

Financial Conflict Of Interest (FCOI) Policy for Public Health Service (PHS) Funding

1. Policy Statement

- A. Nanolmaging Services, Inc. (NIS) is committed to the design, conduct, and reporting of Research in an objective manner, free from bias or undue influence due to financial conflicts of interest (FCOI). The purpose of this Policy is to promote objectivity in research for all grants, cooperative agreements, or contracts funded by any PHS agency or from any other non-PHS organization that has adopted the PHS FCOI Regulations.
- B. This Policy is designed to comply with Public Health Service (PHS) FCOI 2011 Regulations - 42 C.F.R. Part 50 Subpart F (Grants and Cooperative Agreements) and 45 C.F.R. Part 94 (Responsible Prospective Contractors). NIS and each Investigator participating in any Research or Research through subgrantees, contractors, or collaborators that is funded by any PHS agency or any non-PHS organization that has adopted the PHS FCOI Regulations are required to comply with this Policy. This Policy is effective as of August 24, 2012 and will be updated annually, maintained, and made publicly accessible in compliance with most-up-to-date FCOI regulations.

2. Purpose

- A. The FCOI 2011 Regulations promote “objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.” NIS’s FCOI Policy establishes standards and procedures to promote and enforce the PHS Regulations to prevent financial considerations from influencing or seeming to influence an Investigator’s role in the design, conduct, or publication of PHS-funded projects. As part of its institutional responsibilities, NIS will promote and enforce Investigator compliance with regulations on Significant Financial Interest (SFI) disclosure, and will manage FCOIs and provide initial and ongoing FCOI reports to PHS, NIH, or other applicable organizations.

3. Definitions

- A. **Financial Conflict of Interest:** a SFI that could direct and/or significantly affect the design, conduct, or reporting of PHS-funded Research, as determined by the Institutional Official (IO).
- B. **Financial Interest:** anything of monetary value, whether or not the value is readily ascertainable.
- C. **Institutional Official:** the individual designated by NIS within the office of the CFO to be responsible for enforcing this Policy, reviewing disclosures of SFIs, determining whether disclosures constitute a Financial Conflict of Interest, and managing such conflicts.
- D. **Institutional Responsibilities:** an Investigator’s professional responsibilities on behalf of NIS, which may include: 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.
- E. **Investigator:** 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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.
- F. **PHS Awarding Component:** the organizational unit within the Public Health Service that funds the research.

- G. *Research*:** 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). The term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, 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.
- H. *Significant Financial Interest (SFI)*:** a financial interest consisting of one or more of the following interests of the Investigator, the Investigator's spouse/domestic partner, and the Investigator's dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:
- 1) With regard to any publicly traded entity, a SFI 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.
 - 2) With regard to any non-publicly traded entity, a SFI 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).
 - 3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - 4) The occurrence of any reimbursed or sponsored (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) travel, related to their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.
 - 5) Note that this does not include the following:
 - a) salary, royalties, or other remuneration paid by NIS to the Investigator if the Investigator is currently employed or otherwise appointed by NIS;
 - b) Intellectual Property Rights assigned to NIS and agreements to share in royalties related to such rights;
 - c) any ownership interest in NIS held by the Investigator;
 - d) 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;
 - e) 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.S. 1001 an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
 - f) 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; or
 - g) travel that is reimbursed or sponsored by a federal, state, or local government

agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

4. Policy Instructions and Disclosure Procedures

A. Responsibilities of the Institution:

- 1) In compliance with PHS FCOI Regulations, the NIS Institutional Official (IO) will ensure that all Investigators are informed of and in compliance with this Policy regarding financial conflicts of interest, the Investigator's responsibilities of disclosing SFIs, and with PHS FCOI Regulations.
- 2) As applicable, the IO will maintain records of all Investigator disclosures of financial interests and NIS's review of, and response to, such disclosures under NIS's Policy or retrospective review, regardless of whether a disclosure resulted in the Institution's determination of FCOI:
 - a) For at least three years following the submission date of the final expenditures report or from the date of submission of the quarterly or annual financial report; or
 - b) From other dates stipulated by 45 C.F.R. 74.53(b) and 92.42(b).
- 3) All records of Investigator disclosures of financial interests and NIS's review of, and response to, such disclosures will be maintained:
 - a) In hard copy, filed under the "Assurances" tab of the project binder specific to the PHS-funded work; and
 - b) Electronically, filed in the "FCOI" folder in the "3 Assurances" folder of the project file tree specific to the PHS-funded work on the server.

