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Research
Operations
Area Research
Administration

ORI Policy 1.07 - Conflict of Interest Policy for Public Health Service Funding

Inova policies and procedures are confidential and should not be shared outside Inova, including with any third party vendor or organization, unless authorized by leadership.

Purpose:

The United States Department of Health and Human Services (HHS) developed the regulations at **42 CFR Part 50 Subpart F**, "Promoting Objectivity in Research" and **45 CFR Part 94**, "Responsible Prospective Contractors" to promote objectivity in Public Health Service (PHS) funded research for grants, cooperative agreement and research contracts, respectively. The regulations were first published in 1995 and revised the regulations in 2011. This policy implements the requirements of the 2011 revised FCOI regulation for grants and cooperative agreements.

The regulations apply to all National Institutes of Health (NIH) applications and funded grants, cooperative agreements, and research contracts, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and/or awards.

The implementation of the regulation, through the issuance of this policy, establishes standards that provide a reasonable expectation that the design, conduct and reporting of PHS/NIH-funded will be protected from bias resulting from an Investigator's financial conflict of interest (FCOI). This policy also serves to protect the safety of human research participants, the reputation of the recipient institution and of the "Investigator" who participates in PHS/NIH-funded research. These requirements also work together to preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards.

Applies to:

This policy implements the regulatory requirements provided in **42 CFR Part 50 Subpart F** for grants and cooperative agreements issued by the NIH that are subject to the FCOI regulation. The policy also applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in, or who participate in NIH-funded research.

Definitions:

- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- **Institution:** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, Public Health Service (e.g., NIH) funding.
- **Institutional Responsibilities:** Professional activities an Investigator performs on behalf of Inova Health System (e.g., research, development, publication, consulting, administration, public relations, committee memberships, or any other duties defined by their role at the company).
- **Designated Official (DO):** The individual designated by Inova Health System as an Officer to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring team member FCOI training requirements.
- **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 an award or proposed for funding, which may include collaborators or consultants. Inova Health System will consider the individual's role, rather than the title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded research.
- **Research:** 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 the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, 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.
- **PHS-Funded Research:** Any 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.
- **PHS:** 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).

- **NIH:** The biomedical research agency of the PHS.
- **Senior/Key Personnel:** The PD/PI and any other person identified as senior/key personnel by Inova Health System in the grant application, progress report, or any other report submitted to the PHS/NIH by Inova Health System.
- **Significant Financial Interest (SFI):**
 1. A **domestic or foreign** 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 appear to be related to the Investigator's institutional responsibilities (e.g., research, consulting, etc.) performed on behalf of Inova Health System:
 - i. **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. 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. **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).
 - iii. **Intellectual Property Rights and Interests:** A significant financial interest exists upon receipt of income greater than \$5,000 received over the preceding twelve months that is related to such rights and interests (e.g., patents, copyrights).
 2. Investigators must disclose the occurrence of any **reimbursed or sponsored travel** that exceeds \$5,000 (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) related to the Investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel reimbursed or sponsored by the following:
 - i. A federal, state, or local government agency located in the United States,
 - ii. A United States Institution of higher education,
 - iii. An academic teaching hospital,
 - iv. A medical center, or
 - v. A research institute affiliated with a United States Institution of Higher Education.

3. The term 'significant financial interest' does **not** include, and therefore, Investigators are not required to disclose, the following types of financial interests:

- i. Salary, royalties, or other remuneration paid by Inova Health System to the Investigator if the Investigator is currently employed or otherwise appointed by Inova Health System, including intellectual property rights assigned to Inova Health System 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 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 located in the United States, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. Institution of higher education.
- v. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. Institution of higher education.

- **NOTE: Exclusions above do not apply to Foreign Financial Interests:** Investigators must disclose all foreign financial interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Policy Description:

Significant Financial Interest Investigator Disclosure Requirements

Investigators will disclose their SFIs that are related to their "institutional responsibilities" as defined in the policy.

