

Effective Date: August 24, 2012

Revised/Reviewed: October 2015, January 4, 2017, July 12, 2017

Revised Following FCOI 2011 Regulation - 42 CFR Part 50 Subpart F (Grants and Cooperative Agreements) and 45 CFR Part 94 (Responsible Prospective Contractors)

Policy:

Inova must ensure that the integrity of research grants, cooperative agreements and contracts and the safety and/or welfare of research subjects are never subordinate to, or compromised by, financial interests or the pursuit of personal gain. The United States Public Health Service (PHS) 2011 regulations have unique requirements regarding financial conflict of interest (FCOI) reporting and conflict management. In order to ensure compliance with these important regulations, all investigators applying for funds from any PHS agency or from any non-PHS organization that has adopted the regulations are obliged to comply with the requirements of this FCOI Policy.

United States PHS agencies include the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA) and Agency for Healthcare Research and Quality (AHRQ). All PHS agencies require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (42 CFR Part 50, Subpart F) and Responsible Prospective Contractors (45 CFR Part 94)” (FCOI Regulations).

Purpose:

In response to the HHS and PHS Final Rule dated August 25, 2011, Inova’s FCOI Policy will further promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS-supported research grants, cooperative agreements and contracts will be free from bias resulting from investigator conflicts of interest. Concerns are raised when financial considerations may compromise or have the appearance of compromising an investigator's professional judgment and independence in the design, conduct, or publication of PHS-funded projects.

Definitions:

Conflict of interest: Any situation in which financial or personal obligations may compromise or present the appearance of compromising an investigator’s professional judgment in conducting, reviewing or reporting on research or non-research-related projects. This may include, but is not limited to, interests in the research/project itself or in the sponsor (including equity holdings, consulting arrangements, or patent rights), or any other incentives which may bias the collection, analysis, and interpretation of data or negatively impact scientific objectivity and integrity.

Conducting research: Any principal investigator, sub-investigator, or clinical research coordinator involved in designing or directing research projects or protocols; enrolling research subjects (including obtaining subject’s informed consent); making decisions related to eligibility to participate in research; analyzing or reporting research data; or submitting manuscripts for publication about the research.

Covered individual: Any faculty or faculty agent, staff, student, fellow, trainee, or administrator (both Inova employees and Inova-affiliated non-employees) who, under the aegis of the institution or pursuant to the review and approval of the institution’s IRB, conducts research involving human subjects and/or conducts research proposed for funding from federal agencies. Inova includes medical residents and attending physicians in this category.

Investigator: Any Program Director/Principal Investigator (PD/PI) stated in the application and any other personnel who would be responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding, which may include, for example, consultants and unpaid collaborators.

Program Director/Principal Investigator (PD/PI): 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 PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs 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 PD/PI on an application or award does not diminish the responsibility or accountability of any individual PD/PI.

Significant Financial Interest (SFI):

- a. **Publicly Traded Entities:** With regard to any publicly traded entity, an 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.
- b. **Privately Held Entities:** With regard to any non-publicly-traded entity, an 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, domestic partner or dependent child) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- c. **Intellectual Property:** With regard to intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests.
- d. **Travel Reimbursements:** With regard to 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 his or her institutional responsibilities in the twelve months preceding the disclosure; 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.
- e. The definition of an SFI does not include: 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; 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; 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 income from service on advisory committees or review panels for a Federal, state, or local government agency, from an institution of higher education as defined at 20 U.S.C. 1001(a), or from an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- f. With respect to research involving human subjects, SFI shall include cases involving any amount of remuneration and any equity ownership. See also IOR 2.21.

Institutional Responsibilities: An investigator's professional responsibilities on behalf of the institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards.

