

# Conflict of Interest Policy for Research and Public Health Service Funding, ORI 5.09

## PURPOSE:

1. The purpose of this policy is to establish Inova Health System's (Inova's) position concerning conflicts of interest of researchers, research teams, educators, Principal Investigators/Program Directors (PI/PDs), and grant-funded team members. The policy also seeks to foster compliance with Public Health Service (PHS) rules on conflicts of interest when implicated for grant-funded projects.
2. The increasing involvement of research Investigators with industry and private entrepreneurial ventures increases the potential for conflicts of interest (COIs). Conflicts may arise from an individual's opportunities to benefit financially from the outcome of his/her research or other activities conducted as part of a research team and/or grant-funded project. This policy is designed to promote objectivity in research, scholarly, educational, and program activities, including those funded under external grants, contracts, or cooperative agreements. By requiring the review of disclosures of interests made by Inova's Investigators (researchers, trainees, students, PI/PDs, grant-funded team members and subcontractors) and other Inova team members relating to their institutional responsibilities and appointments, the policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of such activities will be free from bias resulting from individual financial and obligatory conflicts of interest.
3. Inova's Institutional Official is responsible for the overall coordination of research for the organization. The Vice President, Research Operations is the Chief Administrative Officer of the Office of Research at Inova (ORI) and has been designated by the Institutional Official to solicit and review disclosures of potential conflicts of interest related to research, scholarly, educational, and other funded grant activities.
4. This policy supplements the existing institutional policy contained in Inova's [Code of Conduct](#) and other Inova policies and procedures on this subject. In the event of conflict as it relates to funded research or scholarly, educational, and/or grant activities funded under external grants, contracts, or cooperative agreements, the provisions of this policy will apply.

## DEFINITIONS:

1. **Conflict of interest:** (COI): An actual or potential interest that could directly and substantially (as determined by the Vice President, Research Operations and/or his/her designee (VP/designee), acting on behalf of the Institutional Official), affect, or be affected by the design, conduct, or reporting of funded research, non-research grants, or of scholarly, educational, and/or program activities funded under external grants, contracts, or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.
2. **Contractor:** An external entity or individual providing property, technical advice, or services under a contract or agreement for the direct benefit or use of an awarding component. The relationship does not include an employer and employee relationship.
3. **Covered Individual:** Any clinical or non-clinical team member, regardless of title or position, who, under the aegis of the institution is responsible for the design, conduct, or reporting of research involving human participants and/or the conduct of research proposed for funding from federal agencies.
4. **Disclosure of Significant Financial Interests:** A covered individual's (collectively, Investigator, PI/PD, educator, researcher, grant-funded team member) disclosure of significant financial interests to Inova.
5. **Financial Conflict of Interest (FCOI):** A financial interest that could directly and substantially affect, or be affected by the design, conduct, or reporting of funded research or scholarly,

- educational, procurement, and/or program activities funded under external grants, contracts, or cooperative agreements.
6. **FCOI Report:** Inova's report of a financial conflict of interest to a funding entity.
  7. **Governmental Agency:** Any governmental agency that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts.
  8. **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of the Institution. These may include: activities such as research, research consultation, consulting, lecturing, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or external advisory boards. Income from, or obligations arising from, any outside activity or commitment that is related to the Investigator's institutional responsibilities must be disclosed to Inova.
  9. **Institution:** Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. ([42 CFR 50.603](#)) For the purposes of this policy, the Institution is Inova.
  10. **Institutional Official:** The individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Federalwide Assurance (FWA).
  11. **Intellectual Property:** An Invention with potential for commercial value, which can be created by one or more Inventors, each of whom must have conceived of an essential element or have contributed substantially to its conceptual development. Copyrightable contributions to commercially distributed or open source software programs will be treated as Intellectual Property in the same fashion as Inventions.
  12. **Invention:** Any new and useful process, machine, composition of matter, life form, article of manufacture, information technology, software, or any new and useful improvement thereof, which did not previously exist, and which is or may be patentable, copyrightable or otherwise protectable under the laws of the United States. Inventions can include, but are not limited to, novel biological materials such as proteins, genes, DNA constructs, cell lines, and transgenic animals; new and improved devices, biological or chemical compounds, diagnostic techniques, or methods of healing; data sets; algorithms or code (source or object); software; analysis or visualization software tools (to include novel tools as well as modifications of tools that have already been invented) and any other system or process yet to be developed whose nomenclature is therefore not known as of the effective date of this Policy.
  13. **Investigator:** The Program Director (PD), Principal Investigator(s) (PIs), Co-Investigators, and any other team member substantively contributing to the design, conduct, or reporting of:
    - a. sponsored research (funded under external grants, contracts, or cooperative agreements)
    - b. other human subject research, or
    - c. sponsored scholarly, educational, and/or grant-funded program activities."Investigator" is used for the purpose of this policy to collectively indicate individuals whose role could be described as that of an educator, researcher, or investigator. This includes sub-awardees, sub-contractor(s), unpaid collaborators, and consultants as well as any individual whose biographical sketch or curriculum vitae is included in the proposal or whose name appears in the proposal budget (including subcontract budgets). The Investigator, as referred to within this policy, includes the investigator's spouse, domestic partner, and dependent children. The phrase "team member" and "PI/PD" are used interchangeably with Investigator. Where questions exist concerning whether an individual qualifies as an Investigator, the decision will be made by the VP/designee.
  14. **Manage:** Taking action to address a COI, which can include reducing, mitigating, or eliminating the COI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
  15. **Obligatory Interest:** A relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, holding scientific advisory, or governing board membership.
  16. **Obligatory Conflict of Interest (OCOI):** A responsibility or commitment that could directly and substantially affect, or be affected, by the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts, cooperative

