



nanoMAG, LLC

Financial Conflict of Interest Policy (Promoting Objectivity in Research) for PHS-Funded Grants and Research Agreements

(42 CFR Part 50 Subpart F)

PURPOSE

This policy serves to document the requirements and responsibilities for identifying and managing financial conflicts of interest (FCOI) in order to:

- 1) Provide a reasonable expectation that the design, conduct, and reporting of nanoMAG LLC research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias due to Investigator FCOI
- 2) Address and comply with federal regulations (defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)). An electronic version of the regulation can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

KEY DEFINITIONS

The following definitions are considered key definitions and are provided as a reference for understanding the federal regulations of FCOI. A complete list of official definitions can be found at [42 CFR 50.603](#).

Financial Interest – means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest (FCOI) – means a Significant Financial Interest (herein defined) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Institution – means any domestic or foreign, public, or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding

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 or will be responsible for the design, conduct, or reporting of research funded by the PHS, which may include, for example, collaborators or consultants.

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 an PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

Research – means a systematic investigation, study or experiment 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 (e.g., a published article, book, or book

chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from PHS 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.

Administrator Human Resources (AHR) – means the employee of nanoMAG LLC designated to be responsible for oversight of the actionable items in this policy.

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 regulation.

Significant Financial Interest (SFI) –

- 1) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities must be disclosed:
 - 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. Upon receipt of income related to intellectual property rights and interests (e.g., patents, copyrights).
- 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 disclosure of reimbursed or sponsored travel must include:
 - i. the purpose of the trip
 - ii. the identity of the sponsor/organizer

- iii. the destination and duration of the trip.

NanoMAG's AHR will then determine if further information is needed, 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:
- i. 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;
 - ii. any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - iii. 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;
 - iv. 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
 - v. income from service on advisory committees or review panels for a federal, state, or local government agency, 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.

Small Business Innovation Research (SBIR) Program – means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

TRAINING

nanoMAG's Financial Conflict of Interest Policy can be found on our website (www.nanomag.us).

Every investigator on a nanoMAG-affiliated, PHS-funded grant or cooperative agreement must complete the PHS Financial Conflict of Interest Survey form annually and submit it to the PI of their specific grant who will, in turn, submit the forms to nanoMAG's AHR. If an investigator has an SFI that requires disclosure under this policy (see below), that individual must complete an SFI Disclosure Form and submit it directly to nanoMAG's AHR.

The complete Federal Regulation addressed by nanoMAG's Financial Conflict of Interest Policy can be found at [42 CFR 50 \(subpart F\)](#).

The following Financial Conflict of Interest tutorial was designed by the NIH to provide training on what constitutes a financial conflict of interest. Completion of this training is required for anyone involved with an PHS-funded project, including all Investigators, consultants and employees of nanoMAG LLC who are engaged in PHS-funded research or its administration.

This tutorial on FCOI is accessible at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Upon completion of the training, employees will record the completion on their training using their individual training binders that are supported by nanoMAG'S Quality Management System. This training is required:

- 1) prior to engaging in research relating to any PHS-funded grant;
- 2) if or when NanoMAG changes its FCOI policy;
- 3) if an investigator is new to the PHS-funded research project; or
- 4) in the event of non-compliance of an Investigator/Key Personnel.

At a minimum, the FCOI training shall be taken every four (4) years.

PROCEDURES

Identification of Persons Required to Disclose a Significant Financial Interest – Prior to the actual submission of an PHS grant application and on an annual basis during the period of funding, nanoMAG's AHR will ensure that the PI of each PHS grant or cooperative agreement distributes the **SFI Survey Form** to all project Investigators, collects the completed forms, and returns them to the AHR within 30 days. The AHR will then review the forms to determine if a potential FCOI exists. If it is determined that a potential FCOI exists, the AHR will provide an **SFI Disclosure Form** directly to that Investigator. The Investigator must complete this form and return it to nanoMAG's AHR within 30 days. In addition, the AHR is responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed and that any Investigator joining an ongoing research project submits an SFI Survey form to the PI of the project who will then communicate the answers to the AHR.

Subrecipients – In the case where a portion of a nanoMAG-associated PHS-funded research project is performed through a subrecipient (e.g., subcontractor or consortium member), nanoMAG will take reasonable steps to ensure that any subrecipient Investigator complies with this subpart. This will be done by incorporating, as part of a written agreement with the subrecipient, terms that establish whether nanoMAG's financial conflicts of interest policy or that of the subrecipient will apply to the subrecipient's Investigators.

