



POLICY TITLE: Individual Financial Conflict of Interest Policy

POLICY PURPOSE: To describe the responsibility for reporting individual significant financial interests and the institutional responsibility for evaluating disclosed interests and managing potential individual financial conflicts of interest.

BACKGROUND:

APPLIES TO: All Fort Hays State University faculty, all other unclassified academic and professional staff, and anyone serving as project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted under the auspices of the University, which may include, for example, collaborators or consultants. (See the definition of “Covered Persons” below).

DEFINITIONS: Covered Persons: All faculty, all other unclassified academic and professional staff, and all Investigators as defined below. Financial interests of a Covered Person include those of the individual’s family or household members as described in the applicable campus reporting forms.

Investigator: The project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted under the auspices of the University. Investigators may include, for example, collaborators or consultants not employed by the University.

University Responsibilities: An individual’s responsibilities on behalf of the University, which may include (but are not limited to), activities such as teaching, research, research consultation, administration, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Conflict of Interest: A conflict of interest that arises in a situation in which a Significant Financial Interest of a Covered Person compromises or has the appearance of compromising the fulfillment of professional duties; teaching, clinical or scientific judgment; integrity of research data and the research process; or the safety and welfare of patients and/or research subjects.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting or other fees, honoraria, paid authorship,

commissions, etc.)

Equity Interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Governmental or Educational Entities include federal, state, or local government agencies; institutions of higher education as defined at 20 U.S.C. 1001(a); and academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.

Significant Financial Interest (SFI): A financial interest that reasonably appears to be related to the individual's University responsibilities, consisting of one or more of the following interests of a Covered Person:

- 1) An interest in any publicly traded entity, if the value of any Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from the entity in the twelve months preceding the disclosure, and any Equity Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- 2) An interest in any non-publicly traded entity, if the value of any Remuneration (including, but not limited to, salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5000, or when the individual holds any Equity Interest.
- 3) Intellectual property rights and interests (e.g., patents, copyrights), regardless of value, upon receipt of income related to such rights and interests.
- 4) Reimbursed or sponsored travel related to an Investigator's University Responsibilities, except for travel that is reimbursed or sponsored by Governmental or Educational Entities as defined above. Sponsored travel in this context means travel which is paid on behalf of the individual and not reimbursed to the individual so that the exact monetary value may not be readily available.

The term Significant Financial Interest does not include the following types of financial interests:

- a) salary, royalties, or other remuneration paid by the University to the individual if the individual is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- b) income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles;
- c) income or other benefits for certain activities sponsored by or in the service of Governmental or Educational Entities (defined above), as follows:

- i. seminars, lectures, or teaching engagements
- ii. service on advisory committees or review panels
- iii. reimbursed or sponsored travel.

CONTENTS:

Fort Hays State University is committed to integrity in teaching, research, clinical care, and service as well as to the welfare of the students, patients and research subjects it serves. This commitment to integrity must not be compromised, nor appear to be compromised, by competing personal interests or obligations. Therefore, a rigorous conflict of interest program has been established to preserve and to ensure the integrity of teaching, research, clinical care and service at the University through reporting and management of potentially conflicting relationships. This policy is intended to comply with federal requirements relating to conflicts of interest in research as well as the policies of the KBOR, FHSU and other regulatory bodies.

The University is committed to helping faculty, staff and all other Investigators participating in University-sponsored research avoid situations involving unmanaged conflicts of interest, because these could infringe on their responsibilities as investigators on projects, including those sponsored by federal agencies. Adherence to institutional Conflict of Interest Procedures is intended to help Investigators avoid these situations and to provide protection for Investigators who may be accused of being motivated by conflicts of interest while acting in their capacity as researchers.

42 CFR Part 50 Subpart F requires institutions to maintain and enforce a FCOI policy that meets or exceeds the regulatory requirements. The policy must apply to each Investigator, as defined by the regulation, who is planning to participate in or is participating in Public Health Service (PHS) funded research. Institutions must be able to certify, in each application for funding, that the Institution:

- Has in effect an up-to-date, written and enforced administrative process to identify and manage FCOI.
- Shall promote and enforce Investigator compliance with the regulation.
- Shall manage FCOI and provide initial and ongoing FCOI reports.
- Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request.
- Shall fully comply with the regulation's requirements

Training Requirements

The University is responsible for providing information to Investigators regarding relevant federal regulations, university policy, and investigator disclosure responsibilities.

Prior to engaging in research funded by relevant federal agencies (e.g.,

PHS), the Investigator must complete FCOI training, to be renewed at least every four years, or immediately if:

- University FCOI policy impacting Investigator requirements is revised.
- The Investigator is new to FHSU
- The Investigator is not in compliance with FHSU FCOI policy or management plan

Disclosure, Review and Monitoring

Investigators (and their spouse and dependent children must follow the FHSU process to disclose Significant Financial Interest (SFI) related to the Investigator's institutional responsibilities that meets or exceeds the definition of SFI:

- No later than at the time of the application for funding from relevant agencies (PHS)
- At least annually during the period of the award
- Within 30 days of discovering or acquiring a new SFI

The Designated Institutional Official will solicit and review disclosures of SFIs of the Investigator and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities, and determine whether the SFI is related to PHS-funded research, and if so related, whether the SFI is a FCOI. If the SFI is a FCOI that could directly and significantly affect the design, conduct, or reporting of the research, a FCOI management plan will be developed and implemented.

