



FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

7th May, 2025

1. INTRODUCTION

The U.S. Department of Health and Human Services (HHS) has issued regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) aimed at promoting objectivity in research. Originally introduced in 1995 and updated in 2011, these regulations outline the responsibilities of both individuals and organizations to ensure objectivity in research supported by the Public Health Service (PHS), including the National Institutes of Health (NIH). These rules apply to all PHS-funded grants, cooperative agreements, and research contracts, but do not extend to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards. This policy outlines how NanoNewron LLC complies with the requirements of 42 CFR Part 50 Subpart F.

2. DEFINITIONS (for purposes of this policy and associated procedures):

Financial Conflict of Interest (FCOI):

A significant financial interest that could directly and significantly influence the design, conduct, or reporting of research funded by the Public Health Service (PHS).

Financial Interest:

Any monetary interest, regardless of whether its precise value can be easily determined.

Institutional Responsibilities:

Professional duties carried out by an Investigator on behalf of NanoNewron LLC, such as conducting or publishing research, providing consulting services, performing administrative tasks, or serving on institutional committees.

Designated Official (DO):

An individual appointed by NanoNewron LLC to manage the financial conflict of interest process. Responsibilities include collecting and evaluating disclosures of SFIs and determining whether an FCOI exists, in accordance with 42 CFR §50.604(f) and this policy.

Investigator:

The Project Director (PD), Principal Investigator (PI), or any person—regardless of job title—who is responsible for the design, execution, or reporting of NIH- or other PHS-funded research. This may include collaborators, consultants, or subcontractors. NanoNewron LLC considers the scope of responsibility and level of independence, rather than the individual's title alone, in determining who qualifies as an Investigator.

Research:

A systematic study or investigation intended to develop or contribute to generalizable knowledge relevant to public health. This includes both basic and applied research, such as published studies, books, and product development (e.g., diagnostics or pharmaceuticals).

PHS-Funded Research:

Research funded by any PHS agency via grants, cooperative agreements, or contracts under the PHS Act or other legal authority.

PHS:

The Public Health Service of the U.S. Department of Health and Human Services, including any of its agencies, such as the National Institutes of Health (NIH), to which authority may be delegated.

NIH:

The biomedical research agency of the PHS.

Senior/Key Personnel:

The PD/PI and any other individual identified as senior/key personnel by the applicant institution in any grant application, progress report, or other submission to the PHS or NIH. This definition is specifically relevant to the policy's public disclosure requirements.

Significant Financial Interest (SFI)

1. A financial interest—domestic or foreign—held by the Investigator, their spouse, or dependent children, that appears reasonably related to their institutional responsibilities at NanoNewron LLC and meets one or more of the following thresholds:

I. Publicly Traded Entities:

An SFI exists if the combined value of any remuneration received in the prior 12 months and any equity interest held on the date of disclosure exceeds \$5,000. Remuneration includes salary and compensation such as consulting fees, honoraria, or paid authorship. Equity interests include stock, stock options, or other ownership interests, valued using public pricing or other fair market assessments.

II. Non-Publicly Traded Entities:

An SFI exists if total remuneration received from such an entity in the past 12 months exceeds \$5,000, or if the Investigator (or their spouse or dependent children) holds any equity interest in the entity (e.g., stock, stock options, or other ownership).

III. Intellectual Property Rights:

Receipt of more than \$5,000 in income from intellectual property (e.g., patents or copyrights) qualifies as a significant financial interest.

2. Travel Disclosures:

Investigators must disclose reimbursed or sponsored travel related to their institutional responsibilities if the value exceeds \$5,000. The initial disclosure must include travel from the past 12 months, identifying the trip's purpose, sponsor or organizer, destination, and duration.

This disclosure requirement does not apply to travel sponsored or reimbursed by:

- U.S. federal, state, or local government agencies
- U.S. institutions of higher education
- U.S. academic teaching hospitals
- U.S. medical centers
- Research institutes affiliated with U.S. higher education institutions

3. Exclusions from SFI Definition:

I. Salary, royalties, or other compensation paid by NanoNewron LLC to its own employees or appointees, including rights assigned to the company and any royalty-sharing agreements.

II. Any equity ownership in NanoNewron LLC held by its employees or appointees, as NanoNewron LLC is a commercial entity. This exclusion applies only when the disclosing party is part of a for-profit organization.

III. Income from investment vehicles like mutual funds or retirement accounts, as long as the Investigator does not directly control investment decisions.

IV. Compensation from teaching, seminars, or lectures sponsored by U.S. government agencies, academic institutions, medical centers, or affiliated research institutes.

V. Income for serving on advisory committees or peer review panels for any of the above entities.

Foreign Financial Interests:

All foreign financial interests must be disclosed if they meet the monetary threshold (e.g., income over \$5,000). This includes compensation for lectures, seminars, teaching, advisory roles, and sponsored travel from foreign entities such as governments or institutions of higher education.