agreements, or procurement purchase.

17. **Principal Investigator/Program Director (PI/PD):** Any individual(s) designated by Inova to have the appropriate level of authority and responsibility to direct the project or program to be supported by PHS funding. Inova may designate multiple individuals as PI/PDs who share authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PI/PDs are named, each is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one PI/PD on an application or award does not diminish the responsibility or accountability of any individual PI/PD.
18. **Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic “bench,” human subject research, and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes any scholarly or educational/program activity for which external funding is available through a contract, grant, or cooperative agreement.
19. **Senior/Key Personnel:** The PI/PD and any other team member identified as senior/key personnel in the grant application, progress report, or any other report submitted to the funding agency by Inova.
20. **Significant Financial Interest:**
  - a. A financial interest consisting of one or more of the following interests of the Investigator (including those of the Investigator’s spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the Investigator’s institutional responsibilities:
    - 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, travel); 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;
    - 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
    - Intellectual property rights and interests (e.g., patents, copyrights, trademarks, licensing agreements).
  - b. The term significant financial interest does not include the following types of interests: salary, travel, royalties, or other remuneration paid by Inova to the Investigator if the Investigator is currently employed or otherwise appointed by Inova, including intellectual property rights assigned to Inova and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for or sponsored by a United States 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.
    - *Note: Significant financial interests must always be disclosed if they are performed for organizations or governments outside of the United States.*
  - c. For PHS funded Investigators this also includes 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 an Investigator’s institutional responsibilities that the VP/designee determines constitutes a COI with the funded research.

# **POLICY:**

This policy is divided into sections to describe the responsibilities of the Inova Investigator; the Sub-awardee/subcontractor/consultant who is not a member of the Inova community; and those of the VP/designee.

## **I. Investigator**

### ***Required Training:***

Each Investigator is required to complete conflict of interest training prior to engaging in research or externally-funded educational activities, at least every four (4) years, and immediately when any of the following circumstances apply:

- a. Inova revises its COI policies or procedures in any manner that affects the requirements of Inova Investigators;
- b. an Investigator is new to Inova; or
- c. Inova finds that an Inova Investigator is not in compliance with Inova's COI policy or management plan.

Conflict of Interest (COI) training is provided through the Collaborative Institutional Training Initiative (CITI) for both Inova-employed team members and any Inova affiliates: <https://www.citiprogram.org/>

### ***Responsibility to Disclose:***

#### **A. Financial and Obligatory Interests**

Covered individuals have principal responsibility for avoiding Financial Conflict of Interest. All Covered Individuals who could be involved in sponsored work must disclose annually to the ORI their institutional responsibilities and financial and obligatory interests that could be perceived to be related to any of their institutional responsibilities. In addition, the Covered Individual must list financial and obligatory interests of his/her spouse and dependent children that are related to the Investigator's institutional responsibilities.

Such disclosures must be made, updated, or certified to the VP/designee:

- For PHS-funded activity at least annually
- prior to an application, project, or contract being submitted for proposed funding
- prior to expending funds for a new award (grant or contract)
- upon joining a project/award/contract team engaged in funded research or scholarly and/or educational/program activities funded under external grants, contracts, or cooperative agreements
- Within 30 days if a new significant financial interest is discovered or acquired (e.g., through activity, purchase, marriage, or inheritance)
- upon transfer to Inova of an externally funded award, contract, or cooperative agreement from another institution or entity.