The NIH will be promptly notified if bias is found with the design, conduct or reporting of NIH-funded research and FHSU will submit a Mitigation Report in accordance with the regulation.

NIH will be promptly notified if an Investigator failure to comply with the Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. FHSU will take corrective action for noncompliance with this policy or the management plan.

Maintenance of Records

FHSU will maintain all FCOI-related records that meet or exceed the regulatory requirements:

- For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).
- From other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Enforcement

The implementation and enforcement of this Policy and the Conflict of Interest Procedures and the handling of violations of the Policy and/or Procedures will be managed in accordance with applicable University policies and procedures. Examples of violations include but are not limited to the failure to file timely reports; filing incomplete, erroneous, or inaccurate reports; or failure to comply with the prescribed Conflict of Interest Procedures for managing or resolving conflicts of interest. Violations relating to a federally funded project shall be managed in accordance with the Conflict of Interest Procedures and the requirements of the applicable awarding authority, e.g., [42 CFR Part 50 and 45 CFR Part 94, see HHS reference below.]

Subrecipient requirements

Where applicable, the university will establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.

Public Accessibility

The University will make this policy publicly accessible.

The University will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds.

POLICY STATEMENT:

Fort Hays State University requires all Covered Persons to regularly report on Significant Financial Interests as defined below. Such reports must be made annually in the time period prescribed by the University. Updated reports are required within thirty days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new Significant Financial Interest. In addition, Investigators conducting externally-sponsored research must have filed an up-to-date report no later than the time of application for externally-sponsored research.

Significant Financial Interests that reasonably appear to be related to the individual's University responsibilities shall be reported in the manner required by the university. All reported Significant Financial Interests will be reviewed in accordance with the applicable campus procedures to determine whether a Financial Conflict of Interest exists. If it is determined that a Financial Conflict of Interest exists, a management plan will be developed, as necessary, to ensure the integrity of teaching, research, clinical care and service. As obliged by federal regulations to promote transparency in research, the University will make certain information concerning those reported interests of investigators that are determined to be Financial Conflicts of Interest available to the public. Investigators should be aware that compliance with the requirement to disclose specified information about interests reported by Investigators is a condition of participation in projects, including those sponsored by federal agencies.

The University has established Conflict of Interest Procedures to implement the requirements of this Policy. This Policy and the Conflict of Interest

Procedures are intended to comply with Kansas Board of Regents policy and state and federal conflict of interest laws and regulations.

Responsibilities of Individuals and Designated Officials:

Individual: It is the responsibility of each Covered Person to file timely reports; file complete and accurate reports; and to comply with approved conflict management plans developed for the purpose of mitigating or resolving any identified Financial Conflicts of Interest. In addition, periodic training is required as specified in campus procedures.

Department or Center: Supervisors are responsible for reviewing reports submitted by those individuals who report to them and verifying the accuracy of the report with the individuals as necessary before signing and forwarding the report to the Office of Scholarship and Sponsored Projects. The Dean of the Graduate School, or his or her designee, serves as the Institutional Official in matters related to conflict of interest.

The Office of Scholarship and Sponsored Projects is responsible for implementing and managing the Conflict of Interest program and for providing support to the Conflict of Interest Committee. The Dean of the Graduate School, or his or her designee, serves as the Institutional Official in matters related to conflict of interest.

EXCLUSIONS OR SPECIAL CIRCUMSTANCES:

RELATED DOCUMENTS:

This policy supplements the Kansas Board of Regents Policy on Conflict of Time Commitment, Conflict of Interest, Consulting, and Other Employment.

Kansas Board of Regents Policy on Conflict of Time Commitment, Conflict of Interest, Consulting, and Other Employment

<https://documents.ku.edu/policies/provost/CommitmentofTimeConflictofInterest.htm>

Institutional Responsibility Regarding Conflicting Interests of Investigators (42 CFR 50, Subpart F, Section 604)

Management of Conflicting Interests (42 CFR 50, Subpart F, Section 605)

FDA Disclosure Requirements (21 CFR 54)

NIH: Financial Conflicts of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards

HHS: Responsibility of Applicants for Promoting objectivity in Research for which Public Health Service Funding is sought and Responsible Prospective Contractors

Other:

Procedures for Reporting and Managing Conflicts of Interest

KEYWORDS: Conflict of Interest, Financial Conflict of Interest, Significant Financial Interest

RESPONSIBLE OFFICE: Graduate School – Office of Scholarship and Sponsored Projects

RESPONSIBLE UNIVERSITY OFFICIAL: Dean of the Graduate School

ORIGINATION DATE: 12/3/2012

CHANGE HISTORY: Adopted by President's Cabinet on 12/3/2012
