



## Ohio Administrative Code

### Rule 3342-10-04.1 Administrative policy on financial interest in sponsored projects.

Effective: July 1, 2019

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(A) In accordance with state and federal regulations, the university is required to manage, reduce or eliminate any actual or potential conflicts of interest that may be presented by a significant financial interest of an investigator. Thus, the university requires that investigators disclose all significant financial interests that may present an actual or potential conflict of interest in relation to a sponsored project, as defined in rule 3342-10-03.1 of the Administrative Code. Sponsored projects for the purpose of this policy includes all direct awards and subawards.

(B) Definitions.

(1) "Conflict of interest" occurs when the relationship between an individual's private interests and his or her professional obligations to the university is such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An "actual" conflict of interest depends on the situation and not on the character or actions of the individual.

(2) "Investigator" means the principal investigator/project director, and co-principal investigator. Investigator also means any other person who is responsible for or involved in the design, conduct, or reporting of research, instructional or service activities funded, or proposed for funding, by an external sponsor. For the purposes of the requirement relating to financial interests, investigator includes spouses and dependent children.

(3) "Project" means any externally funded scholarly activity such as basic, applied, or developmental research, instructional or curricular activities, student aid, career development, or other activity conducted by faculty or staff members on behalf of the university.

(4) Significant financial interest means anything of monetary value or potential monetary value held by an investigator, investigator's spouse, and dependent children, that reasonably appears to be related to the investigator's institutional responsibilities, including:



(a) For public health service (PHS) funded projects (PHS includes, but is not limited to NIH, SAMHSA, HRSA, CDC, AHRQ and, for the purpose of this policy, any other funding sponsor that adopts PHS regulations, and including all subawards originating from PHS or a funding sponsor adopting PHS regulations):

(i) With regard to any publicly traded entity, combined financial remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure that exceeds five thousand dollars. Remuneration includes salary, any payment for services not identified as salary, equity interests and ownership interests;

(ii) With regard to any non-publicly traded entity, combined financial remuneration received from the entity in the twelve months preceding the disclosure that exceeds five thousand dollars, or when the investigator holds any equity interest (e.g., stock, stock option, or other ownership interest), regardless of the equity value; or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

(iv) Any reimbursed or sponsored travel exceeding five thousand dollars from the same entity in the aggregate (i.e., travel is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to the investigators institutional responsibilities must be disclosed. Disclosure of this interest will include the purpose and duration of the trip, the identity of the sponsor/organizer, and the travel destination.

(b) For all other funding (all non-PHS funded research including, but not limited to national science foundation (NSF) Funding):

(i) With regard to a publicly traded entity, combined financial remuneration received from the entity in the twelve months preceding the disclosure that exceeds ten thousand dollars. Remuneration includes salary, any payment for services not identified as salary, equity interests and ownership interests;



(ii) With regard to any non-publicly traded entity, combined financial remuneration received from the entity in the twelve months preceding the disclosure that exceeds ten thousand dollars, or when the investigator holds any equity interest (e.g., stock, stock option, or other ownership interest), regardless of the equity value; or

(iii) A five per cent ownership interest in a single publicly traded entity; or

(iv) Intellectual property rights and interests upon receipt of income related to those rights and interests that exceeds ten thousand dollars during the prior twelve month period.

(5) "Significant financial interests" do not include:

(a) Salary, royalties, or other remuneration paid by the university to the investigator if the investigator is currently employed or otherwise appointed by university; or

(b) Intellectual property rights assigned to the university and agreement to share in royalties related to such rights; or

(c) Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education (this exception does not apply to foreign institutions of higher education or governments of another country); or

(d) Income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education (this exception does not apply to foreign institutions of higher education or governments of another country).

(6) "Financial conflict of interest" (FCOI) means a significant financial interest that is related to externally funded university research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research.



(C) Disclosure requirements for financial interests.

(1) Disclosure requirements. All investigators must submit a listing of the following significant financial interests:

(a) Any significant financial interest that would reasonably appear to be affected by the research, instructional or service activities funded, or proposed for funding, by an external sponsor; or

(b) Any significant financial interest in an entity whose financial interest would reasonably appear to be affected by the research, instructional or service activities funded, or proposed for funding, by an external sponsor.

(2) Regardless of the listed minimum requirements, a faculty or staff member, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

(D) Procedures for disclosure of financial interests.

