Financial Conflict of Interest Policy for Externally Funded Projects

Ursinus College

Introduction

External support of college projects, particularly from the federal government, may require certification of review and subsequent management of any potential Financial Conflicts of Interest (FCOI). These guidelines provide a policy designed to comply with federal regulations as describe in 42 CFR Part 50 Subpart F. Investigators must disclose any Significant Financial Interests (SFIs) at the time or application, and the College with review those SFIs to determine if they meet the level of FCOIs, and if so, will determine how to manage those conflicts, including disclosure to the relevant granting agencies.

Training

To ensure investigators are aware of their responsibilities for financial conflict of interest disclosure, principal investigators, on Ursinus's Internal Proposal Form, must certify they have reviewed this policy. In doing so, they are certifying:

- Awareness of this policy
- Identification of co-investigators and subrecipients, and informing them of these training and disclosure and training requirements
- Recognition of their individual disclosure responsibilities
- Their fulfillment of the <u>CITI Conflict of Interest Course</u> within the last four years or immediately upon revision of the college's FCOI policy, an investigator is new to the institution and conducting PHS supported research, or an investigator is out of compliance with Ursinus's FCOI policy.
- Whether subrecipients are subject to FCOI polies of Ursinus or another institution

Disclosure, Review, and Monitoring

Each investigator and subrecipient is required to disclose any significant financial interest (SFI) meeting the specifications here and here and here and here and here; in general, the threshold for significance is \$5,000 over a 12-month period disbursed to the investigator and immediate family members (spouse and dependent children). This disclosure must be noted on the Ursinus Internal Proposal Form, and followed promptly by full details on the Ursinus Financial Conflict of Interest Form. Such disclosures must be made at the time of application for existing conflicts, within thirty days of any newly arising conflicts, and annually during the period of the award for any continuing conflicts.

A Review Committee, consisting of the Dean of the College, the Vice President and General Counsel, and the lead member of the Corporate, Foundations and Government Relations Office, will review the Financial Conflict of Interest Disclosure Form, and determine if the SFI meets the standards of a FCOI if either of the following apply:

- If that SFI can be affected by the funded research, or
- The SFI is an entity whose financial interest could be affected by the research.

If an FCOI is identified, the Review Committee will impose conditions or restrictions on the research consistent with <u>guidelines</u> offered by the NIH. The Committee will review any SFIs promptly (typically within 30 days of disclosure), whether at the time of application, or following disclosure of subsequent SFIs or existing or added investigators. The College will withhold funds at the initiation of a project until all SFIs are reviewed and identified FCOIs have established management plans.

Reporting to Funding Agencies

The College, through the Review Committee, will send initial and annual FCOI reports to the relevant funding agencies per their specifications, such as those required by the NIH. These reports will be filed prior to expenditure of funds for new grants, or within 60 days of the identification of new FCOIs, or within 60 days of the addition of new investigators with FCOIs. For investigators with ongoing FCOIs, that reporting will in general occur with the annual funding report as required by the relevant agency. The College, through the review Committee, will also report promptly any instances of bias or non-compliance on the part of investigators upon revelation, along with plans for corrective action.

Maintenance of Records

Records of all FCOIs shall be maintained by the Review Committee on behalf of the college for a minimum period of three years, or as specified by relevant funding agencies.

Enforcement

Failure to comply with the requirements of this policy will typically result in the withholding of funding until compliance is re-established and reviewed by the Review Committee. If the Review Committee finds that non-compliance may be deliberate and remains unremediated, the investigator is subject to the review and potential sanction for Scholarly Misconduct policy specified within the Ursinus Faculty Handbook. In any event, non-compliance incidents will trigger a retrospective review within 120 days of the College's determination of non-compliance.

Subrecipient Requirements

Ursinus College is responsible for ensuring that all subrecipients are compliant with federal regulations regarding Financial Conflict of Interest. The College shall enter a written agreement with all subrecipients that shall specify that they have fulfilled these regulations through their home institutions. Where applicable, Ursinus will obtain a certification from the subrecipient's home institution.

Public Accessibility

This policy is posted on the <u>Ursinus College website</u>. Information regarding identified FCOIs may be requested from the Corporate, Foundations and Government Relations Office, and will be supplied as specified by <u>NIH guidelines</u>.

September 15, 2021