



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

NEMA Research Inc.

Financial Conflict of Interest (FCOI) Policy for PHS/NIH-Funded Research

Effective Date: January 1, 2026

Policy Owner: NEMA Research Inc.

1. PURPOSE

This Financial Conflict of Interest Policy, (the “FCOI Policy” or the “Policy”), identifies certain legal and regulatory obligations applicable to Investigator disclosure of potential conflicts of interest, (“FCOI”). This Policy requires compliance with applicable law in order to ensure the objectivity of research conducted by NEMA and its employees, contractors, subcontractors, and consultants.

NEMA requires that all employees, contractors, subcontractors, consultants, collaborators, and subgrantees conduct all research without bias and with the highest scientific and ethical standards. As such, NEMA requires that the conduct of research affiliated with grants and cooperative agreements or contracts funded by the National Institute of Health, (“NIH”), or other U.S. Public Health Services, (“PHS”), be in compliance with 42 CFR 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought,” and 45 CFR 94, “Responsible Prospective Contractors.”

2. DEFINITIONS

The following definitions apply to the terms of this Policy:

Disclosure of significant financial interests means: an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means: a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means: an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means: anything of monetary value, whether or not the value is readily ascertainable.

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



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

Institution means: any domestic or foreign, public or private, entity, or organization (excluding a federal agency).

Institutional Official: means the person designated by the Institution who solicits and reviews disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

Institutional responsibilities means: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding. For purposes of the requirements of this Policy relating to financial interests, Investigator includes the Investigator's spouse and dependent children.

Manage means: 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.

PD/PI means: 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 this subpart.

PHS means: 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).

PHS Awarding Component means: the organizational unit of the PHS that funds the research that is subject to this Policy.

Public Health Service Act or PHS Act means: the statute codified at [42 U.S.C. 201](#) *et seq.*

Research: means 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. As used in this Policy, the term includes any such 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.



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

Senior/key personnel means: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* 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 the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of 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; provided, however, that 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. The Institution's FCOI Policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI Policy, the Institutional official(s) will determine if further information is needed,



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; 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.

Contractor means: an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

3. TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH-funded project, which includes all Investigators employees, contractors, subcontractors, and consultants of NEMA engaged in NIH-funded research or its compliance.

The course is accessible at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Upon completion of the training, a certificate of completion must be turned into the Institutional Official for record retention. This training is required prior to engaging in research relating to any PHS-funded grant or as deemed necessary by NEMA due to changes in the FCOI Policy, non-compliance of the Investigator/Key Personnel or for any other reason as determined by NEMA. At a minimum, the FCOI training shall be taken every two (2) years.



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

4. DISCLOSURE REQUIREMENTS

All Investigators are required to disclose their financial interests as defined above to the Institutional Official on an annual and *ad hoc* basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms.

(1) Annual Disclosures

All Investigators must disclose their significant financial interests, and those of the Investigator's spouse and dependent children, that are related to the Investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis.

(2) Ad Hoc Disclosures

All Investigators must submit an ad hoc disclosure of any significant financial interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the significant financial interest.

(3) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities. Such disclosures must be submitted within thirty (30) days of the date of travel and include, at a minimum, the purpose of the trip, the start and end dates, the sponsor/organizer, the destination, and, if known, the monetary value. The Institutional Official will determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's PHS-sponsored research.

5. REVIEW OF DISCLOSURE FORMS/REVIEW PROCESS

The Institutional Official will review any significant financial interest that has been identified in a disclosure form; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the significant financial interest is related to the PHS/NIH-funded research and, if so, whether the significant financial interest creates a FCOI related to that research award.

6. FCOI MANAGEMENT

If it is determined that there is a potential FCOI, then the Institutional Official will work with a member of NEMA's Executive Team to determine what measures are needed to address the significant financial interest identified in the disclosure form. A management plan ("Management Plan") may be required to outline the terms, conditions and restrictions, if any, to ensure compliance with this policy. The Management Plan may require one or more of the following



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

actions (but not limited to these actions) to be taken in order to manage, reduce or eliminate any actual or potential conflict of interest:

- The public disclosure of significant financial interests;
- The review of research protocols by independent reviewers;
- The monitoring of research by independent reviewers;
- The modification of the research plan;
- The disqualification from participation in all or a portion of the PMS-funded research;
- The divestiture of the significant financial interest(s);
- The severance of relationships that create actual or potential conflicts.

All Management Plans are required to be signed by the Investigator and the Institutional Official. Compliance with the Management Plan shall be monitored by the Institutional Official and implemented within 60 days of identified FCOI.

7. REPORTING TO PHS

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institutional Official shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with 42 CFR 50.605.

For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report, and during an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component within sixty (60) days an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a Management Plan in accordance with 42 CFR 50.605.

The FCOI report shall include the following items:

- The name of the project or project number.
- The name of the Investigator with the FCOI.
- The name of the entity with which the Investigator has an FCOI.
- The nature of the FCOI (e.g., equity, consulting fee, travel reimbursement, honorarium).
- The value of the FCOI.
- Description of how the FCOI relates to the PHS-Funded Research and why the Institution determined that the financial interest conflicts with such research.
- 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;



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

- The conditions of the Management Plan;
- How the Management Plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the Management Plan;
- How the Management Plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

8. RECORD KEEPING

Records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI) and all actions under the Institution's policy or retrospective review, if applicable, will be retained for at least three (3) years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in [2 CFR 200.334](#) for different situations.

9. VIOLATIONS OF FCOI POLICY

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented.

An Institution's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institution, will be described in a written explanation of the decision to the Investigator, and where applicable the IRB, and will notify the individual of the right to appeal the decision. Additionally, the Institution shall follow federal regulations regarding the notification of the sponsoring agency and/or PHS.

10. RETROSPECTIVE REVIEW

If a FCOI was not identified or managed in a timely manner the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Institutional Official shall document the retrospective review and such documentation shall include the following:

- The name of the project or project number.
- The name of the Investigator with the FCOI.
- The name of the entity with which the Investigator has an FCOI.



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

- The reason(s) for the retrospective review.
- The detailed methodology used for the retrospective review.
- The findings of the review.
- The conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

11. SUBAWARDS

Collaborators/subrecipients/subcontractors from other organizations must either comply with this policy or provide a certification that their organizations are in compliance with Federal policies regarding Investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.

12. PUBLIC ACCESSIBILITY

NEMA will provide public access to this policy on its publicly accessible website www.nema.net. The Institutional Official will ensure that any updated versions of this policy are provided for updated posting immediately upon implementation.

Information regarding FCOI's will be made available to the public within five (5) business days of a request for information concerning any significant financial interests disclosed that meet the following three criteria:

- (1) The significant financial interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the Investigator, and any other person identified as senior key personnel in the award application, progress report, or any other report submitted to PHS;
- (2) NEMA has determined that the significant financial interest is related to the research funded through an award; and
- (3) NEMA has determined that the significant financial interest is an FCOI.

NEMA will provide a written response to any requestor within five (5) days of request which will include, at a minimum, the following:

- The Investigator's name;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the significant financial interest is held;



868 106th Avenue North • Naples, Florida 34108 • Tel: 239-597-3564

- The nature of the significant financial interest; and
- The approximate dollar value of the significant financial interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000-\$19,999; amounts between \$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.

13. Contact Information

For questions or additional information regarding this FCOI Policy, please contact finance@nema.net.