project director/principal investigator or contact project director/principal investigation if a multiple project director/principal investigator model is used;
  - d. Name of the Investigator with the Financial Conflict of Interest;
  - e. Name of the Business Entity with which the Investigator has a Financial Conflict of Interest;
  - f. Reason(s) for the retrospective review;
  - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - h. Findings of the review; and
  - i. Conclusions of the review.
3. Based on the results of the retrospective review, if appropriate, the Conflict of Interest Office shall update any previously submitted financial conflict of interest reports, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.
4. Following the retrospective review, if the Conflict of Interest Office determines that there was bias in the design, conduct, or reporting of the Research conducted during the time-period of noncompliance, the Conflict of Interest Office shall:

- a. Promptly notify the PHS or other federal sponsor; and
  - b. Submit a mitigation report to the PHS or other federal sponsor that includes, at a minimum, all of the following:
    - i. The elements documented as part of the retrospective review;
    - ii. A description of the impact of the bias on the Research project; and
    - iii. A description of the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on 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).
5. If a federal sponsor establishes requirements related to retrospective reviews of Financial Conflicts of Interest that differ from the PHS requirements, the Conflict of Interest Office shall comply with the federal sponsor's requirements for Research funded by the federal sponsor.

**C. Public Accessibility of Information Concerning Conflicts of Interest Related to Federally Funded Research**

1. Prior to the University's expenditure of funds under a Research project funded by the PHS (or other federal sponsor with substantially similar requirements, such as the United States Department of Energy), the University shall ensure public accessibility, via a publicly accessible website or written response to any request within five business days of a request, of information concerning any Significant Financial Interest disclosed to the University that meets the following criteria:
  - a. The Significant Financial Interest was disclosed and is still held by the Senior/Key Personnel;

- b. The University determines the Significant Financial Interest is related to the Research; and
    - c. The University determines the Significant Financial Interest is a Financial Conflict of Interest.
  2. If the University uses a publicly accessible website to meet the public accessibility requirement, the University shall:
    - a. Update the website at least annually;
    - b. Update the website 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 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 Research project, if the University determines that the Significant Financial Interest is related to the Research and is a Financial Conflict of Interest; and
    - c. 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 60 calendar days of the University's identification of a new Financial Conflict of Interest.
  3. The information that the University makes available on the website or in response to a written request shall include, at a minimum, all of the following:
    - a. Investigator's name;
    - b. Investigator's title and role with respect to the Research project;
    - c. Name of the Business Entity in which the Significant Financial Interest is held;
    - d. Nature of the Significant Financial Interest; and

- e. 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.
  4. If the University responds to a written request, the University shall 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 60 calendar days of the University's identification of a new Financial Conflict of Interest which should be requested subsequently by the requestor.
  5. Information concerning a Significant Financial Interest of an individual described in this procedure shall remain available for responses to written requests or for posting via the University's publicly accessible website for at least three years from the date that the information was most recently updated.
  6. If a federal sponsor establishes requirements related to public accessibility to Financial Conflict of Interest information that differ from the PHS requirements, the Conflict of Interest Office shall comply with the federal sponsor's requirements for research funded by the federal sponsor.
- D. Record Retention for Federally funded Research Projects
1. Unless state or federal law requires a longer period of retention, the Conflict of Interest Office shall retain records related to the following for at least three (3) years from the date the final expenditures report is submitted to the federal sponsor that provided the funding or, for federal awards that are renewed quarterly or annually, from the date of submission of the quarterly or annual financial report, respectively, as reported to the federal sponsor or pass-through entity in the case of a Subrecipient:

- a. Investigator disclosures of Financial Interests;
- b. 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;
- c. All actions under a retrospective review; and
- d. All actions under Policy 1-006 and its associated University regulations.

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*\*\*User 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.\*\**

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#### **IV. Policies/ Rules, Procedures, Guidelines, Forms and other Related Resources**

- A. Policies/ Rules.
  1. Policy 1-006 Individual Financial Conflict of Interest Policy
  2. Rule 1-006C Individual Financial Conflict of Interest in Research

#### **V. References**

- A. 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).
- B. 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**

Renumbering: Not Applicable

Revision History.

- A. Current version. Revision 0. Effective April 12, 2022
  - 1. Legislative History for current version.