The disclosure will not be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.

The Investigator SFI Disclosures will be retained by the Institution as part of the record maintenance requirements.

Procedure:

Investigators will disclose their SFIs at the following times:

- **At the time of application:** The Principal Investigator and all other individuals who meet the definition of 'Investigator' must disclose their SFIs to Inova Health System' Designated Official. Any new Investigator who, after applying for NIH funding or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the Designated Official promptly and prior to participation in the project.
- **Annually:** Each Investigator participating in research under an NIH award must submit an updated disclosure of SFI at least annually (on or before January 31), during the period of the award. The annual disclosure must include any information not disclosed initially to Inova Health System pursuant to this Policy or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- **Ad Hoc Basis - New SFIs During the Award:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance). Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Review of SFI Disclosures by Inova Health System Designated Official

The SFI disclosures will be reviewed as described below:

- **Prior to the expenditure of awarded funds (e.g., during the Just-in-Time stage):** The Designated Official(s) will review the Investigator's SFI(s) prior to the NIH issuing a new award. If an FCOI is identified, Inova Health System will submit an FCOI report to the NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.
- **Annual Disclosure:** The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The Designated Official(s) will review the Investigator's annual disclosure and use the updated information to determine if any changes are needed to an existing management plan. Any changes to an existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.
- **Ad Hoc Basis – New SFIs During Award Period:** Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the Designated Official(s) will, within 60 days: review the disclosure of SFI, determine whether the SFI is related to the 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. Inova Health System will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

Guidelines for Determining 'Relatedness' of SFI to PHS/ NIH-Funded Research and a Financial Conflict of Interest

The Designated Official will determine whether an Investigator's SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

- **Relatedness Test:** An Investigator's SFI is related to the research when the Designated Official reasonably determines the SFI:
 1. Could be affected by the PHS/NIH-funded research; or
 2. Is in an entity whose financial interest could be affected by the PHS/NIH- funded research.
- **Investigator Involvement:** The designated official(s) may involve the Investigator in determining whether an SFI is related to the NIH-funded research.
- **FCOI Determination:** A financial conflict of interest exists when the Designated Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. 'Significantly' means that the financial interest would have a material effect on the research.

Management of Significant Financial Interests that Pose Financial Conflict of Interest

If a financial conflict of interest exists, the Designated Official(s) will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the Institution's Institutional Review Board, Institutional Animal Care and Use Committee, Data Safety and Monitoring Board, etc.);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification 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.

If the Designated Official determines that a conflict exists, it will communicate its determination and the means developed for managing the FCOI in writing to the individual.

No expenditures on an NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Designated Official(s) necessary to manage the Financial Conflict of Interest. The FCOI Designated Official(s) of Inova Health System will submit the FCOI report to NIH via the eRA Commons FCOI Module.

Appeals

If an Investigator does not agree with the management plan, the Investigator may appeal the decision one time to the Institutional Official. If the Investigator remains unsatisfied with the subsequent ruling, he or she can further appeal the determination to Inova's CEO, whose decision will be final.

For an appeal to be valid, the Investigator must file each appeal with the VP/Designee in writing within ten (10) business days of receiving the management plan.

Monitoring Investigator Compliance

Inova Health System will monitor Investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the Investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the Designated Official which will serve as documentation for compliance with the management plan.

Public Accessibility of the FCOI Policy and FCOI Information Held by Senior/Key Personnel

FCOI Policy: A copy of the FCOI policy is posted on the institution's public website per the NIH requirements in the NIH Grants Policy Statement Section **4.1.10 Financial Conflict of Interest** at https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm.

Inova Health System will ensure public access to its FCOI policy by posting it on its publicly accessible website (<https://www.inova.org/about-us/grants-management>).