- i. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient will certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement will state that subrecipient Investigators are subject to nanoMAG's financial conflicts of interest policy for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

- ii. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above will specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to PHS as required by this subpart;
- iii. Alternatively, if the subrecipient's Investigators must comply with nanoMAG's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution via the PI, as described above (Identification of Persons Required to Disclose a Significant Financial Interest). Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

SFI Disclosure Form Submission and Review – If the review of an Investigator's **SFI Disclosure Form** by nanoMAG's AHR determines that there is a FCOI, steps will be taken to determine what measures are needed to address the FCOI identified. An SFI management plan will be written by the AHR in order to ensure compliance with this policy.

Management and reporting of financial conflicts of interest –

- 1) The SFI management plan may require one or more of the following actions (but not limited to) be taken in order to manage, reduce, or eliminate any actual or potential conflict of interest:
 - Public disclosure of significant financial interests;
 - Review of research protocols by independent reviewers;
 - Monitoring of research by independent reviewers;
 - Modification of research plan;
 - Disqualification from participation in all or a portion of the research funded;
 - Divesture of significant financial interests;
 - Severance of relationships that create actual or potential conflicts
- 2) All management plans must be signed by both the Investigator and the AHR. Compliance of the management plan shall be monitored by the AHR on an ongoing basis until the completion of the PHS-funded research project.
- 3) Annual Reporting and After-Acquired Significant Financial Interests – If required by an ongoing management plan, the Investigator needs to provide updated **SFI Disclosure Forms** annually or more frequently if stated in the management plan. Any Investigator who acquires a new

or increased SFI shall promptly submit a new **SFI Disclosure Form** within 30 days of discovering or acquiring the new SFI.

- 4) Violations of Conflict of Interest Policy – Investigators are expected to comply fully and promptly with this policy. Whenever a person has violated this policy, including failure to make a required disclosure of significant financial interests or failure to comply with a requirement of the management plan, the AHR will make recommendations to the President regarding the impositions of sanctions or disciplinary proceedings against the violating individual.
- 5) In addition, nanoMAG will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.
- 6) Record Keeping – Records relating to all Investigator disclosures of financial interests and to nanoMAG’s review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under nanoMAG’s policy or retrospective review, if applicable, shall be retained by the AHR for at least three years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 75.361 for different situations.
- 7) Sub-award Recipient Requirements – Sub-award recipients must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research* ([42 CFR part 50 subpart F](#)) and that their portion of the research project, as detailed in their sub-award agreement, is in compliance with their institutional policies. If an SFI is identified by the sub-award recipient, they are required to notify nanoMAG of the existence of the conflicting interest within 30 days of the identification of the interest. In addition, the sub-award recipient must certify and assure that any reported conflicting interest has been managed, reduced, or eliminated in accordance with federal regulations.
- 8) Public Accessibility – Before nanoMAG spends any of any funds under an PHS-funded research project, nanoMAG will ensure public accessibility of information concerning any Significant Financial Interest disclosed to nanoMAG that meets the following criteria by a written response to any requestor within five business days of a request:
 - The Significant Financial Interest was disclosed and is still held by the senior/key personnel and
 - nanoMAG determines that the Significant Financial Interest is related to the PHS-funded research
 - i. The information that nanoMAG will make available as a written response to any requestor within five business days of a request, will include, at a minimum, the following:
 - the Investigator's name, title, and role with respect to the research project
 - the name of the entity in which the Significant Financial Interest is held

- the nature of the significant financial interest
 - an approximate dollar value of the Significant Financial Interest 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.
- ii. nanoMAG will respond to written requests for information for the purposes of this subsection and will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of nanoMAG's identification of a new financial conflict of interest.
 - iii. The information concerning the Significant Financial Interests of an Investigator will be available for responses to written requests for at least three years from the date that the information was most recently updated.
- i) Federal Reporting – In accordance with applicable federal requirements, the AHR is responsible for the reporting of all matters involving disclosures of SFI in accordance with applicable federal requirements. The following reports are required by PHS and must include the information specified in [42 CFR part 50 subpart F \(50.605\)](#):
- i. Initial report – Prior to nanoMAG's expenditure of any funds under an PHS-funded research project, nanoMAG will provide PHS with a FCOI report regarding any Investigator's Significant Financial Interest found to be in conflict and ensuring that nanoMAG has implemented an appropriate management plan. In cases where a FCOI is identified but eliminated prior to the expenditure of PHS-awarded funds, an FCOI report will not be submitted to PHS.
 - ii. If an FCOI is identified subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), nanoMAG will submit an FCOI report regarding the FCOI to PHS within sixty days and ensure that nanoMAG has implemented a management plan. If this FCOI report involves an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed (e.g., was not timely reviewed or reported by a subrecipient), nanoMAG will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, nanoMAG will notify the PHS promptly and submit a mitigation report as required.
 - iii. Annual FCOI report – For any FCOI previously reported by the nanoMAG with regard to an ongoing PHS-funded research project, nanoMAG will provide to PHS an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. We will provide these annual FCOI reports to the PHS for the duration of the project period (including extensions with or without funds) in the time and manner specified by PHS.