

NE Scientific LLC

Financial Conflict of Interest (FCOI) Policy for Public Health Service (PHS) Funding (in accordance with 42 CFR Part 50- Subpart F)

Policy version 1.4 – Last updated March 5th, 2024

I. PURPOSE & SCOPE

This Policy implements the 2011 Public Health Service (PHS) regulations on Promoting Objectivity in Research. The Policy is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, or proposal for supplemental funding. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a PHS Research Activity. The Policy is applicable to all research activities supported by a PHS funder, most notably the National Institutes of Health (NIH), through a grant or cooperative agreement (either directly or via another institution as a sub- awardee), and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research.

II. KEY DEFINITIONS

PHS means the Public Health Service of the United States 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.

Investigator is defined as 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, which may include, for example, collaborators or consultants. To ensure personnel are correctly identified for the purpose of policy compliance, consider the role of those involved rather than their title and the degree of independence with which they work.

Institutional Responsibilities are defined as an Investigator's professional responsibilities on behalf of NE Scientific LLC, e.g. research, technical development, research consultancy, professional practice, service on scientific panels.

A **Financial Conflict of Interest (FCOI)** exists when NE Scientific LLC, through its CEO and/or Board of Advisors (BOA) reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS- funded research.

A **Significant Financial Interest (SFI)** is anything of monetary value that:

- meets the PHS/NIH thresholds (see Section IV below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse or registered domestic partner and dependent children; and
- reasonably appears to be related to or is in the same field of expertise as the Investigator's

Institutional Responsibilities.

Examples of SFIs include:

- Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside of NE Scientific LLC.
- Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
- Receipt of income from any organization other than NE Scientific LLC for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers.
- The occurrence of travel by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, excluding 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 term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by NE Scientific LLC to the Investigator if the Investigator is currently employed or otherwise appointed by NE Scientific LLC, 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.

PHS means the Public Health Service of the United States 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.

CEO means the CEO of NE Scientific LLC

BOA means the Board of Advisors of NE Scientific LLC

III. KEY STAFF INVOLVED

Key staff required to administer the policy are:

- All **Investigators**
- The **Chief Operating Officer (CEO)**

- The **Board of Advisors** (BOA)

IV. INVESTIGATOR RESPONSIBILITIES

Each Investigator must disclose to the CEO any domestic or foreign Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. If the Investigator is the CEO himself/herself, he/she needs to disclose any domestic or foreign SFI (and those of his/her spouse and dependent children) that reasonably appear to be related to his/her Institutional Responsibilities to the BOA.

Disclosures must be made using NE Scientific's Financial Conflict of Interest Disclosure form prior to applying for PHS-funded research, within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest, and at least annually during the period of the award.

Investigators disclose SFIs that meet the following thresholds:

1. For a publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a non-publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds \$5,000, or equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.

[Investigators are not required to disclose (a) payments made by NE Scientific LLC, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by 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 located in the United States of America]

3. Intellectual property rights and interests: Income received during the previous 12 months that exceeds \$5,000 for such rights and interests.

[SFIs do not include royalties received from NE Scientific related to patents or copyrights]

4. Travel: The occurrence of any sponsored or reimbursed travel (any amount) must be

disclosed whether payment is made to the Investigator directly or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:

- a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
- b. Within 30 days of the occurrence if the trip wasn't reported prospectively.

[Investigators are not required to disclose travel that is reimbursed or sponsored by 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 located in the United States of America]

Investigators must cooperate in a timely manner with the CEO and the BOA in developing a management plan for any SFI deemed to be an FCOI and complying with such plan.

Each Investigator, including sub-recipient Investigator(s), must complete training prior to engaging in PHS- funded research and at least every four years, and immediately under certain circumstances (see <https://grants.nih.gov/faqs>, Section L), such as when a new Investigator joins a PHS/NIH-funded project.

NIH training is available through an online module - <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>, as well as through familiarization with any additional information provided by NE Scientific LLC.

