

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>

PURPOSE

Nemours is committed to maintaining public trust in the integrity of our Research-related activities. To ensure the integrity of Research in the setting related to financial and fiduciary interests, Nemours has adopted a Policy of Financial Conflicts of Interest in Research. This policy is compliant with 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*. It addresses the crucially important responsibilities of The Nemours Foundation (Nemours), and any affiliates or subsidiaries, Investigators and staff in both safeguarding Research objectivity and complying with the requirements of all applicable state and federal regulations. The goal of this policy is to require timely and accurate reporting of interests by the investigator and ensure that financial conflicts of interest are identified and managed.

POLICY

1. Associates are required to comply with the Conflict of Interest for All Associates Policy (Policy #5.4.11) in general, and as it applies to outside employment, paid faculty arrangements, consultant or research contracts (see Policy #5.4.11 as well as Covered Individual Guidance or Non-Covered Individual Guidance, as applicable).
2. Associates are required to exercise sound judgment unclouded by personal interests or divided loyalties and must conduct their duties for the purpose, benefit, and interest of Nemours.
3. Associates should never participate in activities or accept any gift, compensation, gratuity or courtesy, if there is any interest or potentially perceived interest to influence decisions or create expectations regarding the design, conduct or reporting of research results.
4. Project Directors/PDs and Principal Investigators/Pis, and Investigators for all externally-funded research projects are required to disclose all financial interests, activities or relationships that are reasonably related to their Institutional

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 Investigators' Significant Financial Interest (SFI) disclosures and determine if the SFI is related to the Investigators' research. SFI is related to the research when the Chair can reasonably determine that

- the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research. The Chair may obtain input and information from the Investigator as needed to inform this determination. SFI disclosures may be escalated to the CRI for further review.
- b) Depending on the nature of the disclosed SFI, the Chair and/or CRI may implement measures regarding the Investigator's participation in a research project between the date of disclosure and the completion of the SFI review. In such case, the Chair and/or CRI will provide a summary of the interim plan to the Investigator and Institutional Review Board (IRB) of record.

3) MANAGEMENT AND MONITORING OF FCOI

- a) FCOI Determination. For any SFI that is determined to be related to research, the CRI will determine if the SFI constitutes a FCOI. An SFI constitutes a FCOI if the CRI reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the research.
- b) Management Plan – The CRI will establish a Management Plan for any identified FCOI, specifying terms and conditions that in the reasonable judgement of the CRI will ensure, to the extent possible, that the design, conduct, and reporting of the Research will be free from bias. Actions, conditions or restrictions to manage the FCOI may include but are not limited to:
 - i) Public disclosure of the FCOI (e.g., in presentation or publications);
 - ii) Disclosure of the FCOI directly to participants in human research;
 - iii) Appointment an independent monitor to protect the design, conduct and reporting of Research from bias;
 - 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) Reduction or elimination of the financial interest (e.g., sale of the equity interest); and
 - vii) Severance of relationships that create financial conflicts.
- c) In developing a Management Plan, the CRI may conduct factual inquiries and consult with and receive recommendations from senior leadership in Compliance or Research, and other persons or committees as CRI deems necessary and appropriate.
- d) Whenever a Management Plan is implemented, CRI will take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan until the completion of the research project or until the Management Plan is no longer required.
- e) For PHS or DOE- funded research, the review and management of SFI will be completed prior to the expenditure of research project funds, or within 60 days of a disclosure of an SFI during the course of a research project by an existing Investigator or an Investigator new to the project.

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 the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report will be submitted annually for the duration of the research project at the same time as the submission of the annual progress report, multi-year progress report, if applicable, or at the time of extension.
- b) Any FCOI report submitted to a PHS or DOE Awarding Component will include the minimum elements as required by 42 CFR Part 50, Subpart F (or DOE policy, as applicable) and will contain sufficient information to understand the nature and extent of the FCOI and assess the appropriateness of the Management Plan.

5) RESEARCH THROUGH SUBRECIPIENTS FOR PHS- OR DOE-FUNDED RESEARCH

- a) Prior to issuing subawards, Nemours will ensure the agreement terms specify whether Nemours' FCOI policy or the subrecipient's FCOI policy will apply to the subrecipient's Investigators.
 - i) If the subrecipient's FCOI policy applies, the agreement terms will:
 - (1) include a certification that the subrecipient's FCOI policy complies with applicable federal regulations; and
 - (2) specify the time period(s) for the subrecipient to report FCOI to Nemours.
 - ii) If the Nemours' FCOI policy applies, the agreement terms will specify the time period(s) for subrecipient Investigator's to disclose SFI to Nemours.

6) RETROSPECTIVE REVIEW FOR PHS- OR DOE-FUNDED RESEARCH

- a) If an FCOI is not identified or managed in a timely manner, as required by applicable regulation, Nemours will complete a retrospective review of the Investigator's activities to determine whether the SFI is related to research, and if so, whether FCOI exists.
- b) If FCOI exists, the CRI will implement a Management Plan in compliance with this Policy.
- c) If bias was introduced into the research during the time of noncompliance, the CRI will develop a mitigation plan and a mitigation report and notify the PHS or DOE awarding component.
- d) The retrospective review will be completed and documented within 120 days after discovering the non-compliance.