3. SFI DISCLOSURE REQUIREMENTS

At the time of submission for NIH funding, the Principal Investigator and all individuals who meet the definition of “Investigator” must disclose any Significant Financial Interests (SFIs) to NanoNewron LLC’s Designated Official. Any individual who is added to the project after the time of application and intends to participate in the research must also disclose all relevant SFIs before engaging in project-related activities. All Investigators involved in NIH-funded research must update their SFI disclosures at least annually (by January 1st) throughout the duration of the award. These annual updates must include any new information not previously reported to NanoNewron LLC under this policy—such as SFIs identified in NIH-funded work as a direct awardee or subrecipient institution—and must also provide updated details for any previously disclosed SFI (e.g., revised valuation of an equity interest).

Additionally, Investigators are required to disclose any new SFI within thirty (30) days of discovering or acquiring it (e.g., via purchase, marriage, or inheritance). Disclosures of reimbursed or sponsored travel must likewise be submitted within 30 days of the travel event.

4. REVIEW OF SFI DISCLOSURES BY NANONEWRON LLC DESIGNATED OFFICIAL

The Designated Official is responsible for reviewing all submitted SFI disclosures. Each disclosed SFI will be evaluated in relation to the specific PHS/NIH-funded research project for which the Investigator is responsible for the design, conduct, or reporting. The Designated Official will assess whether the SFI is related to the NIH-funded project and, if so, whether it constitutes a FCOI requiring management.

5. GUIDELINES FOR DETERMINING ‘RELATEDNESS’ OF SFI TO PHS/NIH- FUNDED RESEARCH AND A FINANCIAL CONFLICT OF INTEREST

The Designated Official will assess whether an Investigator’s SFI is related to research supported by an NIH award and, if so, whether it constitutes a FCOI.

An SFI is considered related to the research if the Designated Official reasonably concludes that:

- The SFI could be influenced by the PHS/NIH-funded research; or
- The SFI involves an entity whose financial interests could be affected by the PHS/NIH-funded research.

The Designated Official may consult with the Investigator during this determination process.

A Financial Conflict of Interest is deemed to exist when the Designated Official reasonably determines that the SFI could have a direct and significant impact on the design, conduct, or reporting of the NIH-funded research. “Significant” in this context implies a material influence on the research.

6. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT OF INTEREST

If a FCOI is identified, the Designated Official will determine the appropriate management conditions and/or strategies required to mitigate the conflict. Examples of possible management measures include, but are not limited to:

1. Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the Institutional Review Board, Institutional Animal Care and Use Committee, Data and Safety Monitoring Board, etc.);

2. Disclosure of the FCOI to human subjects in the informed consent form, for studies involving human participants;
3. Appointment of an independent monitor with the authority to safeguard the research from bias in its design, conduct, or reporting;
4. Adjustment or modification of the research plan;
5. Reassignment of personnel duties, replacement of specific individuals, or removal of personnel from some or all research activities;
6. Reduction or divestiture of the financial interest (e.g., sale of equity holdings);
7. Termination of relationships that give rise to the financial conflict.

Once a conflict is confirmed, the Designated Official will communicate the determination and the approved management plan in writing to the Investigator, the relevant Principal Investigator/Project Director, and the Investigator's direct supervisor.

No funds from an NIH award may be expended until the Investigator has fulfilled all disclosure obligations under this policy and has agreed in writing to comply with any required management plan. The Designated FCOI Signing Official (SO) at NanoNewron LLC will submit the FCOI report to NIH using the eRA Commons FCOI Module.

7. MONITORING INVESTIGATOR COMPLIANCE

NanoNewron LLC will oversee Investigator adherence to the FCOI management plan for the duration of the NIH-funded award or until the identified financial conflict is resolved. This monitoring will include verifying that required public disclosures are made in publications and presentations, confirming that the FCOI is appropriately acknowledged.

To support ongoing oversight, Investigators must provide written disclosure of the FCOI to all research personnel involved in the study and forward a copy of this communication to the Designated Official.

8. PUBLIC ACCESSIBILITY TO INFORMATION RELATED TO FINANCIAL CONFLICTS OF INTEREST

Before any funds are expended under an NIH award, NanoNewron LLC will ensure public accessibility to information about SFIs by providing a written response to any requestor within five business days, provided the SFI meets all of the following criteria:

1. The SFI was disclosed and is still held by senior/key personnel, defined as the Project Director/Principal Investigator (PD/PI) and any other individual designated as senior/key personnel by NanoNewron LLC in the grant application, progress report, or other official submissions to the NIH;
2. NanoNewron LLC has determined that the SFI is related to the NIH-funded research; and
3. NanoNewron LLC has determined that the SFI constitutes a FCOI.

