

3349-20-30 Financial conflict of interest in research.**(A) Purpose**

The university is committed to ensuring that the financial interests of investigators do not affect, or appear to affect, the design, conduct or reporting of research or compromise the welfare of human or animal subjects.

The purpose of this rule is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by an investigator's conflicting financial interest. This rule establishes procedures for the disclosure, evaluation, management, reduction, and/or elimination of investigator's significant financial interests. This rule complies with the following federal regulations:

- (1) Title 42 code of federal regulations (CFR), part 50, subpart F, responsibility of applicants for promoting objectivity in research for which public health service "PHS" funding is sought
- (2) Title 45 code of federal regulations (CFR), part 94, responsible prospective contractors.

(B) Scope

- (1) This rule applies to all investigators applying for, conducting, supervising, or reporting research at the university. This rule acknowledges that individual financial conflicts of interest may be inherent in the research process and does not preclude research in which a financial conflict of interest exists. This rule applies only to financial conflicts of interest in research.
- (2) This rule applies to any investigator who is planning on participating in or is participating in research funded by the public health service "PHS" and any other funding agency that has adopted the "PHS" regulations or requires a conflict of interest rule. The research contemplated under this rule

includes a research grant, contract, cooperative agreement, sub grant, subcontract, or sub-cooperative agreement which is funded in whole or in part by “PHS” funds (with the exception of “Phase I SBIR/STTR” phase I small business innovation research/small business technology transfer research applications).

- (3) For purposes of determining the existence of a significant financial interest, this rule extends to the financial interests of the investigator and the investigator’s immediate family.

(C) Definitions

- (1) “Conflict of Interest Management Plan” is a written plan developed by the institutional officials in collaboration with the investigator to address the management, reduction or elimination of a financial conflict of interest.
- (2) “Financial Conflict of Interest” refers to situations in which the university determines that an investigator’s significant financial interests related to a externally funded research project could directly and significantly affect the design, conduct or reporting of the externally funded research.
- (3) “Financial Interest” refers to anything of monetary value, whether or not the value is readily ascertainable.
- (4) “Immediate Family” refers to the spouse (including individuals who are recognized as lawfully married under the law of any state) and dependent children of an investigator.
- (5) “Investigator” refers to the project director or principal investigator and any other person, regardless of their title or position, who is responsible for the design, conduct, or reporting of research that is “PHS” funded, which may include, for example, collaborators or consultants. For the purposes of this rule, the term investigator includes financial interests held by the investigator’s immediate family.

- (6) “Institutional Responsibilities” refers to an investigator’s professional responsibilities on behalf of the university and set forth in this rule. Institutional responsibilities include research, research consultation, teaching, professional practice, university committee membership and service on panels such as the institutional review board.
- (7) “Institutional Officials” refer to the collaborative efforts of the chief technology transfer officer and the vice president for research.
- (8) “Public Health Service Awarding component” is the organizational unit of the “PHS” that funds the research, e.g., national institute of health.
- (9) “Principal Investigator” refers to the individual who is the project director or investigator who has primary responsibility for the design, conduct or reporting of the proposed research.
- (10) “Research” is a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development and includes any such activity for which research funding is available from an external source, including a “PHS” awarding component, through a grant or cooperative agreement.
- (11) “Significant Financial Interest” is a financial interest consisting of one or more of the following interests held by the investigator or the investigator’s immediate family that reasonably appears to be related to the investigator’s institutional responsibility:
 - (a) Remuneration received from a publicly traded company that, when aggregated for an investigator and the investigator’s immediate family for the past twelve months, or expected over the next twelve

months, exceeds five thousand dollars.

Remuneration includes:

- (i) Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship).
 - (ii) Equity interests (e.g., stocks, stock options or other ownership interests);
 - (iii) Intellectual property rights (e.g., patents, copyrights and royalties from such rights).
- (b) Remuneration received from a non-publicly traded company that, when aggregated for an investigator and the investigator's immediate family for the past twelve months, or expected over the next twelve months, exceeds five thousand dollars or when the investigator or the investigator's immediate family holds any equity interest in the company;
- (c) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- (d) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator), related to the investigator's institutional responsibilities, except for travel that is reimbursed or sponsored by a United States (U.S.) government agency, ~~an~~ a U.S.-based institution of higher education or a teaching hospital, a medical center, or a research institute that is affiliated with ~~an~~ a U.S.-based institution of higher education.
- (e) The term "significant financial interests" does not include:
- (i) Salary, royalties, or other remuneration paid by the university, including intellectual property

rights assigned to the university and agreements to share in royalties related to such rights;

- (ii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in those vehicles;
- (iii) Income from seminars, lectures, or teaching engagements sponsored by a U.S. government agency, ~~an~~ a U.S.-based institution of higher education or a teaching hospital, medical center, or research institute affiliated with ~~an~~ a U.S.-based institution of higher education;
- (iv) Income from service on certain advisory committees or review panels by a government agency, an institution of higher education or a teaching hospital, medical center, or research institute affiliated with an institution of higher education.

(12) “Small business innovation research” refers to highly competitive programs that encourage domestic small businesses to engage in federal research/research and development with potential for commercialization.