#### **B. Reimbursed or sponsored travel**

Investigators funded by, or involved in the design, conduct, or reporting of PHS-funded research/activities must also disclose the occurrence of any reimbursed travel 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.

The details of this disclosure include:

- the purpose of the trip,
- the identity of the sponsor/organizer,
- the monetary value,
- the destination,
- the duration, and
- additional information requested by the institutional official(s) as it relates to travel

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 VP/designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a COI with PHS-funded research.

During the pendency or the term of an award or contract, investigators are required to update disclosures regarding reimbursed or sponsored travel **within thirty (30) days** of the occurrence of the travel.

## **II. Sub-recipients, sub-awardees, sub-contractor, and consultant responsibilities**

### **Responsibility to Comply:**

Sub-recipients, sub-awardees, sub-contractors, and consultants on sponsored awards, contracts or cooperative agreements are required to comply with all aspects of the PHS COI regulations. In instances that the sub-awardee, sub-contractor, or consultant's organization does not have a federally compliant COI program, they must comply with Inova's COI policies and procedures. Failure to comply with this policy or adhere to a COI Committee management plan may result in termination of participation in the associated project.

### **Methods of Compliance:**

Inova (as an awardee Institution) takes reasonable steps to ensure that any sub-recipient Investigator complies with the PHS conflict of interest policy by written agreement with the sub-recipient with terms that establish whether this policy or that of the sub-recipient will apply to the sub-recipient's Investigators.

- A. If the sub-recipient's Investigators must comply with the sub-recipient's COI policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts. If the sub-recipient cannot provide such certification, the agreement shall state that sub-recipient Investigators are subject to Inova's COI policy for disclosing significant financial interests that are directly related to the sub-recipient's work for Inova;
- B. Additionally, if the sub-recipient's Investigators must comply with the sub-recipient's COI policy per the agreement referenced above, the sub-recipient will report all identified COI to the VP/designee within twenty (20) days. This time period is required to enable Inova to provide timely COI reports, as necessary, to the awarding component.
- C. Alternatively, if the sub-recipient's Investigators must comply with Inova's COI policy, the agreement referenced above shall specify that the sub-recipient must submit to Inova all disclosures of financial and obligatory interests related to the Investigator's institutional

responsibilities within fifteen (15) business days of submission of the grant or contract proposal. Disclosures are to be submitted directly to the VP/designee. This time period is required to enable Inova to comply with its review, management, and reporting obligations in a timely manner.

## **III. Inova Health System**

### **Review of Disclosures:**

Disclosures of financial and obligatory interests and their levels of significance will be reviewed by the VP/designee. The VP/designee shall determine whether an actual or potential COI exists and have the authority to manage or eliminate such COIs by imposing conditions and restrictions (see “Management” section below). The VP/designee is responsible for assuring that determinations are the result of consistently applied guidelines, including, but not limited to, a review of:

- A. the nature of the relationship (including the name of the entity) between the Investigator and the research;
- B. a risk/benefit analysis for human subjects if involved in the research;
- C. the specific role (e.g., patient screening and enrollment; data acquisition, analysis, and interpretation) of the Investigator and consideration of how that role can affect the outcome of the research; and,
- D. the expertise of the Investigator and extenuating circumstances as to why he or she should be involved in the research.

An interest will be determined to be a COI if it exceeds the threshold limits put forth by this policy and it directly and significantly affects, or will be affected by, the design, conduct, reporting, or outcome of the funded research, scholarly, and/or educational activities funded under external grants, contracts, or cooperative agreements.

### **Management:**

Management of an identified COI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Examples of conditions or restrictions that might be imposed to manage or eliminate actual or potential conflict of interest include, but are not limited to:

- public disclosure of COIs;
- disclosure of COIs in informed consent documents;
- disclosure of COIs in publications resultant from research activities;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in specific portion(s) of the funded research that would be affected by the COI or from the research in its entirety;
- divestiture or reduction of significant financial interests; or
- severance of relationships that create actual or potential conflicts.

The Investigator will affirm in writing that he/she agrees to comply with the condition(s) and/or restriction(s) imposed by the VP/designee within ten (10) days of receiving the determination letter or management plan.