V. DISCLOSURES BY COLLABORATORS

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from NE Scientific LLC are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by NE Scientific LLC will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending to NE Scientific LLC a notification of their ability to manage the identified conflicts, in accordance with PHS reporting requirements.

VI. REVIEWS AND REPORTING

The CEO and/or the BOA must review all SFI's disclosed by Investigators to determine whether any are related to research funded through a U.S. Public Health Service funder and if so, whether they constitute a Financial Conflict of Interest.

A Financial Conflict of Interest exists when the CEO and/or BOA reasonably determine that an Investigator's Significant Financial Interest is related to a NIH-funded research project (i.e., the Significant Financial Interest could be affected by the research or is the Significant Financial Interest in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research.

If an SFI is determined to be an FCOI, the CEO together with the BOA will set out a plan to manage, reduce or eliminate the conflict.

VII. MANAGEMENT PLAN

The management plan could include the following actions:

- Public disclosure of financial conflicts of interests (e.g. when presenting or publishing the research; to staff members working on the project, to relevant ethics committees);
- For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.

The management plan should also include the following details:

- The role and principal duties of the conflicted Investigator in the research project;
- 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;
- Other information as needed.

VIII. DUTIES OF THE CEO AND BOA

Before the Institution's expenditure of PHS/NIH funds:

- The CEO and/or BOA should review all Investigator's SFI disclosures.
- Determine whether any SFI relates to the Investigator's PHS/NIH funded research.
- Determine whether an FCOI exists.
- Develop and implement a management plan to manage any identified FCOI.

When an Investigator who is new to participating in a PHS/NIH funded project discloses a new SFI, or when an existing Investigator discloses a new SFI, the CEO/BOA will review the within sixty (60) days the disclosures, determine whether the SFIs are related to the Investigator's PHS/NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI.

Whenever NE Scientific LLC identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by NE Scientific LLC during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the CEO/BOA will review within sixty (60) days the disclosure of SFI, determine whether the SFI is related to the Investigator's NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI going forward.

Finally, the CEO/BOA should take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with

management plans until completion of the project.

IX. REPORTING TO THE NIH

Unless an FCCOI is eliminable, NE Scientific LLC will submit a report to the PHS funder; in the case of the NIH this will be via the electronic Research Administration (eRA) Commons FCOI Module. The CEO is responsible for ensuring that reports are submitted on time as and when required. The CEO has authorized access to submit forms through the eRA Commons Financial Conflict of Interest Module and hence will submit the Conflict of Interest disclosure report.

Updated or annual FCOI reports will include the status of the management plan (i.e. whether the financial conflict is still being managed or an explanation of why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted.

NE Scientific LLC will submit reports prior to any expenditure of funds under a PHS-funded project.

Note that reports need only be made if the CEO/BOA determines that an SFI constitutes an FCOI. But reports must also be submitted if an Investigator does not disclose an SFI in the timeframe required or NE Scientific LLC does not review a disclosure but later determines that an FCOI exists.

For new Investigators who join a project, for any SFI disclosed which is judged to be an FCOI, the FCOI report must be submitted within 60 days.

For a new SFI that is deemed to be an FCOI, NE Scientific LLC will submit an FCOI report within 60 days of disclosure.

For any FCOI previously reported, NE Scientific LLC must provide an annual FCOI report to address the status of the financial interest and any changes to the management plan. The plan must specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

NE Scientific LLC will submit annual reports via eRA Commons for the duration of the project period (including extensions with or without funds) at the same time as submitting the annual progress report.

NE Scientific LLC will submit a report after a retrospective review to update a previously submitted report, if new information is discovered following the completion of the review.

Based on the results of a retrospective review, NE Scientific LLC will notify PHS/NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and submit the required Mitigation Report. The Mitigation report includes the key elements of the Retrospective review plus information to explain what action(s) have been or will be taken to mitigate the effects of the bias (i.e., 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.

To ensure compliance with retrospective review and bias mitigation reporting requirements, the submitted reports will include all of the key elements documented in the retrospective review as well as the elements of a mitigation report.

