

5.9.6 Financial Conflicts of Interest in Research

This document applies to: All Nemours associates

<i>Policy Committee Approval Date: 8/19/2024</i>			
Effective Date	<i>8/19/2024</i>	Supersedes Date	<i>11/18/2019</i>
Originating Dept.	<i>Research</i>	Responsible Party	<i>Enterprise Physician-in-Chief and Chief Scientific Officer</i>

Responsibilities. For the purposes of this policy, the term Investigator may include Research Team Members (RTM) if an RTM is responsible for the design, conduct or reporting of the Research (see Definitions).

5. This Policy must be publicly accessible on the Nemours website <https://www.nemours.org/terms-of-use.html>.

PROCEDURE

1) INVESTIGATOR RESPONSIBILITIES

- a) Disclosure of Financial Interests and Outside Activities
 - i) All Investigators are required to disclose financial interests
 - (1) Annually;
 - (2) Within 30 days of discovering or acquiring a new significant financial interest;
 - (3) As part of the on-boarding process after joining Nemours; and
 - (4) Upon direction from the Institution (e.g., Office of Sponsored Projects (OSP), the Committee for Research Integrity (CRI), etc.)
- b) Investigators must ensure their Financial Interest disclosure is up-to-date prior to the submission of a proposal/application to OSP.
- c) Management Plan Compliance. All Investigators are required to comply with any Management Plan established by the CRI.
- d) FCOI Training Requirements. All Investigators are required to complete FCOI training:
 - (1) At least every four (4) years;
 - (2) As part of the on-boarding process after joining Nemours;
 - (3) As mandated by the CRI, upon determination of non-compliance with this policy;
 - (4) Whenever Nemours makes changes to this Financial Conflicts of Interest in Research policy or as otherwise directed by CRI.
- e) Travel Disclosure Requirements. Investigators must disclose reimbursed or sponsored travel within thirty (30) days after each occurrence.
 - (1) Travel disclosures must include, at a minimum, the following information: (a) the purpose of the trip; (b) the identity of the sponsor/organizer of the trip; (c) the destination of the trip; and (d) the duration of the trip (start and end dates). The CRI will determine if additional information is necessary.
 - (2) This requirement does not apply to Nemours sponsored travel or to travel that is reimbursed or sponsored by a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

2) REVIEW OF DISCLOSURES

- a) The Chair will review disclosures
SFI is related to the research when the Chair can reasonably determine that

4) FCOI REPORTING TO PHS OR DOE AWARDING COMPONENTS FOR PHS OR DOE FUNDED RESEARCH

- a) When the CRI determines a FCOI exists that cannot be eliminated, the Vice President, Research Administration will submit FCOI reports to a PHS or DOE Awarding Component:
 - i) Prior to expenditure of research project funds;
 - ii) Within 60 days of identifying an FCOI during an ongoing research project;
 - iii) Annually for any FCOI previously reported regarding an ongoing PHS-funded research project. The report will specify the status of the FCOI (if

- e) Documentation of retrospective reviews, and mitigation reports submitted to PHS or DOE awarding components, will include all elements as specified by 42 CFR Part 50, Subpart F (or DOE policy, as applicable).

7) INVESTIGATOR NON-COMPLIANCE

- a) If an Investigator fails to comply with this policy, including the requirement to submit required disclosures or failure to comply with a Management Plan, senior leadership in Compliance and Research will take reasonable steps to respond appropriately to violations. This may result in:
 - i) Suspending research activity expenditures;
 - ii) Administratively suspending any research project related to the FCOI;
 - iii) Other corrective action, as determined by the CRI and senior leadership in Compliance and Research, and Human Resources, up to and including termination.

8) PUBLIC DISCLOSURE OF FCOI RESEARCH

- a) When required by the research sponsor, information concerning FCOI held by Senior/Key Personnel (as defined in this policy) will be made available to the public, upon written request for such information.
 - i) For PHS-funded research, such information will consist of the minimum elements, as required by 42 CFR Part 50 Subpart F (or DOE policy, as applicable) and will be provided by written response to the requestor within five business days of the request.
 - ii) For research sponsored by other funding agencies, the information will consist of the minimum elements as specified by the sponsor.

Conflict of Interest, Policy No. 5.4.11, Conflict of Interest for All Associates.
Record Retention Policy No. 1.5.4.4

REFERENCES

42 CFR Part 50 and 45 CFR Part 94. - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

Department of Energy Interim COI Policy
<https://www.energy.gov/sites/default/files/2022-10/Department%20of%20Energy%20Interim%20Conflict%20of%20Interest%20Policy.pdf>

20 U.S. Code § 1001. General definition of institution of higher education.
<https://www.govregs.com/uscode/20/1001>

DEFINITIONS

Aggregate the consolidated total of monies received from a single entity (i.e., through remuneration, sponsored travel, equity interests, etc.).

Nemours Committee for Research Integrity (CRI) a standing committee of the Nemours Biomedical Research Department that serves as a liaison to Nemours divisions and departments that conduct Research, organization leadership, the Nemours IRBs, governmental regulatory entities, and non-governmental entities, as appropriate and as required by Nemours policies. The CRI functions as a conflicts of interest committee in the review of all SFI disclosures, determination of FCOI, and development of Management Plans.

DHHS the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

DOE - the U.S. Department of Energy, the National Nuclear Security Administration (NNSA), and any components of the DOE to which the authority involved may be delegated.

DOE Program Office - the organizational unit of DOE, led by an officer of the Department who has been appointed by the President by and with the advice and consent of the Senate, that funds and/or manages the awards.

Financial Conflict of Interest (FCOI) a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research
FCOI Report the Nemours report of a Financial Conflict of Interest to a PHS or DOE Awarding Component.

Project Director (PD) or Principal Investigator (PI) - any person designated with the title of Project Director or project having primary responsibility for the scientific and technical conduct,

Subrecipient a subcontractor or consortium member conducting PHS-funded or other externally funded research for Nemours (the awardee institution).

APPENDIX None