Management plans are distributed to all relevant individuals, administrative offices, Service Line leadership, and other units as required by the conditions of the plan, including, but not limited to the Investigator, the Investigator’s supervisor, the Grants Management Office, Human Research Protections Office (HRPO), the IRB of record, Business Office, Legal Counsel, and Office of Sponsored Research Programs.

Investigator compliance with the management plan is subject to monitoring and review by the ORI and the Conflict of Interest Committee within the ORI and/or other Inova compliance offices.

## **Appeals:**

If an Investigator does not agree with the decision of the VP/designee, 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.

## **Retrospective Review:**

Whenever an interest related to funded research, scholarly, and/or educational activities funded under external grants, contracts, or cooperative agreements is not identified or managed in a timely manner including failure by the Investigator to disclose a financial or obligatory interest, or failure by Inova to review or manage an interest, the VP/designee has sixty (60) days to determine if the disclosure constitutes a COI.

If determined to be a COI related to PHS funding, or upon learning that an Investigator failed to comply with a prior COI management plan for PHS-funded research, Inova shall complete a retrospective review of the Investigator's activities within one hundred and twenty (120) days of the discovery of nondisclosure/determination of noncompliance in order to determine whether the research or scholarly activity, or any portion thereof, conducted during the time period of noncompliance, was biased in design, conduct, or reporting.

The retrospective review will include the following documentation at a minimum:

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

Further, regardless of the type of COI or origin of funding, Inova has the option to conduct a similar retrospective review in order to determine if the design, conduct, or reporting of the research or scholarly activity was biased.

Depending on the nature of the interest, the VP/designee may determine that additional interim measures are necessary with regard to the Investigator's participation in the funded research project or scholarly activity until the completion of the Institution's review.

If bias is found, Inova will notify and submit a mitigation report to the awarding component (as required). The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and Inova's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the PHS funded research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Inova will submit COI reports annually for the duration of the funded project, including extensions with or without additional funding.

Further, if the NIH 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 an COI that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the COI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **Enforcement and Sanctions:**

Regardless of funding source, failure to comply with a determination of the VP/designee or failure to comply with this policy will be brought to the attention of the Covered Individual's supervisor, Service Line Leadership, and Institutional Official. 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, contract, 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: (a) formal admonition; (b) ineligibility to engage in Research; or (c) 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.

## **Public Access**

Inova shall make this policy available via a publicly accessible website. Inova shall ensure public accessibility of financial disclosures for PHS-funded research by providing the requestor a written response within five (5) business days of a request for information concerning any significant financial interest held by a Covered Individual and disclosed to Inova that meets the following three criteria:

- A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
- B. Inova determines that the significant financial interest is related to funded research or to scholarly and/or educational activities funded under external grants, contracts, or cooperative agreements; and
- C. Inova determines that the significant financial interest is a COI.

Requests for disclosures must be sent to COI Review, Office of Research at Inova, Grants Management Office, 8095 Innovation Park Drive, Building D, Fairfax, Virginia 22031-4868 or by email to: [gmo@inova.org](mailto:gmo@inova.org). The information provided will include the Investigator's name; the Investigator's 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; and the 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.

## **Advising External Funding Entity:**

The VP/designee will be responsible for advising an external funding entity regarding actual or potential conflict of interest according to the policies/requirements of the external entity. Inova does not disclose information related to potential or actual conflict of interest unless it is required by the awarding entity.

## **Record Retention:**

Records of financial interests, significant financial interests, determinations of the VP/designee, appeals and compliance documents, and documents regarding all actions taken to resolve actual or potential conflict of interest will be maintained by the VP/designee for at least five (5) years following the submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

## **Compliance with Federal Regulations:**

Any regulations promulgated by a governmental agency on conflict of interest will be incorporated by



reference in this policy.

## **References and Related Resources:**

*Inova Health System Human Resources Policies and Procedures*

*Inova [Code of Conduct](#)*

*PHS Grants Policy Statement and Code of Federal Regulations 42CFR50, 42CFR94*

*NSF Grants Policy Manual*

*2 CFR part 376—Nonprocurement debarment and suspension (HHS)*

*42 CFR part 50, subpart D—Public Health Service grant appeals procedure*

*45 CFR part 16—Procedures of the Departmental Grant Appeals Board*

*45 CFR part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*

*45 CFR part 79—Program fraud civil remedies*

*[76 FR 53283, August 25, 2011, as amended at 81 FR 3006, Jan. 20, 2016]*