(1) Special requirements/disclosures for PHS-funded research. Pursuant to public health service (PHS) regulations (42 CFR 50) institutions receiving funds from any PHS agency (PHS agencies include NIH, SAMHSA, OPHS, IHS, HRSA, FDA, CDC, AHRQ) or other agencies adopting PHS financial conflict of interest policies, must comply with the following requirements:

(a) Each investigator who is planning to participate in PHS-funded research is required to disclose to Kent state university officials the investigator's significant financial interests reasonably related to the investigator's institutional responsibilities (and those of the investigator's spouse and dependent children) no later than the time of application for PHS-funded research. Each investigator must complete the appropriate certification process required by the university.

(b) Each investigator who is participating in PHS-funded research is required to complete an updated certification either within thirty days of discovering or acquiring a new significant financial interest, or at least on an annual basis during the period of the PHS funding award.



(c) Disclosure of all externally-funded travel reimbursements: PHS-funded investigators must disclose all travel reimbursements that are either sponsored by (that is paid by an outside entity directly to the investigator) or reimbursed directly to the investigator from an outside entity with some exceptions. Exceptions include: travel reimbursements from an institution of higher education, a federal/state/local government, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education. This disclosure requirement does not apply to funding provided to the investigator by the university (for example as part of sponsored research projects, paid from departmental discretionary or gift funds). Travel reimbursements must be reported within thirty days of its occurrence.

(d) Mandatory training requirements: All PHS-funded investigators must complete online FCOI training provided by Kent state university prior to the expenditure of funds of any newly-funded projects, including noncompeting continuation awards. Training must be completed at least every four years. For the purposes of mandatory training, the term "investigator" includes the principal investigator (PI) and any other person (regardless of title or position) that the PI identifies as independently responsible for the design, conduct, or reporting of the research.

(E) Disclosure statement reviews

(1) Review by conflict of interest review committee. The vice president for research and sponsored programs, or official designee, will conduct an initial review of all disclosure statements submitted to determine whether a FCOI exists and, if so, determine what actions should be taken by the university to manage, reduce, or eliminate the FCOI. If a determination is made that there may be a potential or actual FCOI, the investigator, in cooperation with his/her dean, chair or director, will develop and present to the vice president for research and sponsored programs a plan to manage, reduce or eliminate any potential or actual FCOI presented by the disclosed significant financial interest.

(2) The proposed plan shall be referred to the university conflict of interest review committee (CIRC) which will advise the vice president for research and sponsored programs. The CIRC shall consist of five faculty members representing a cross section of academic disciplines and up to three tenured administrators with faculty rank. Committee members are appointed by the vice president for research and sponsored programs. The CIRC will select its own Chair from among its members.



(3) The CIRC shall review the plan and recommend it as presented, or suggest conditions or restrictions which may include the following: (a) public disclosure of FCOI; (b) monitoring of the research by an independent reviewer; (c) for research projects involving human subjects research, disclosure of FCOI directly to participants; (d) modification of the research plan; (e) disqualification from participation in all or the portion of the funded research that would be affected by the significant financial interest; (f) divestiture of significant financial interests; or (g) severance of relationships that create conflicts.

(4) If the CIRC determines that imposing conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or public health and welfare, then the CIRC may recommend that the research go forward without imposing such conditions or restrictions.

(5) The plan, if approved by the vice president for research and sponsored programs, will be incorporated into a memorandum of understanding that details the conditions or restrictions imposed upon the investigator in the conduct of the project and/or the relationship with the business enterprise or entity. The memorandum of understanding shall be signed by the investigator and the investigator's cognizant university official (usually a dean, chair or director) and the vice president for research and sponsored programs. The university shall monitor compliance with the plan on an ongoing basis until completion of the funded research project.

(6) Actual or potential conflicts of interest must be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to expenditure of any funds under the award. If actual or potential conflict cannot be satisfactorily managed, the sponsoring agency must be informed.

(F) Failure to comply. non-compliance. When an investigator is found to have violated this policy or the terms of the memorandum of understanding, the CIRC may recommend to the appropriate vice president that sanctions be imposed consistent with procedures established by university policy and/or an applicable collective bargaining agreement affecting the employee and his/her employment relationship with the university. Disciplinary action may range from a letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under university policies regarding misconduct in science, the CIRC shall defer a decision on sanctions until the misconduct in science process is completed. In cases of violation, the



vice president for research and sponsored programs will notify the appropriate funding agency.

(G) University reporting and records.

(1) Reporting. The university will provide initial and ongoing reports of its management of FCOI to external sponsors of university research as required by law and in accordance with this policy.

(2) Records. Records relating to all investigator disclosures of significant financial interests and the university's review and management of such disclosures, will be maintained by the university in the case of externally-funded research for:

(a) Three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements); or

(b) Three years from the final payment (in the case of research contracts), or

(c) Resolution of any government action involving the records, or

(d) As otherwise required by law.