

 Policy #5.9.6	Financial Conflicts of Interest In Research	Effective Date	1/1/16
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		Originating Dept.	Research
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Document applies to: Nemours		Required	Not Required

## 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*, referred to as the Final Rule. It addresses the crucially important responsibilities of Nemours, Investigators and staff in both safeguarding Research objectivity and complying with the requirements of all applicable state and federal regulations.

## POLICY

1. Associates are expected to exercise sound judgment unclouded by personal interests or divided loyalties and must conduct their duties for the purpose, benefit, and interest of Nemours. Associates are expected to avoid engaging in activities or relationships that are deemed by Nemours to be a research Financial Conflict of Interest.
2. Associates should never participate in activities or accept any gift, compensation, gratuity, or courtesy if there is any interest to influence decisions or recreate expectations in regards to the design, conduct or reporting of research results.
3. Project Directors/PDs and Principal Investigators/Pis of Public Health Service (PHS)-funded research projects; and Investigators (as defined under the Final Rule) which includes Investigators and Research Team Members) for all externally-funded research projects (see Definitions Section, below) are expected to disclose all activities or relationships that may present an actual or potential conflict of interest.
4. This Policy must be publicly accessible on the Nemours website – Nemours.org.

## DISCLOSURE OF RESEARCH SIGNIFICANT FINANCIAL INTERESTS

1. In addition to the disclosure process required under the Nemours Conflict of Interest Policy, No. 1.5.4.3, Investigators and Research Team Members must also follow the Financial Conflict of Interest in Research, Policy No. 5.9.6 disclosure requirements for protocols submitted to the Nemours Institutional

Review Boards (“IRBs”), Clinical Research Review Committee (“CRRC”), Nemours Office of Sponsored Projects (“NOSP”) or other research oversight body, and/or the initiation of any research-related agreement, such as Material Transfer Agreements (MTAs), product testing agreements, etc., when such agreement is not an integral component to a submission previously described.

2. Responsibilities of the Institution regarding Investigator/Research Team Member Financial Conflicts of Interest. Nemours Research shall:

- a. Maintain up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 CFR Part 50, Subpart F, and make such policy available via the publicly accessible website.
- b. Inform each Investigator of the Nemours policy on Financial Conflicts of Interest in research, the Investigator’s responsibilities regarding disclosure of significant financial interests, and of these regulations, and
- c. Require each investigator to complete training in Financial Conflicts of Interest in research prior to engaging in Research.
- d. PHS-funded and other externally funded research conducted through a subrecipient (subcontractor or consortium member), with Nemours as the awardee. Nemours must take reasonable steps to ensure that any subrecipient Investigator complies with the Final Rule (the regulation) by:
  - i. Incorporating as part of a written agreement with the subrecipient, the terms that establish whether the financial conflicts of interest policy of the awardee institution or that of the subrecipient will apply to the subrecipient’s Investigators and
  - ii. Providing Financial Conflict of Interest (FCOI) reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part; i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

3. Investigator/Research Team Member responsibilities.

- a. All investigators are required to complete a Conflict of Interest Declaration Form and submit it to the Committee for Research Integrity (“CRI”):
  - i. Annually, on or before August 24;
  - ii. Within 30 days of discovering or acquiring a new significant financial interest;
  - iii. As part of the on-boarding process after joining Nemours;
  - iv. Upon direction from NOSP to ensure their Conflict of Interest disclosure is up-to-date prior to the submission of a proposal/application to NOSP.
- b. Comply with any Management Plan established by the CRI.
- c. FCOI Training Requirements. All Investigators are required to complete FCOI training:
  - i. At least every 4 years;

- ii. As part of the on-boarding process after joining Nemours;
  - iii. As mandated by the CRI, upon determination of non-compliance with this policy;
  - iv. Whenever Nemours makes changes to this Financial Conflicts of Interest in Research policy or as otherwise directed by NOSHP.
- d. Travel Disclosure Requirements. As part of the annual disclosure and update to an existing disclosure, Investigators must disclose reimbursed or sponsored travel related to their Institutional Responsibilities. This requirement does not apply to Nemours sponsored travel or to travel that is reimbursed or sponsored by a Federal, State, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- i. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.
  - ii. 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).