Identified FCOIs held by Senior/Key Personnel: Prior to the expenditure of any funds under an NIH award, Inova Health System will ensure public accessibility by providing a written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel (PD/PI and any other person identified as senior/key personnel by Inova Health System in the award application, progress report, or any other report submitted to the NIH);
2. Inova Health System has determined that the SFI is related to the research funded through an award; and

3. Inova Health System has determined that the SFI is a financial conflict of interest.

The information made available via the public website or in a written response will include, at a minimum:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. 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.

The written response will note 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 the Institution's identification of a new FCOI, which should be requested subsequently by the requester.

If the Inova Health System uses a publicly accessible website to meet this requirement, the information posted will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI is being disclosed by Senior/Key personnel joining the project and determined by the designated official to be related to the research and an FCOI.

Information on SFIs subject to the public accessibility requirement will remain available for at least three years from the most recent update.

Reporting of Identified Financial Conflicts of Interest

Inova Health System will assign an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified (i.e., no award – no FCOI and no FCOI – no FCOI report). The FCOI Module User Guide is available at https://www.era.nih.gov/files/fcoi_user_guide.pdf to assist in submitting reports to the NIH.

The following types of reports are submitted:

Initial Or Original (Original) FCOI Reports

The Original FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52888>.

The Initial or Original Report will be submitted as prescribed below:

- **Prior to the Expenditure of Funds:** When an FCOI is identified upon the issuance of a new NIH

award, the FCOI SO will submit a NIH "2011 FCOI" Original report prior to the expenditure of any funds under an NIH award.

- **Within 60 days of Identifying a new FCOI During Award Period:** When an FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator, or upon the participation of a new Investigator), Inova Health System will provide to NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the financial conflict of interest.

Annual FCOI Reports

While the award is ongoing (including any extensions with or without funds), Inova Health System will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI (i.e., whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable.

The Annual FCOI report will be submitted at the same time as when the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if applicable, per the NIH guidance (see NIH's FAQ H.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52860>). The NIH will send an annual report email notification to the Institution when an annual report is due. Annual FCOI reports are not submitted as part of grant closeout.

Revision (or Mitigation) FCOI Reports

Following the completion of a retrospective review, the Institution will provide NIH with a Revision if new information is discovered or a Mitigation Report if bias is found.

The types of FCOI reports and their requirements are summarized below:

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH through the 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.	i. Prior to expenditure of fundsor ii. 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	When bias is found as a result of a retrospective review.

	FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	
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Training Requirements

Each Investigator will be informed about Inova Health System' Financial Conflict of Interest Policy and trained on the Investigator's responsibility to disclose foreign and domestic SFIs per this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- Inova Health System revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators;
- An Investigator is new to Inova Health System research under an NIH award (training is to be completed prior to his/her participation in the research); or
- Inova Health System finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the Designated Official(s)).

To fulfill the FCOI training requirement of the FCOI regulation, Inova Health System requires its Investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at https://grants.nih.gov/grants/policy/foi/tutorial2018/story_html5.html in accordance with the requirements and expectations of this Policy. All Investigators must print a certification of completion at the end of training and retain it for audit purposes.

Failure to Comply with Inova Health System Financial Conflict of Interest Policy Applicable to Public Health Service Funded Award

Whenever the Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) will within 60 days: review the SFI, determine whether the SFI is related to 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 such FCOI going forward. The Institution will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI Module.

In addition, whenever an 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 Inova Health System to constitute a FCOI;
- Failure by Inova Health System to review or manage such an FCOI; or

- Failure by the Investigator to comply with a management plan;

Inova Health System will, within 120 days of determining non-compliance:

- Complete a retrospective review of the Investigator's activities and the PHS/NIH- funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of research;
- Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52895>.

If bias is found, Inova Health System shall notify NIH promptly and submit a mitigation report per the regulation at 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff52896> to NIH via the eRA Commons FCOI Module that shall address:

- Impact of the bias on the research project, and
- Inova Health System's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Inova Health System will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart above. Depending on the nature of the Financial Conflict of Interest, Inova Health System may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Inova Health System' independent retrospective review.

