

F.28 Investigator Significant Financial Interest Disclosure Policy

Date

1/25

(Applicable to all sponsored project proposals and awards)

Requirements

Federal regulations (including Code of Federal Regulations ([42 CFR Part 50.601](#) et seq.)) require institutions of higher education to have policies and procedures in place that ensure that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relation to externally sponsored projects. Such disclosures must be made prior to the submission of the proposal for funding, and institutions must develop specific mechanisms by which conflicts of interest will be reviewed and satisfactorily managed, reduced, or eliminated prior to acceptance of an award. The purpose of this policy is to promote objectivity in the conduct of sponsored projects.

In addition, if a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required. Additional related policies and guidance are available from the Office of Sponsored Projects and Research.

Applicability

This policy applies to all investigators and their spouse and dependent children. "Investigator" is defined as the principal investigator, project director, co-principal investigators, and any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by an external sponsor.

Elements Subject to Disclosure

Each investigator must disclose all significant financial interests:

- that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

"Significant financial interests" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- salary, royalties, or other remuneration from the University;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities; or financial interests in business enterprises or entities if the value of such interests do not exceed \$10,000 (or \$10,000 per annum if such interests represent salary, fees, or other continuing payments) or represent more than 5 percent

ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children. ***For federal funding under Public Health Service (PHS) grants or cooperative agreements, the maximum allowable financial interest is \$5,000 per year.***

Disclosure Procedures

Investigators applying for extramural grant funding an updated determination form must be completed and included in the administrative review process prior to the submission of each grant application. If awarded, updated disclosures are completed annually during the award period and within thirty (30) days of any new reportable significant financial interests that arise.

If a significant potential conflict of interest is identified, the investigator will be required to report the conflict to the Office of Sponsored Projects and Research for review by the USI Conflict of Interest (COI) Review Committee. Investigators may be required to provide additional information and documentation to the USI COI Review Committee to ensure that all conflicts real or perceived are mitigated.

Review Procedures

After preliminary review by the Director of the Office of Sponsored Projects and Research, and on determination that the conflict is both real and sufficiently significant, supporting documentation should be submitted to the Office of Sponsored Projects and Research. Disclosure packets will be reviewed, within thirty (30) days following disclosure, by the USI Conflict of Interest (COI) Review Committee, comprised of the Director of the Office of Sponsored Projects and Research, dean of the investigator's college or equivalent administrator, Director of Internal Audit or Business Office representative, and Vice President for Government Affairs and General Counsel. Resolutions to conflicts of interest must be completed prior to award acceptance.

Conflict Resolution and Management

If there is a determination that there is a conflict of interest, the University is obligated to take actions to manage, reduce, or eliminate conflict; to maintain records three years after completion of the research or educational activity; and to establish enforcement mechanisms and sanctions. The USI COI Review Committee will determine the resolution to be recommended: conditions or restrictions to manage, reduce, or eliminate the conflict of interest. Enforcement mechanisms and sanctions may include requiring one or more of the following options to minimize bias in the research and to maintain the integrity of the research or educational activity:

- public disclosure of the conflict in the publication of research
- monitoring of research by independent researchers who will review the design of research, data collections, etc.
- modification of the research or educational activity to eliminate the conflict
- withdrawal from some or all of the research or educational activity
- divestiture of financial interests severance of relationships.

If any identified conflict or non-compliance requires reporting to the sponsoring federal agency, OSPR will produce such a report in accordance with applicable regulations.

Subrecipients and Subawardees

When the University works with subrecipients or subawardees of grant funds from the federal agencies to which this policy applies, it will enter into written agreements specifying whether the subrecipient institution will follow USI's Financial COI Policy or its own. Subrecipients and subawardees will be required to comply with any applicable federal regulations.

Training

Each investigator federally required to participate in Financial COI disclosure is required to complete Financial COI training prior to starting the federally funded project (e.g., Public Health Service awards) and to renew this training at least every four (4) years thereafter. Additionally, training within thirty (30) days will be required when any of the following apply:

- a. This Financial COI policy is materially revised in any manner that affects the requirements of the investigator to comply;
- b. An investigator is newly appointed to the University of Southern Indiana; or
- c. The University of Southern Indiana finds that an investigator is not in compliance with this policy or their Financial COI management plan.

Public Accessibility

This policy and disclosure of investigators' Financial Conflicts of Interest shall be available to the public to the extent required by applicable federal regulation.