



## Ohio Administrative Code

### Rule 3349-20-30 Financial conflict of interest in research.

Effective: December 12, 2025

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#### (A) Purpose

Northeast Ohio medical university (NEOMED), "The university" is committed to ensuring that the financial interests of faculty and staff 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 and sponsored projects by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research and sponsored projects 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:

#### (B) Scope

(1) This rule applies to all investigators applying for, conducting, supervising, or reporting research and sponsored projects at the university. This rule acknowledges that individual financial conflicts of interest may be inherent in the research and sponsored projects process and does not preclude research in which a financial conflict of interest exists.

(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 all non-PHS funded projects that have adopted the "PHS" regulations and/or requires a conflict of interest rule. The activities 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 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" (FCOI) refers to situations in which the university determines that an investigator's significant financial interests related to an externally funded research project could directly and significantly affect the design, conduct or reporting of the externally funded project.

(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 or involved in the design, conduct, or reporting of research, instructional, or service activities that are externally 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 project, e.g., national institute of health (NIH), substance abuse and mental health services administration (SAMHSA), health resources and services administration (HRSA).

(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) "Sponsored Project" refers to an activity that is funded in whole or in part by external sources for which there is an expectation for performance, deliverables, or outcomes.

(11) "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.

(12) "Significant Financial Interest" (SFI) 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 ten thousand dollars. For PHS funded research, the limit is 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 ten thousand dollars (five thousand dollars for PHS funded projects) 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, a U.S.-based institution of higher education or a teaching hospital, a medical center, or a research institute that is affiliated with 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, a U.S.-based institution of higher education or a teaching hospital, medical center, or research institute affiliated with 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.

(13) "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 and other sponsored projects 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) . All investigators who engage in externally funded sponsored projects must complete an institutionally approved FCOI and other support training prior to engaging in the funded research; at least every four years; and immediately upon obtaining employment as a NEOMED 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 disclosure form annually to NEOMED's institutional officials and to update it 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 a FCOI 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 FCOI 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 FCOI. The university will submit a FCOI report to the awarding agency as required, but within sixty days of the disclosure.



- (d) The COI 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 COI management plan may include the following limitations or restrictions to manage the financial COI:
- (i) Public disclosure of financial COIs;
  - (ii) Disclosure of financial COIs 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 COIs 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 respective awarding component when a financial COI has been disclosed by the investigator and that a plan to manage, reduce or eliminate the financial COI is in place to protect the research from bias.

(c) If any bias was identified with respect to the design, conduct, or reporting of the funded research, the submitted report by the institutional officials will include the finding and a mitigation plan.

(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. NEOMED's institutional officials will maintain all financial COI records for at least three years from the date the final expenditure report is submitted to the awarding component, unless otherwise required by regulation, awarding component COI rule, or the university's record retention schedule.

(7) Failure to comply, non-compliance, and 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 consistent with procedures established by university policy, up to and including reprimand and/or termination or dismissal.

(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) NEOMED will make its financial conflict of interest in research rule publicly accessible on its website. NEOMED will respond to written requests for financial conflict of interest information within five days of receipt of the request.

(9) Subrecipient compliance. NEOMED 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 annually. The office of sponsored research programs will not submit grant proposals if an investigator's disclosure form has not been submitted.

(2) Update the disclosure form within thirty days after acquiring a new significant financial interest once annually upon request by the office of sponsored research programs.

(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.