Policy Instructions/Explanations For Disclosure Procedures

1. Mandatory Training Requirements
 - (a) The Grants Management Office (GMO) shall be responsible for ensuring that each investigator is informed about
 - (i) Inova's FCOI Policy;
 - (ii) the investigator's responsibilities regarding disclosure of Significant Financial Interests (SFIs) relating to the investigator's institutional responsibilities; and
 - (iii) PHS FCOI Regulations.
 - (b) In accordance with FCOI Regulations, GMO requires each investigator to complete a mandatory training module prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies:
 - (i) This FCOI Policy, the PHS Financial Disclosure Form or the GMO procedures are revised in any manner that affects the requirements of the investigators;
 - (ii) An investigator is newly appointed at Inova;
 - (iii) Inova finds that an investigator is not in compliance with this FCOI Policy or management plan.
 - (c) The FCOI training is provided through Collaborative Institutional Training Initiative (CITI) for both Inova personnel and any Inova affiliates: <https://www.citiprogram.org/>
2. Disclosure, Review and Monitoring Requirements
 - (a) Inova's GMO requires investigators planning to participate in PHS-funded research to complete an electronic PHS Financial Disclosure Form using an online system. .
 - (b) The PHS Financial Disclosure Form shall document information that the investigator will submit no later than the time the respective application is submitted to PHS; at least annually during the period of the award; and within 30 days of discovering or acquiring a new SFI. The lead PD/PI on a proposed PHS application for funding is responsible for obtaining a PHS Financial Disclosure Form for all participating investigators/key personnel.
 - (c) Inova's GMO will solicit and review disclosures of SFI(s) of the investigator and those of the investigator's spouse, domestic partner or dependent child related to an investigator's institutional responsibilities.
 - (d) The occurrence of any reimbursed or sponsored travel related to the investigator's institutional responsibilities must be disclosed, UNLESS the reimbursed or sponsored travel is by a federal, state, or local government agency, or an institution of higher education as defined by 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.
 - (e) Inova's PHS Financial Disclosure Form conforms to Inova's FCOI regulation requirements. For SFI (a) –(c), above, the disclosure must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one without a readily determined value, and any supporting documentation as determined by the designated official(s) from Inova's GMO as needed to make a determination of whether an FCOI exists (such as a copy of the applicable consulting agreement or stock purchase agreement). For SFI (d), above, the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value. In addition, the investigator must cooperate with all requests from the applicable PHS Awarding Component for additional information as needed. All such internal disclosures shall be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information.
 - (f) The investigator shall update the disclosure during the period of the award at least annually. One annual disclosure will suffice to cover all ongoing PHS awards. With respect to transfers, an annual disclosure shall be made to Inova's GMO promptly to support acceptance of the appointment or employment at Inova. The reporting and management plan requirements

described in Management of Financial Conflicts of Interest (Section 4) shall then be required to be completed prior to expending any funds under a PHS-funded grant, cooperative agreement or contract. In addition, an investigator participating in PHS-funded research shall submit an updated PHS Financial Disclosure Form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. An investigator who is new to participating in PHS-funded activities shall submit a PHS Financial Disclosure Form at the time the investigator is identified as a possible participant in a PHS-funded research project, such that training can be completed and timely reporting of a FCOI (if any) can be made to the respective funding agency. The PHS Financial Disclosure Form shall notify the investigator of this requirement to provide updated disclosures.

- (g) All disclosures are required to be reviewed by Inova's GMO and/or an Inova Authorized Official(s) in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the SFI can be made, a management plan can be developed and all the necessary reviews and approvals can be secured. This process will ensure that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that an FCOI (as defined in Maintenance of Records, Section 9) exists. The investigator's timely cooperation with the efforts of the designated institutional official(s) is needed to ensure timely reporting. Upon failure to make timely reporting to the PHS funding agency of an FCOI, Inova is required under the FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project.