B. Policy Application to Subawardees, Subcontractors, and NIS Affiliates

- 1) Subawardees, subcontractors, and other NIS affiliates collaborating on PHS-funded research will be required to confirm that they have their own FCOI policy in place that conforms to PHS FCOI 2011 Regulations prior to a grant being funded. If they do not have their own FCOI policy, they will be required to comply with this NIS Policy.

C. Mandatory Training Requirements

- 1) Per PHS FCOI Regulations, all Investigators will be required to complete FCOI training on both Federal and Institutional policies. This training must be completed prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately if any of the following circumstances apply:
 - a) The NIS FCOI Policy or procedures contained within or the PHS Financial Disclosure Form are revised in any manner that affects the requirements of Investigators;
 - b) An Investigator joins NIS; or
 - c) NIS is made aware of an Investigator who is not in compliance with this FCOI Policy or management plan.
- 2) To fulfill the Institutional training requirement, all NIS personnel will be required to read through this NIS FCOI Policy for PHS Funding and sign to attest to the fact that they have read and understood all policies, rules, and regulations contained within this document, and that they understand their responsibilities as an Investigator to disclose any and all significant financial interests.
- 3) To fulfill the Federal training requirement, all NIS investigators must complete one of the following training programs:
 - a) Completion of the NIH Office of Extramural Research's web-based "Financial Conflict of Interest Online Tutorial" (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) is required. At

5. Management of Financial Conflicts of Interest

A. Review of SFI disclosure

- 1) All disclosures of SFIs will be reviewed by NIS's Authorized Official(s) in a prompt manner such that within 60 days of receipt of the disclosure, the SFI can be assessed, a management plan developed, and all reviews and approvals necessary can be obtained.

The Authorized Official(s) will:

- a) Record and review all "Financial Disclosure for Investigators in PHS Research" forms from PHS-funded Investigators at NIS;
- b) Assess the nature of the SFI to determine whether the Investigator working on the PHS-funded research has a FCOI;
- c) Provide information concerning FCOIs to the expenditure of PHS funds, which will be updated at least annually and within 60 days of changes to Statement of Financial Interest Disclosure forms, whichever occurs first.

B. Management of FCOIs

- 1) The NIS Authorized Official(s) will develop a management plan based on the nature of the FCOI and will monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Examples of conditions or restrictions that could be established include, but are not limited, to:
 - a) Public disclosure of FCOIs;
 - b) Appointment of independent monitor(s) who will be able to prevent the FCOI from biasing the design, conduct, and reporting of PHS-funded research;
 - c) Modification of the research plan;
 - d) Change of Investigator(s) or roles/responsibilities of Investigator, or exclusion of Investigator from participating in all or a portion of research;
 - e) Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
 - f) Severance of relationships that create FCOIs.

C. NIS Reporting Requirements

- 1) Per PHS FCOI Regulations, NIS will submit to the NIH through the eRA Commons FCOI Module both initial and ongoing FCOI reports:
 - a) Prior to the expenditure of funds;
 - b) Within 60 days of identifying a new FCOI during the period of the award; and
 - c) Annually when grantee is required to submit the annual progress report, including multi-year progress report, or at time of extension, to report on the status of FCOI and any changes in the management plan.
- 2) As per the PHS FCOI Regulations, FCOI reports will include:
 - a) Grant number;
 - b) PD/PI or contact PD/PI;
 - c) Name of Investigator with FCOI;
 - d) Name of entity with which Investigator has FCOI;
 - e) Nature of FCOI;
 - f) Value of the financial interest, reported as a range (\$0-4,999; \$5,000-9,999; \$10,000-19,999), in increments of \$20,000 if between \$20,000-100,000, in increments of \$50,000 if above \$100,000, or a statement that the value cannot be readily determined.
 - g) Description of how the SFI relates to PHS-funded research and basis for NIS's determination that the SFI conflicts with this research; and

7. Acknowledgment of Understanding of the NIS FCOI Policy for PHS Funding

I, _____ (print name), acknowledge that I have read and understood the policies, rules, and regulations contained above in the NIS FCOI Policy for PHS Funding. In signing my name, I attest that I understand my responsibilities as an Investigator, as defined by the PHS, to disclose any and all significant financial interests via the procedures detailed in this Policy.

Signature Date