Upon request or through a publicly accessible website, NanoNewron LLC will provide, at a minimum, the following information:

1. The Investigator's name;
2. The Investigator's title and role in the NIH-funded project;
3. The name of the entity in which the SFI is held;
4. The nature of the financial interest; and
5. The approximate dollar value of the SFI, reported in the following ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; in \$20,000 increments for amounts between \$20,000 and \$100,000; and in \$50,000 increments for amounts over \$100,000—or a statement indicating that the value cannot be readily determined through public pricing or other reasonable means.

If NanoNewron LLC maintains a publicly accessible website for FCOI disclosure, the posted information will be updated at least annually and within 60 days of receiving or identifying a new SFI that meets the disclosure criteria. This includes new SFIs disclosed by existing senior/key personnel or SFIs disclosed by personnel newly involved in the NIH-funded project, provided the Designated Official determines that the SFI is related to the research and qualifies as an FCOI.

Information regarding disclosed SFIs will remain publicly accessible—either via NanoNewron LLC’s website or through written responses—for a minimum of three years from the date of the most recent update.

9. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

Before any funds are expended under an NIH-funded award, NanoNewron LLC will submit a FCOI report to the NIH, in accordance with NIH regulations, for any Investigator with a SFI determined to be a conflict. NanoNewron LLC will also ensure that the Investigator has agreed to and begun implementing the required management plan.

An institutional official will be designated as the FCOI Signing Official (SO) within the NIH eRA Commons FCOI Module. This individual will have the authority to submit FCOI reports to the NIH. Instructions and guidance for using the module are available in the [FCOI Module User Guide](#).

Throughout the life of the award—including any extensions, whether funded or unfunded—NanoNewron LLC will submit an annual FCOI report to NIH. This report will indicate whether the conflict is still being managed or has been resolved, and will detail any updates to the management plan, if applicable.

If a new FCOI is identified during the course of the project—such as when an Investigator acquires a new SFI, or a new Investigator joins the NIH-funded research—NanoNewron LLC will submit an updated FCOI report to NIH within 60 days of identifying the conflict. The company will also confirm that a management plan has been established and agreed to by the Investigator.

The initial FCOI report must include all information required under 42 CFR Part 50.605(b)(3), or as outlined in NIH’s FAQ H.5, available at: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888>.

Types of FCOI Reports Summary Chart for NIH:

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE		
REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	Prior to expenditure of funds Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the Institution is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

10. TRAINING REQUIREMENTS

Each Investigator will be informed of NanoNewron LLC’s FCOI Policy and trained on their responsibilities for disclosing both foreign and domestic SFIs, in accordance with this policy and the federal regulations outlined in 42 CFR Part 50 Subpart F. FCOI training must be completed:

- Before an Investigator begins work on any PHS/NIH-funded research;
- At least once every four years; and
- Immediately (as defined below) when any of the following circumstances occur:
 1. NanoNewron LLC updates this Policy or related procedures in a way that impacts Investigator obligations;
 2. An Investigator joins a NanoNewron LLC project funded by NIH (training must be completed prior to participation); or
 3. It is determined that an Investigator has failed to comply with this Policy or an assigned management plan (training must be completed within 30 days as directed by the Designated Official).

To meet the training requirement, all Investigators must complete the NIH Financial Conflict of Interest tutorial, available at:

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.

A certificate of completion must be printed and retained for audit purposes.

Additionally, NanoNewron LLC encourages all Investigators to view the NIH Virtual Seminar on developing or refining institutional FCOI policies for compliance, available here:

<https://www.youtube.com/watch?v=D292YZ6BX24>.

11. FAILURE TO COMPLY WITH NANONEWRON LLC FINANCIAL CONFLICT OF INTEREST POLICY APPLICABLE TO PUBLIC HEALTH SERVICE FUNDED AWARD

If a FCOI is not identified or managed in a timely manner—such as when an Investigator fails to disclose a SFI that is later determined to be an FCOI, when the institution fails to review or manage an identified FCOI, or when an Investigator fails to comply with a management plan—NanoNewron LLC will, within 120 days of discovering the noncompliance:

1. Conduct a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any portion of the research conducted during the period of noncompliance was biased in its design, conduct, or reporting;
2. Document the findings of this review in accordance with 42 CFR 50.605(a)(3)(ii)(B), or as outlined in NIH's FAQ I.2: <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895>.

If the review reveals that bias occurred, NanoNewron LLC will promptly notify NIH and submit a mitigation report through the eRA Commons FCOI Module. The report will include:

1. An assessment of the impact of the bias on the research project; and
2. A detailed description of the corrective actions taken or planned to eliminate or mitigate the effect of the bias.

