

Investigator Significant Financial Interest Disclosure Policy

Date

7/15

Item

F.28

(Applicable to all sponsored project proposals)

Requirements

Federal regulations 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. 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.

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 grant funding from the Department of Health and Human Services, 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 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 Administration for review by the USI Conflict of Interest 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 Chief Data Officer, 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 Administration. Disclosure packets will be reviewed by the USI Conflict of Interest (COI) Review Committee, comprised of the Chief Data Officer, the dean of the investigator's college, and a graduate faculty member representative to the Graduate Council from either the College of Nursing and Health Professions or the Pott College of Science, Engineering, and Education. Resolutions to conflicts of interest must be completed prior to award acceptance.

Solutions to Conflict

If there is 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 research; and to establish enforcement mechanisms and sanctions. The COI Review Committee will determine what solution will 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 ensure that the science is intact:

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