## **REVIEW, MANAGEMENT AND MONITORING OF RESEARCH CONFLICTS OF INTEREST**

1. The Committee for Research Integrity (“CRI”) will review all disclosures before funding is dispensed to the Investigator.
2. Financial Conflict of Interest is found. If the CRI finds a FCOI related to an Investigator’s or Research Team Member’s Institutional Responsibilities, it will recommend a Management Plan in consultation with the Chief Compliance Officer and Operational Vice President, Research and forward that Plan to the Nemours group/s overseeing the research; i.e., IRB, CRRC and/or NOSP, for approval.
3. Management Plan – The action taken to address a Research FCOI to either reduce or eliminate the conflict and to ensure the design, conduct, and reporting of Research are free from bias. The Plan will include a description of the following key elements:
  - a. Role and principal duties of the conflicted Investigator or Research Team Member in the research project;
  - b. Conditions of the Management Plan;
  - c. How the Management Plan is designed to safeguard objectivity in the Research project;
  - d. Confirmation of the Investigator’s or Research Team Member’s agreement to the Management Plan;

- e. How the Management Plan will be monitored to ensure Investigator or Research Team Member's compliance; and
  - f. Other information, as needed.
4. Action, Conditions or Restrictions to manage a Research FCOI
- a. FCOI disclosure to the public and/or direct disclosure to Research participants;
  - b. Appointment of an independent monitor to protect the design, conduct and reporting of Research from bias;
  - c. Modification of the research plan;
  - d. Change or disqualification of personnel;
  - e. Elimination of the FCOI by severing the relationships that create the FCOI.
5. The CRI will confirm that the Investigator or Research Team Member accomplishes the action(s) identified in the Management Plan.
6. Conflict of Interest Resolution or Appeals Process (see Resolution and Appeals Process).
7. Review of New Investigator or Research Team Member Disclosures for Ongoing Research. When a New Investigator or Research Team Member joins an ongoing Research project after Research funding has been dispensed, the CRI must determine whether they have a Financial Conflict of Interest related to their Institutional Responsibilities within 60 days of the New Investigator or Research Team Member joining the project.
8. Review of Newly Discovered Significant Financial Interests. When an Investigator or Research Team Member has a new Significant Financial Interest that becomes known after research funding has been dispensed, the CRI must determine within 60 days of the disclosure whether a Financial Conflict of Interest exists.

## **REPORTING RESEARCH FINANCIAL CONFLICTS OF INTEREST TO PHS AWARDING COMPONENT**

1. Newly Funded Research – Initial FCOI Report. When the CRI, in consultation with the Nemours Chief Compliance Officer and the Operational Vice President, Research, determines a Research Financial Conflict of Interest exists and that it cannot be eliminated, the Operational Vice President, Research, will report the conflict to the PHS Awarding Component through its electronic Research Administration (eRA) Commons, Financial Conflicts of Interest (“FCOI”) Module. Reports must be made prior to dispensing funds and must include the following items:
- a. Project number;

- b. Project Director or Principal Investigator's name and contact information;
  - c. Name of the Investigator with the Financial Conflict of Interest;
  - d. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium, etc.)
  - e. Value of the financial interest (dollar ranges are permissible): \$0 - \$4,999; \$5,000 - \$9,999; \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
  - f. A description of how the financial interest relates to the PHS-funded Research and why the Institution determined that the financial interest conflicts with such Research;
  - g. A description of the key elements of the Institution's Management Plan, including the role and principal duties of the conflicted investigator in the Research project and conditions of the Management Plan. These conditions include:
    - i. How the Management Plan is designed to safeguard objectivity in the Research project;
    - ii. Confirmation of the Investigator's agreement to the Management Plan;
    - iii. How the Management Plan will be monitored to ensure Investigator compliance; and
    - iv. Other information, as needed.
2. Ongoing Research – Newly Discovered FCOI Report. When the CRI determines, in consultation with the Nemours Chief Compliance Officer and Operation Vice President, Research, that a new Research Financial Conflict of Interest exists after federal funds were dispensed to the Investigator, either because a new Investigator has joined an ongoing Research project and discloses a Significant Financial Interest or because an existing Investigator discloses a new Significant Financial Interest, the Operational Vice Preside, Research, will report the conflict within 60 days of determining the disclosure is a Research Financial Conflict of Interest to the PHS Awarding Component through its eRA Commons FCOI Module. Reports must include the criteria outlined above.
3. Annual FCOI Report. Nemours must submit annual FCOI reports to the PHS Awarding Component through the eRA Commons for grants and cooperative agreements, for the duration of the project period. Reports must address the status of the financial interest and any changes to the Management Plan and specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists.
- a. Annual reports must be submitted (including extensions with or without funds) at the same time as annual progress reports (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting

continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a PHS prior approval request, whichever is applicable). Note: The Annual FCOI Report is NOT to be submitted as part of the Annual Progress Report. The Annual FCOI Report is submitted to PHS separately through the eRA Commons FCOI Module.