3. Management of Financial Conflicts of Interest

- (a) Inova's GMO will solicit and review PHS Financial Disclosure Forms from each investigator planning to participate in, or participating in, PHS-funded research.
- (b) Inova's GMO, with the help of an objective Conflict of Interest (COI) Committee (described below), will review all PHS Financial Disclosure Forms and determine whether an investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. An investigator's SFI is related to PHS-funded research when the COI Committee reasonably determines that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. An FCOI exists when the COI Committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In making the determination, the designated institutional official(s) can take into account financial interests in that same entity related to PHS or other federally funded research disclosed in an earlier disclosure by the investigator.
- (c) The following examples illustrate when an investigator would be deemed to have an FCOI:
 - (i) if the investigator (together with the investigator's spouse, domestic partner or dependent child) has an SFI in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or
 - (ii) the investigator (together with the investigator's spouse, domestic partner or dependent child) has an SFI in an entity that licenses technology from Inova which has resulted in license income and the technology being the subject of a proposed PHS-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.
- (d) Following initial review by Inova's GMO, all cases involving the disclosure of an SFI having a value greater than \$5,000 in value (measured by aggregating the various categories of interests reported) shall be submitted to the Inova's designated institutional official(s) or Research Integrity Committee (RIC) Chair (IOR 2.22) for consideration for expedited or full review by a COI Committee (depending on the level of financial interest involved). Following initial review by Inova's designated institutional official(s), for all cases involving the disclosure of an SFI having a value less than \$5,000, the designated institutional official(s) shall be responsible for determining whether the potential FCOI can be managed and, if approved by the designated institutional official(s), the necessary components of the management plan.

- (e) When Inova's designated institutional official(s) or the RIC Chair determines that a full COI Committee needs to review the COI, the COI will either be referred to the next RIC meeting or the RIC Chair will convene a special meeting of the RIC committee. The RIC Committee is a sub-set of the Executive Research Oversight Committee, and members of the COI Committee will be selected from the RIC membership, along with any needed content experts, to serve as an Ad Hoc COI Committee. An example of recommended composition for a COI Committee:
 - (i) a representative from Compliance;
 - (ii) a representative from Legal;
 - (iii) a representative from Grants Management Office;
 - (iv) a representative from Human Research Protection Program;
 - (v) the Vice President for Research for IHS or designee; and
 - (vi) at least two Covered Individuals.
 - (vii) Any individual who has a conflicting interest shall be prohibited from participating in the COI Committee.
 - (f) The COI Committee will decide upon one of the following dispositions of the case: approval, approval with conditions or restrictions, or prohibition. All conflicts which are approved shall include a management plan which shall be implemented by GMO.
 - (g) The standards for review differ between Inova's Conflict of Interest Policy (IOR 2.21) and this FCOI Policy (and the FCOI Regulations). The standard for review under IOR 2.21 is the existence of an actual or potential conflict between the personal interests of a covered individual and the interests of Inova or the public or simply the reasonable appearance of such a conflict to the public (defined as a "Conflict of Interest"). The standard for review under this FCOI Policy (and the FCOI Regulations) is whether an FCOI exists. This FCOI Policy shall govern the disclosure, management and reporting of FCOIs for PHS funded studies at Inova.
 - (h) For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
 - (i) public disclosure of SFIs;
 - (ii) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 - (iii) modification of the research plan;
 - (iv) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (v) reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - (vi) severance of relationships that create financial conflicts. Additional conditions and restrictions (including a lower threshold for review) shall apply to cases involving human subjects as provided under the Human Research Protection Program guidelines.
 - (i) For all management plans, GMO is required to monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
4. Reporting Requirements to PHS
- (a) Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, Inova must report to the applicable PHS funding agency the existence of any FCOI and assure that Inova has implemented a management plan in accordance with the FCOI Regulations and the Conflict of Interest Policy. If Inova identifies an FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, Inova is not required to submit an FCOI report to the respective agency. The requirements of the FCOI Regulations do not apply to PHS-funded Phase I Small Business Innovation Research Grant (SBIR) or Small Business Technology Transfer Grant (STTR) funding; instead, those financial interests are subject to disclosure and management under the Conflict of Interest Policy and any other applicable Inova procedures.
 - (b) For any FCOI reported to the respective agency relating to an ongoing PHS-funded research project, an annual report that conforms to the requirements of the FCOI Regulations shall be made to the applicable funding agency by Inova for the duration of the research project in the time and manner specified by the applicable funding agency.

