(A) PURPOSE

Northeast Ohio Medical University (NEOMED) “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 Policy 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 policy establishes procedures for the disclosure, evaluation, management, reduction, and/or elimination of Investigator’s Significant Financial Interests. This Policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors

(B) SCOPE

(1) This Policy applies to all Investigators applying for, conducting, supervising, or reporting research at the University. This Policy 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 Policy applies only to Financial Conflicts of Interest in research.

(2) This Policy 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 policy. The research contemplated under this policy includes a research
grant, contract, cooperative agreement, subgrant, subcontract, or sub-cooperative agreement which is funded in whole or in part by PHS funds (with the exception of Phase I SBIR/STTR applications).

(3) For purposes of determining the existence of a significant financial interest, this Policy 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 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 Policy, 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 policy. 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 (PHS) Awarding Component” is the organizational unit of the PHS that funds the research, e.g., National Institutes of Health.

(9) “Principal Investigator” (PI) 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” (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:
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<th>POLICY TITLE: Financial Conflict of Interest in Research</th>
<th>EFFECTIVE DATE: August 24, 2012</th>
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<tr>
<td>RESPONSIBLE DEPARTMENT: Office of Research &amp; Sponsored Programs</td>
<td>REVISED AND UPDATED: June 23, 2014</td>
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(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 $5,000. 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 $5,000 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 government agency, an institution of higher education or a teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(e) The term “Significant Financial Interests” does not include:
(D) BODY OF THE POLICY

(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 FCOI exists if the Institutional Officials conclude that an Investigator’s SFI 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 COI training prior to engaging in the PHS funded research; at

(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 government agency, an institution of higher education or a teaching hospital, medical center, or research institute affiliated with an 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.
least every four years; and immediately upon obtaining employment as a NEOMED employee or as required by modifications to this policy.

(4) Disclosure Requirements and Management Plans.

(a) Investigators are required to submit a Financial Conflict of Interest in Research Disclosure Form to NEOMED’s Institutional Officials with each new grant application (and to update it annually during the period of the award, or within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Interest Financial Interest.

(b) Within sixty (60) 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 FCOI exists. If the Significant Financial Interest was not timely disclosed, the Intuitional Officials shall further conduct a retrospective review within 120 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 policy.

(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 PHS Awarding Component within sixty (60) 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 (30) business days of obtaining such interest.

(5) Reporting Financial COIs to the PHS Awarding Component.

(a) NEOMED’s Institutional Officials will manage and timely report Financial COIs reports to the PHS Awarding Component as required by 42 CFR 50.604(h) and 605(b).

(b) Institutional Officials will promptly notify the PHS 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) 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.

(6) Records. NEOMED’s Institutional Officials will maintain all Financial COI records for at least three (3) years from the date the final expenditure report is
submitted to the PHS Awarding Component, unless otherwise required by regulation.

(7) Enforcement. Failure to complete the requisite training, file the annual Research Conflict of Interest Disclosure Form, provide information required by this policy or to comply with any conditions or restrictions imposed by the Institutional Officials regarding FCOIs 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) NEOMED will make its FCOI in Research Policy publicly accessible on its website. NEOMED will respond to written requests for Financial COI information within five (5) day 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 Policy, which will include, but is not limited to, incorporating COI compliance requirements as set forth in this Policy into any written subrecipient grant agreements in which it is a party.

(E) RESPONSIBILITIES

(1) Investigator

(a) Complete a Financial Conflict of Interest in Research Disclosure Form for each new proposal submitted to the Office of Sponsored Research Programs (OSRP). OSRP will not submit grant proposals if an Investigator’s disclosure forms are not included with the application.
(b) Update the disclosure form within thirty (30) days after acquiring a new Financial Interest and at the time of annual review of each approved proposal.

(c) 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.

(d) Investigators conducting research under Food and Drug Administration (FDA) 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.

(e) Comply fully and promptly with all COI Management Plans put in place.