- b. When a FCOI ceases to exist during the ongoing project period, Nemours should update the status of FCOI at the time of the next annual FCOI report submission deadline (i.e., at the time of the submission of annual progress report).

### **FAILURE TO SUBMIT A CONFLICT OF INTEREST DECLARATION FORM ANNUALLY**

1. Investigators and Research Team Members will receive at least one automated notification indicating that their Annual Conflict of Interest Declaration is due 30 days prior to the due date.
2. If the Investigator's/Research Team Member's form is not submitted by the due date, they will receive an email from the FCOI mailbox ([fco1@nemours.org](mailto:fco1@nemours.org)) indicating they are out of compliance with the policy and that all external activities in their TimeKeeper profile will be removed on a given date.
3. If the form is not submitted by the date provided, the Investigator's/Research Team Member's TimeKeeper profile will be changed and all external activities will be removed.

### **RETROSPECTIVE REVIEW FOR FINANCIAL CONFLICTS OF INTEREST NOT DISCLOSED OR MANAGED PRIOR TO DISPENSING RESEARCH FUNDING**

1. When an Investigator fails to disclose a Significant Financial Interest or when a Research Financial Conflict of Interest is not managed prior to Research funding being dispensed, the CRI must complete a retrospective review within 120 days after discovering the undisclosed Significant Financial Interest or the unmanaged financial conflict, to determine whether the Research conducted during the period of noncompliance was biased in the design, conduct, or reporting.
2. Retrospective Reviews – steps that must be reported to the PHS Awarding Component.
  - a. Project number;
  - b. Project title;
  - c. Lead Investigator name and contact information;
  - d. Name of the Investigator with the FCOI;
  - e. Name of the entity with which the Investigator has the FCOI;

- f. Reason(s) for the retrospective review;
  - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
  - h. Findings of the review; and
  - i. Conclusions of the review.
3. **Mitigation Reports** – If bias is found, Nemours must notify the PHS Awarding Component promptly and submit a mitigation report. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm and analysis of whether the research project is salvageable).

### **INVESTIGATOR NON-COMPLIANCE**

1. When an Investigator fails to comply with the Nemours Research Financial Conflict of Interest policy or Management Plan, Nemours will complete a Retrospective Review within 120 days of becoming aware of the Investigator’s non-compliance. The review will follow the steps outlined above.

### **PUBLIC DISCLOSURE FOR PHS FUNDED RESEARCH FINANCIAL CONFLICTS OF INTEREST**

1. If the CRI, in consultation with the Nemours Chief Compliance Officer and Operational Vice President, Research, determines a Senior/Key Research Team Member has a Financial Conflict of Interest on PHS funded Research, the following information must be disclosed on the Nemours website – Nemours.org.
  - a. Investigator’s name;
  - b. Investigator’s title and role with respect to the Research project;
  - c. Name of the entity in which the Significant Financial Interest is held;
  - d. Nature of the Significant Financial Interest; and
  - e. Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0 - \$4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. The information shall be updated at least annually and within sixty (60) days of Nemours becoming aware of any of the following:
    - i. Any additional Significant Financial Interest of the Senior/Key personnel for the PHS funded Research project that was not previously disclosed;

- ii. Disclosure of a Significant Financial Interest of Senior/Key personnel related to the PHS funded Research that the CRI, in conjunction with the Nemours Chief Compliance Officer and Operational Vice President, Research, determines is a Financial Conflict of Interest.
  - f. The Nemours website shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of Nemours identifying a new Research Financial Conflict of Interest.
- 2. If the Department of Health and Human Services determines a FCOI has not been disclosed in a timely manner or reviewed according to the Section on Disclosure of Research Significant Financial Interests and the Section on Review, Management and Monitoring of Research Conflicts of Interest, above, and if the federally-funded Research is designed to evaluate the safety or effectiveness of a drug, medical device or treatment, then the Investigator must disclose the FCOI:
  - a. At all public presentations discussing study results, and
  - b. As an addendum to all previously published presentations.

## **MAINTAINING INVESTIGATOR AND RESEARCH TEAM MEMBER DISCLOSURES**

- 1. Records relating to all Investigator and Research Team Member disclosures of Significant Financial Interest and Nemours' review of and response to disclosures must be kept for three years after the final expenditures report, invoice, or payment. The records will be maintained by the CRI.

