



Policy

Financial Conflicts of Interest In Research

Effective Date

11/18/19

PROCEDURE

- i) 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.
- ii) Inform each Investigator of the Nemours policy on Financial Conflicts of disclosure of significant financial interests, and of these regulations, and
- iii) Require each investigator to complete training in Financial Conflicts of Interest in research prior to engaging in Research.
- iv) PHS-funded and other externally funded research conducted through a

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

- (2) Disclosure of a Significant Financial Interest of Senior/Key personnel related to the PHS-funded Research that the CRI in consultation with senior leadership in Compliance 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.
- g) If the Department of Health and Human Services determines a FCOI has not been disclosed in a timely manner or reviewed according to Sections 4 (Disclosure of Research Significant Financial Interests) and 5 (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:
 - i) At all public presentations discussing study results and
 - ii) As an addendum to all previously published presentations.

8) MAINTAINING INVESTIGATOR AND RESEARCH TEAM MEMBER DISCLOSURES

Records relating to all Investigator and Research Team Member disclosures

disclosures must be kept for three (3) years after the final expenditures report, invoice, or payment. A designee of the CRI will maintain the records in a secure and confidential database.

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.

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>

Conflict of Interest, Policy No. 5.4.11, Conflict of Interest for All Associates.

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

Investigator

PD/PI a Project Director or Principal Investigator of a PHS-funded research project.
The PD/PI is included in the definitions of Senior/Key Personnel and Investigator under 42 CFR Part 50

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 externally sponsored Research.

Research Team Member (RTM)

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

APPENDIX None