- (c) For any SFI that Inova identifies as being an FCOI subsequent to Inova's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new SFI received by the investigator during the ongoing research project, or an SFI held by an investigator who is new to the research project. However, if that FCOI is one that was not made in a timely manner to the applicable funding agency, for whatever reason, Inova is required under the FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports must be made in accordance with the requirements of the FCOI Regulations.
 - (d) The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations. The FCOI Regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.
 - (e) Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, Inova shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning an SFI which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be an FCOI. The information shall consist of the information required to be provided under the FCOI Regulations.
5. Enforcement Mechanisms, Remedies And Noncompliance
- (a) If an investigator fails to comply with this FCOI Policy (see Appendix A) or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, Inova, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action to be taken. In every respect, Inova shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding or requiring Inova to take further action to maintain the objectivity of the research.
 - (b) For clinical research projects supported by PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with an FCOI that was not properly disclosed or managed as required under the FCOI Regulations, Inova must require the investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.
 - (c) All persons subject to this FCOI Policy are expected to comply with it fully and promptly. Whenever an investigator has violated this FCOI Policy, for example by failure to disclose an SFI, GMO may refer the matter to the appropriate Authorized Official for disciplinary or other appropriate action.
 - (d) Violations of this FCOI Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective Inova policy and procedures governing allegations of research misconduct.

6. Subrecipient Requirements

- (a) All proposed subrecipients of funds under Inova-led PHS-funded research shall have an FCOI Policy that conforms to the requirements of the FCOI Regulations. With respect to these subgrantees, subcontractors, and collaborators, Inova's GMO must require these entities to enter into a written agreement and make a certification to Inova at the time of award that its FCOI Policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.
- (b) Inova will report to the PHS funding agency any FCOI which is identified by any subgrantee, subcontractor, or collaborator to Inova in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

7. Disclosure Procedures

- (a) Prior to Inova's expenditure of any funds under PHS-funded research, Inova shall ensure public accessibility, via a written response within five (5) business days of a request (request should be sent to FCOI Review, Grants Management Office, 5580 Port Royal Road, Springfield, VA 22151), of information concerning any SFI disclosed to Inova that meets all of the following three criteria:
 - (i) The SFI was disclosed and is still held by the investigator(s) for the PHS-funded research project identified by Inova in the grant application, progress report, or any other required report submitted to PHS;
 - (ii) Inova determines that the SFI is related to the PHS-funded research;
 - (iii) Inova determines that the SFI is an FCOI.
- (b) The information that Inova makes available via a written response shall include, at a minimum, the following:
 - (i) Investigator's name;
 - (ii) Investigator's title and role with respect to the research project;
 - (iii) Name of the entity in which the SFI is held;
 - (iv) Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.); and
 - (v) Approximate dollar value of the SFI (dollar ranges are permissible: \$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.

8. Sanctions and Penalties

Sanctions and penalties for those that knowingly and willfully disregard this policy, or refuse to comply with its terms, will be determined by the COI Committee. Sanctions will include, but are not restricted to:

- (a) letter of reprimand,
- (b) inclusion in staff member's file of a letter indicating that the staff member's good standing as a researcher has been called into question
- (c) notification to funding agencies and/or professional journals or societies
- (d) termination of research project
- (e) suspension
- (f) termination

9. Maintenance of Records

Inova is required pursuant to the FCOI Regulations to maintain all PHS Financial Disclosure Forms and all related records of actions taken by Inova with respect to disclosures of financial interests for a period of three (3) years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

INOVA OFFICE OF RESEARCH

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

IOR 5.09

Approved by Executive Research Oversight Committee on July 12, 2017:

Zobair Younossi, MD, MPH
Vice President for Research
Inova Health System

Date

INOVA OFFICE OF RESEARCH

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

APPENDIX A

IOR 5.09A

Notification of FCOI Non-compliance

1. Principal Investigator (PI) receives initial email from GMO regarding failure to comply with FCOI Disclosure Form and/or CITI Training. Email is sent with a read receipt and five day turnaround response time. A copy is sent to the GMO project lead.
2. If still non-compliant after first notice, PI receives second notification from GMO with five day turnaround response time. A copy is sent to the GMO project lead, department chair, and research manager. Project lead telephones investigator.
3. If still non-compliant, PI receives third and final email from GMO with five day turnaround response time. Project lead telephones department chair and research manager.
4. Non-compliant investigators are reported to the Research Integrity Committee (RIC) and the Vice President of Research.

Potential Consequences

1. Application process halted
2. Funds withheld
3. Issues reported to department chair