- 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.
- b) If the Department of Health and Human Services determines a PHS-Funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, has been designed, conducted or reported by an Investigator with FCOI that was not managed or reported by Nemours, the Investigator will be required to disclose the FCOI:
 - i) In each public presentation discussing research results; and
 - ii) As an addendum to all previously published presentations.

9) RECORD RETENTION

- a) Nemours will maintain records relating to all Investigator SFI Disclosures, Nemours' review of and response to disclosures, and all actions under the Nemours' policy or retrospective review for three (3) years from the date the final expenditures report is submitted unless other requirements apply (e.g., 45 CFR 74.53(b) or 45 CFR 94.42(b)).

RELATED DOCUMENTS

Code of Business Practices
Conflict of Interest, Policy No. 1.5.4.3, Conflict of Interest – For Board Members, Corporate Officers, and Key Associates

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.

Financial Conflict of Interest Training - The CITI (Collaborative Institutional Training Initiative) web-based course, available to Investigators and Research Team Members at <https://www.citiprogram.org>

Financial Interest – anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities – all work performed at or on behalf of Nemours, including, but not limited to: research, research consultation, teaching, professional practice, management duties, and service on institutional committees (e.g., steering committees, IRBs, Data and Safety Monitoring Boards, etc.)

Institutional Review Board (IRB) – is a committee of scientists, non-scientists, and community members who are required by federal law to review all research involving humans as study participants.

Investigator – the Project Director, Principal Investigator, or any other person regardless of title or position (e.g., Research Team Member), who is responsible for the design, conduct or reporting of Research, which may include, for example, collaborators or consultants.

Manage – action taken to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Management Plan – a written plan to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Office of Sponsored Projects – (OSP) is responsible for reviewing, negotiating, and submitting proposals to extramural sponsors for grants and contracts and ensures institutional compliance with Federal and State regulations and sponsor policies.

Public Health Services (PHS) – the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). The current list of HHS Offices and Agencies (often referred to as Operating Divisions, OPDIVs) is found at <https://www.usphs.gov/about-us>

PHS Awarding Component – the organizational unit of the PHS that funds the Research.

PHS-Funded Research – a Research activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Project Director (PD) or Principal Investigator (PI) - any person designated with the title of “Project Director” or “Principal Investigator” of a research or sponsored project having primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration, and implementation.

Reimbursed Travel – a travel activity for which the travel expenses are paid directly by the Investigator, who is then reimbursed by an entity for such travel expenses. This does not include travel expenses reimbursed by a Nemours’ research study budget.

Research – a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Research Team Member (RTM) – An individual, whether a Nemours Associate or not, participating in the conduct of a Research protocol under the supervision/direction of a Nemours Principal Investigator.

Senior/Key Personnel –the Project Director (PD)/Principal Investigator (PI) and any other person identified as senior/key personnel by Nemours in the grant application, progress report, or any other report submitted to the PHS by Nemours under 42 CFR Part 50.

Significant Financial Interest (SFI) – a financial interest consisting of one or more of the following interests of the Investigator (e.g. PI, Research Team Member, etc.) (and those of that individual’s spouse and dependent children), that reasonably appears to be related to their Institutional Responsibilities.

1. SFI with a Publicly Traded Entity – a SFI exists if the value of any Remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in that entity as of the date of the disclosure, when aggregated, exceeds \$5,000.
 - a. Remuneration - includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, etc.);
 - b. Equity Interest - includes any stock, stock option, or other ownership interest, as determine through reference to public prices or other reasonable measures of fair market value.
2. SFI with a Non-Publicly Traded Entity – a SFI exists if the value of any Remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000 or when the Investigator/Research Team Member (or the Investigator/Research Team

Member's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

a. Significant Financial Interests include:

- i. Salary and any payment for services not otherwise identified as salary (such as consulting fees, honoraria, paid authorship, etc.) from either a publicly traded or non-publicly traded entity; or
- ii. Non-Nemours intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. The Investigator/Research Team Member receives direct payment from an entity other than Nemours ; or
- iii. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator/Research Team Member and not reimbursed to the Investigator/Research Team Member, so that the exact monetary value may not be readily available). Investigators must submit an updated disclosure of reimbursed or sponsored travel within thirty (30) days after each occurrence.

b. Significant Financial Interests do NOT include the following types of Financial Interests:

- i. 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 these vehicles.
- ii. Salary, royalties, or other remuneration paid by Nemours to the Investigator/Research Team Member, if they are currently employed or otherwise appointed by Nemours, including intellectual property rights assigned to Nemours and agreements to share in royalties related to such rights.
- iii. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- iv. Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research Institute that is affiliated with an Institution of higher education.

Sponsored Travel – travel expenses paid directly by an entity on behalf of an Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available. This does not include travel expenses paid directly by a Nemours' research study budget.

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

APPENDIX – None