NE Scientific LLC will notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan appears

to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

All FCOI reports must include sufficient information to enable the PHS-funder to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

- Project number;
- Project title;
- Programme Director (PD)/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$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;
- A description of how the financial interest relates to the NIH-funded research and why NE Scientific LLC determined that the financial interest conflicts with such research.

NOTE THAT THERE IS NO REQUIREMENT TO SUBMIT A REPORT IF NE SCIENTIFIC DETERMINES THAT NO DISCLOSURE OF AN SFI CONSTITUTES AN FCOI.

X. RECORDS ACCESS AND RETENTION

PHS regulations require that NE Scientific LLC respond within 5 business days to any request for information about SFIs held by Key Personnel when NE Scientific LLC has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs.

Records relating to unfunded projects will not be retained. All records of all Investigator disclosures of financial interests and NE Scientific LLC's review, or response to, such disclosure (whether or not a disclosure resulted in determination of an FCOI), and all actions under our own policies or retrospective review, will be retained by NE Scientific LLC for at least 3 years from the date of submission of the final expenditures report (or other dates as specified in the regulations (see http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3160, Section A, 9).

XI. RETROSPECTIVE REVIEW

Whenever a FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by NE Scientific, LLC to constitute a Financial Conflict of Interest;
- Failure by NE Scientific, LCC to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

NE Scientific, LLC shall, within 120 days of NE Scientific, LLC's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

If a bias is found, NE Scientific, LLC will notify the PHS/NIH and provide a mitigation plan and thereafter report annually as normal, unless NE Scientific LLC decides further interim measures are necessary.

NE Scientific, LLC shall document the retrospective review including at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review.

Failure to comply with NE Scientific, LLC FCOI policy on part of an Investigator, can, at the sole discretion of the CEO and/or BOA, and depending on the severity of the FCOI, result in penalties for the Investigator that include a reprimand letter, a fine deducted from the compensation of the Investigator, or dismissal. NE Scientific, LLC might also decide to remove the Investigator from the specific PHS/NIH-funded project, or from all PHS/NIH-funded projects, for a period of time, or indefinitely.

XII. UNMANAGED FINANCIAL CONFLICT OF INTEREST

Should, for any reason, the PHS/NIH determine that an Investigator, who has participated in PHS/NIH sponsored research (design, conduction, reporting) related to the evaluation of a medical device, drug, or treatment, has a FCOI; or should NE Scientific LLC, for any reason, discover an FCOI, and that the FCOI was not reported, for any reason, by NE Scientific LLC to the PHS/NIH funding agency, NE Scientific LLC, will require the Investigator to:

- Disclose the FCOI in each public presentation of the results of research, and
- Request an addendum stating the FCOI to the previously published presentations / scientific publications.

XIII. REQUIREMENTS FOR SUB-RECIPIENTS

NE Scientific LLC might engage in PHS/NIH-funded research projects where part of the research is performed by sub-recipients. NE Scientific LLC will act as follows with respect to sub-recipients:

- Develop written sub-award/consortium agreement implementing the requirements of 42 CFR 50.604(c) and of the NIH Grants Policy Statement – Section 15.2.1.
- Obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
- Include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows NE Scientific LLC to report identified FCOIs to the NIH as required by the regulation.

XIV. PUBLIC ACCESSIBILITY REQUIREMENTS

- A copy of the present policy is made public through NE Scientific LLC website at the following URL: <http://ne-scientific.com/public-information/>
- Prior to the expenditure of funds, and during the performance period of any PHS/NIH-funded research, NE Scientific LLC will publish at the following URL: <http://ne-scientific.com/public-information/> any identified FCOI for any senior/key personnel involved in such research.
- The published information will be updated at least annually, and within sixty (60) days of any newly identified FCOI.
- The information will be kept available for a period of 3 years from the date it was most recently updated.
- Upon any request for update on part of a funding PHS/NIH agency, NE Scientific LLC will update the public information within five (5) working days.