Following submission of the mitigation report, NanoNewron LLC will continue to submit annual FCOI updates to NIH as required by applicable regulations and the terms and conditions of the award.

Depending on the severity of the FCOI, NanoNewron LLC may also implement interim measures to limit or suspend the Investigator's participation in the research project during the period between identification of the FCOI and completion of the retrospective review. If the review determines that no bias occurred, no further action will be required.

12. CLINICAL RESEARCH REQUIREMENTS

If the U.S. Department of Health and Human Services (HHS) determines that a clinical research project it funded—intended to evaluate the safety or effectiveness of a drug, medical device, or treatment—was designed, conducted, or reported by an Investigator with a FCOI that was neither properly managed nor reported by NanoNewron LLC, the company will require the Investigator to:

- Disclose the FCOI in all public presentations of the research findings; and
- Request an addendum to any previously published presentations or publications to reflect the FCOI.

13. SUBRECIPIENT REQUIREMENTS

A subrecipient relationship is established when federal funds are passed from or through NanoNewron LLC to another individual or entity responsible for conducting a substantive portion of a PHS-funded research

project. The subrecipient is accountable to NanoNewron LLC for both programmatic outcomes and regulatory compliance. Subrecipients may include, but are not limited to, collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees. As part of this relationship, NanoNewron LLC will take reasonable steps to ensure that any subrecipient Investigator complies with the federal FCOI regulations set forth in 42 CFR Part 50 Subpart F.

NanoNewron LLC will include in its written agreement with each subrecipient provisions establishing whether the NanoNewron LLC FCOI Policy or the subrecipient institution's FCOI policy will apply to the subrecipient's Investigators. (See NIH Grants Policy Statement Section 15.2.1 on Written Agreements: https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_othe_r_requirements.htm).

If the subrecipient's FCOI policy applies, the subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement must also define a timeframe within which the subrecipient will report any identified FCOIs to NanoNewron LLC to ensure timely submission of FCOI reports to NIH. For example, the agreement may require subrecipients to report FCOIs to NanoNewron LLC within 50–55 days of identification, enabling NanoNewron LLC to meet the NIH's 60-day reporting deadline. NanoNewron LLC's assigned FCOI Signing Official (SO) will then submit the FCOI report (subrecipient report) via the eRA Commons FCOI Module.

If the subrecipient is unable to certify compliance with the FCOI regulation, the agreement will specify that the subrecipient Investigators must adhere to NanoNewron LLC's FCOI Policy, including the disclosure of SFIs related to their work on the PHS-funded project. In this case, all SFI disclosures must be submitted directly to NanoNewron LLC. The agreement will establish adequate timeframes for NanoNewron LLC to review disclosures, implement management plans, and fulfill its reporting obligations under federal regulations.

If an FCOI is identified in this context, NanoNewron LLC will:

- Develop and implement a management plan;
- Monitor the subrecipient Investigator's compliance with the plan; and
- Submit the required FCOI report for the subrecipient via the eRA Commons FCOI Module.

14. MAINTENANCE OF RECORDS

NanoNewron LLC will maintain comprehensive records of all Investigator disclosures of financial interests, as well as the institution's review, determinations, and responses to those disclosures—regardless of whether the disclosure resulted in a determination of a FCOI. This includes all documentation related to actions taken under NanoNewron LLC's FCOI policy or any retrospective reviews conducted.

These records will be retained for a minimum of three years from the date of submission of the final expenditure report, or longer if required by specific provisions outlined in 45 C.F.R. §75.361, depending on the applicable circumstances. NanoNewron LLC will ensure records are maintained for each competitive segment in accordance with federal requirements.

15. FAILURE TO COMPLY WITH THIS POLICY

Compliance with this policy is a condition of employment and/or participation in PHS/NIH-funded research for all applicable Investigators. Any Investigator who fails to adhere to the requirements of this policy may be subject to disciplinary action. Such actions may include, but are not limited to: written reprimands, restrictions on access to research funds, suspension or termination of employment, or disqualification from further involvement in any PHS/NIH-funded projects—whichever measures are deemed appropriate based on the nature and severity of the non-compliance.

16. USEFUL FCOI AND NIH RECORDS

- FCOI Regulation 42 CFR Part 50 Subpart F—Promoting Objectivity in Research: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- Financial Conflict of interest: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>

- FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>
- FCOI Frequently Asked Questions (FAQs): <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=3875>
- Information for Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- NIH's Welcome Wagon letter at NIH 'WELCOME WAGON' LETTER Information for New Recipient Organizations: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>

17. POINT OF CONTACT

If you have a question related Financial Conflict of Interest Policy of NanoNewron LLC or would like to disclose financial interest, contact Marco Taglietti, MD at marco.taglietti@nanonewron.com