If bias is not found, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update previously submitted report information (e.g., increase in value of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

If the failure of an Investigator to comply with an Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, the Institution shall promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken. The PHS/NIH Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS/NIH-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS/NIH award or when the transfer of a PHS/NIH grant(s) involves such an Investigator.

Clinical Research Requirements

If the Department of Health and Human Services determines that one of its funded clinical research projects, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or

treatment, has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Inova Health Technologies, Inova Health System shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through Inova Health System to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research project and is accountable to Inova Health System for programmatic outcomes and compliance matters. Subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to Inova Health System' terms and conditions. Inova Health System will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

Inova (as an awardee Institution) takes reasonable steps to ensure that any sub-recipient Investigator complies with the PHS financial conflict of interest policy of their institution by written agreement.

- **If the subrecipient's FCOI policy applies:** The subrecipient institution will certify as part of the agreement with Inova Health System that its policy is in compliance with the federal FCOI regulation. The agreement shall specify the time period for the subrecipient to report all identified FCOIs to Inova Health System (e.g., within 55 days of identification to allow Inova Health System to report within 60 days) to enable Inova Health System to provide timely FCOI reports to the PHS/NIH as required by the regulation. The Inova Health System assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
- **A sub-recipient's institution without a federally compliant COI program:** at the time of award, will not be permitted to participate in grant-funded.

Maintenance of Records

Inova Health System will keep all records of all Investigator disclosures of financial interests and Inova Health System' review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a Financial Conflict of Interest), and all actions under this policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 2 CFR 200.334 for different situations. Inova Health System will retain records for each competitive segment, as required by the regulation. Management plans will be retained as part of the Inova Health System' records.

In addition, the Institution will make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to such disclosure whether or not the disclosure resulted in the Institution's determination of an FCOI per the regulation 42 CFR 50.606(b).

Enforcement Actions When an Investigator Fails to Comply with This Policy

Failure to comply with this policy will be brought to the attention of the Service Line Leadership, the Research Oversight Committee and Institutional Official. The Research Oversight Committee and/or the Institutional Official will have the option of taking appropriate action(s) including but not limited to:

- withdrawal of pending proposals
- and/or placing a hold on, or terminating, an active award, or cooperative agreement.

In addition, if required, Inova will notify the awarding component of the Covered Individual's failure to comply with the determination and/ or policy. Possible sanctions to be imposed on the individual may include, but are not limited to:

- Formal admonition;
- Ineligibility to engage in research;
- Or dismissal.

Violations that constitute falsification in proposing, performing, reporting, or reviewing research shall be handled in accordance with the respective Inova policies and procedures governing allegations of research misconduct.

Useful FCOI and NIH Resources

- NIH's email address to send FCOI-related inquiries: FCOICompliance@mail.nih.gov
- FCOI Regulation 42 CFR Part 50 Subpart F: <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?anchorff3875>
- Information for Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- NIH's Welcome Wagon Letter: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>
- NIH Grants Policy Statement: <https://grants.nih.gov/policy/nihgps/index.htm>
- NIH Guide for Grants and Contracts: <https://grants.nih.gov/funding/guide.htm>
- NIH Extramural Nexus: <https://public.govdelivery.com/accounts/USNIHOER/subscriber/new?qsppfCODERED>

Point of Contact

For questions related to Inova Health System's Financial Conflict of Interest Policy or to disclose an SFI or potential FCOI, contact: coi@inova.org.

Inova policies and procedures are confidential and should not be shared outside Inova, including with any third party vendor or organization, unless authorized by leadership.

Approval Signatures

Step Description	Approver	Date
Submit - VP of Research Operations and Research Oversight Committee Approval	Gity Porjosh: VP Research Operations	7/21/2026
Area Manager/Editor Approval	Gity Porjosh: VP Research Operations	7/21/2026

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