## **RELATED DOCUMENTS**

Code of Business Practices, Policy No. 1.5.4.1

Conflict of Interest, Policy No. 1.5.4.3, Disclosure of COI for Directors, Managers, Officers, and Key Employees

## **REFERENCES**

Conflict of Interest Guidance, Resolution and Appeals Process (see Resolution and Appeals Process.pdf at <http://teamshare/legal/compliance/resources/Conflict%20of%20Interest/Resolution%20and%20Appeals%20Process.pdf>)

Joint Commission Standard: Ethics Rights and Responsibilities R1.20 Conflict of Interest

Internal Review Service Code 501c(3)

AAHRPP (Association for the Accreditation of Human Research Protection Programs, Inc.), Tip Sheet 10: Financial Conflict of Interest for Research and Research Staff.

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 (This Action: known as the Final Rule).  
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

## **DEFINITIONS**

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

Clinical Research Review Committee (CRRC) – A standing committee of Nemours Biomedical Research that assesses the scientific merit of Research Protocols involving Nemours Investigators.

Nemours Committee for Research Integrity (CRI) – A standing committee that serves as a liaison to Nemours divisions and departments that conduct Research, organization leadership, the IRBs, governmental regulatory entities, and non-governmental entities, as appropriate and as required by Nemours policies.

Disclosure of Significant Financial Interests – An Investigator's disclosure of Significant Financial Interests to Nemours.

FCOI Report – The Nemours report of a Financial Conflict of Interest to a PHS Awarding Component.

Financial Conflict of Interest Training – Investigators and Research Team Members must complete the CITI (Collaborative Institutional Training Initiative) web-based, Financial Conflicts of Interest (FCOI) course. CITI FCOI training is 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 – An investigator or Research Team Members' professional responsibilities on behalf of Nemours, which may include activities such as research, research consultantships, teaching, clinical practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs).

Institutional Review Board (IRB) – This 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., a Nemours research Team Member), who is responsible for the design, conduct or reporting of research, or proposal for funding, which may include, for example, collaborators or consultants.

Manage – Taking action 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.

Material Transfer Agreement (MTA) – A contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for research purposes. The MTA defines the rights of the provider and recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials. MTAs are also used for other types of materials, such as chemicals and some types of software.

Nemours Office of Human Subject Protection (NOHSP) – Ensures that all research and experimental use of drugs and devices involving human subjects conducted under the auspices of any Nemours entity is conducted in a manner that assures the full protection of every participant as required by law and is in accordance with generally accepted precepts of the ethical conduct of research and with Nemours policy.

NOSP – Nemours Office of Sponsored Projects

Public Health Services Act (or PHS Act) – The statute codified at 42 U.S.C. 201 *et seq.*

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) is found at <http://www.usphs.gov/aboutus/agencies/hhs.aspx>.

PHS Awarding Component – The organizational unit of the PHS that funds the research.

PHS 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.

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 Financial Conflict of Interest (FCOI) – A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

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 Investigator.

Senior/Key Personnel – Means 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 external funding source.

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

Significant Financial Interest (FSI) – A financial interest consisting of one or more of the following interests of the investigator or Research Team Member (and those of that individual's spouse and dependent children), that reasonably appears to be related to the Investigator's or Research Team Member's institutional responsibilities.

- SFI-Publicly Traded Entity – A SFI exists if the value of any remuneration RECEIVED from the entity in the twelve months preceding the disclosure AND the value of any equity interest in that entity (as determined through reference to public prices or other reasonable measures of fair market value), as of the date of the disclosure, when aggregated, exceeds \$5,000.
- SFI-Non-Publicly Traded Entity – A SFI exists if the value of any remuneration RECEIVED from the entity in the twelve 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 or other ownership interest.

Significant Financial Interests Include –

- 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
- Stock, stock option, or other ownership interest in either a publicly traded or non-publicly traded entity, the value of which is determined through reference to public prices or other reasonable measure of air market value; or
- Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, INVESTIGATORS MUST SUBMIT AN UPDATED DISCLOSURE OF REIMBURSED OR SPONSORED TRAVEL WITHIN 30 DAYS OF EACH OCCURRENCE. This disclosure requirement does not apply to 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.

Significant Financial Interests Do NOT Include –

- 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.
- Salary, royalties, or other remuneration paid by Nemours to the Investigator if they are currently employed or otherwise appointed by Nemours. This includes intellectual property rights assigned to Nemours and agreements to share in royalties related to such rights.
- Income from seminars, lectures, or teach 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.

**APPENDIX – None**