(D) Body of the rule

- (1) University employment is a trust conferred by a public authority for a public purpose. Such status forbids employees from placing themselves in a position in which a private interest would conflict with a public duty. This principle applies to all research conducted on the university campus or supported by university resources.
- (2) A financial conflict of interest exists if the institutional officials conclude that an investigator’s significant financial interest

could directly and significantly affect the design, conduct, or reporting of the externally funded research.

- (3) Training for investigators. All investigators who engage in “PHS” funded research must complete conflict of interest training prior to engaging in the “PHS” funded research; at least every four years; and immediately upon obtaining

employment as a university employee or as required by modifications to this rule.

- (4) Disclosure requirements and management plans.
 - (a) Investigators are required to submit a financial conflict of interest in research disclosure form to university’s institutional officials with each new grant application (and to update it annually during the period of the award, or within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant interest financial interest.
 - (b) Within sixty days of the disclosure, whether the disclosure was timely or not, the university’s institutional officials or their designee(s) will review the significant financial interest disclosed by the investigator and determine, with or without consultation with the investigator, whether the significant financial interest is related to “PHS” funded research and whether a financial conflict of interest exists. If the significant financial interest was not timely disclosed, the institutional officials shall further conduct a retrospective review within one hundred twenty days of the untimely disclosure to determine if the research was biased during the period of non-disclosure and report any such finding of bias according in accordance with this rule.

- (c) If it the institutional officials determine that a financial conflict of interest exists, they shall work with the investigators to develop a management plan that specifies the actions that have been, or will be, taken to manage the financial conflict of interest. The university will submit a financial conflict of interest report to the “PHS” awarding component within sixty days of the disclosure.

- (d) The conflict of interest management plan shall include the following information, at a minimum:
 - (i) The role and principal duties of the conflicted investigator in the research project;
 - (ii) Conditions of the management plan;
 - (iii) How the management plan is designed to safeguard objectivity in the research project;
 - (iv) Confirmation of the investigator’s agreement to the management plan;
 - (v) How the management plan will be monitored to ensure investigator compliance throughout the duration of the award; and
 - (vi) Other information as needed.

- (e) The conflict of interest management plan may include the following limitations or restrictions to manage the financial conflict of interest:
 - (i) Public disclosure of financial conflict of interests;

- (ii) Disclosure of financial conflict of interests to participants;
 - (iii) Appointment of an independent monitor;
 - (iv) Modification of the research plan;
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (vi) Divestiture of significant financial interest; or
 - (vii) Severance of relationships that create actual or potential conflicts.
- (f) Disclosure of any reimbursed or sponsored travel requires detailed information on the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the estimated expense of the travel.
- (g) If a significant financial conflict of interest arises during the term of the grant, the investigator must immediately notify institutional officials in writing within thirty business days of obtaining such interest.
- (5) Reporting financial conflict of interests to the “PHS” awarding component.
- (a) University’s institutional officials will manage and timely report financial conflict of interest reports to the “PHS” awarding component as required by 42 C.F.R. 50.604(h) and 605(b).
 - (b) Institutional officials will promptly notify the “PHS” awarding component when a financial conflict of interest has been disclosed by the investigator and

that a plan to manage, reduce or eliminate the financial conflict of interest is in place to protect the research from bias.

- (c) Reporting by the institutional officials will further include a finding as to whether any bias was found with respect to the design, conduct, or reporting of the “PHS” funded research and a mitigation report where any bias has been identified.
 - (d) If the PHS awarding component determines that research designed to evaluate a drug, medical device or treatment was conducted by an investigator with an undisclosed or unmanaged conflict of interest, the investigator must disclose the conflict in any public presentation of the research.
- (6) Records. University’s institutional officials will maintain all financial conflict of interest records for at least three years from the date the final expenditure report is submitted to the “PHS” awarding component, unless otherwise required by regulation or the university’s record retention schedule.
 - (7) Enforcement. Failure to complete the requisite training, file the annual research conflict of interest disclosure form, provide information required by this rule or to comply with any conditions or restrictions imposed by the institutional officials regarding financial conflict of interests may result in disciplinary actions being taken against the investigator.
 - (8) Confidentiality
 - (a) The financial disclosure forms and the decisions of the institutional officials will be kept confidential to the extent permitted by law.
 - (b) University will make its financial conflict of interest in research rule publicly accessible on its website. University will respond to written requests for financial

conflict of interest information within five days of receipt of the request.

- (9) Subrecipient compliance. University will take reasonable steps to ensure that subrecipient investigators also comply with the terms of this rule, which will include, but is not limited to, incorporating conflict of interest compliance requirements as set forth in this rule into any written subrecipient grant agreements in which it is a party.

(E) Responsibilities

Investigator

- (1) Complete a financial conflict of interest in research disclosure form for each new proposal submitted to the office of sponsored research programs. The office of sponsored research programs will not submit grant proposals if an investigator's disclosure forms are not included with the application.
- (2) Update the disclosure form within thirty days after acquiring a new financial interest and at the time of annual review of each approved proposal.
- (3) Identify all individuals who are responsible for the design, conduct or reporting of the proposed research and to ensure that all such individuals complete and submit a disclosure form.
- (4) Investigators conducting research under food and drug administration regulations related to applications for a human drug, biological product or device must update the financial conflict of interest in research disclosure form during the study and for one year following completion of the study.
- (5) Comply fully and promptly with all conflict of interest management plans put in place.

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CERTIFIED ELECTRONICALLY

Certification

11/18/2020

Date

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