Corporate Compliance Program

Subject:	Financial Conflicts of Interest in Research	**Effective Date:**	4/1/2026
Section:	Research Compliance	**Supersedes Policy Date:**	4/1/2025
Number:	3	**Review Date:**	3/1/2026

Table of Contents

I. Policy

Investigators actively engaged in research at Atlantic Health System ("Atlantic Health") must conduct their research in accordance the Food and Drug Administration (FDA), Public Health Services (PHS) including the Office of Human Research Protections (OHRP) within the National Institutes of Health (NIH) regulations, other applicable laws and regulations and with Atlantic Health policies.

Atlantic Health requires objectivity and integrity in the conduct of all clinical research through the diligent identification, investigation, monitoring, and resolution of conflicts of interest, actual or apparent, that involve research personnel.

The purposes of this policy are to (i) ensure compliance with laws, regulations and policies, (ii) describe the process for disclosure of potential financial conflicts of interest related to research activities, and (iii) set forth the process to be followed to manage, reduce or eliminate financial conflicts of interest in research conducted at Atlantic Health.

Disclosures required by this policy are in addition to any other disclosures required by Atlantic Health's Corporate Compliance policy(ies).

II. Definitions

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any such person has an ownership or equity interest.

Financial Conflict of Interest ("FCOI") means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of a research study.

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

Institution means, for purposes of this policy, Atlantic Health.

Institutional Responsibilities mean an Investigator's professional responsibilities on behalf of Atlantic Health, which may include research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator means the project director, principal investigator, sub-investigator, research coordinator, study team member and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research. For purposes of the requirements of this policy relating to financial interests, "Investigator" also includes:

- Investigator's spouse and dependent children

- Subrecipients, subgrantees and collaborators

Research Integrity Officer ("RIO") means the person (or his/her authorized designee) responsible for reviewing and managing FCOIs under this policy.

Significant Financial Interest ("SFI")

1. **Significant Financial Interest** means a Financial Interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator's Institutional Responsibilities:
    a. 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. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); and 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. 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 holds any equity interest (e.g., stock, stock option, or other ownership interest).
    c. Intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests.
    d. 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 the Investigator's Institutional Responsibilities; provided, however, that SFI does not include such reimbursed or sponsored 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. Financial Interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).
2. **SFI does not include** the following types of financial interests:
    a. salary, royalties, or other remuneration paid by Atlantic Health to the Investigator if the Investigator is currently employed or otherwise appointed by Atlantic Health, including intellectual property rights assigned to Atlantic Health and agreements to share in royalties related to such rights;
    b. 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;
    c. 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

d. income from service on advisory committees or review panels for 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.

Sponsor means an individual or entity who initiates a clinical research investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical research investigation or has initiated a research-related idea or concept is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

III. Procedures

Disclosure Process

1. All individuals who are planning to participate or who are participating as an Investigator in research at Atlantic Health must comply with federal regulations and this policy and disclose all Financial Interests that could reasonably be related to their Institutional Responsibilities, as follows:
    a. At or before the time of application for PHS-funded research
    b. At or before the time of initial submission of a sponsored or federally funded study to the Atlantic Health Institutional Review Board ("IRB")
    c. At least annually while a sponsored or funded study is being conducted at an Atlantic Health facility
    d. Within thirty (30) days after discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
2. When an investigator discloses financial interest in an entity sponsoring or funding a study in which the investigator is participating, the RIO and/or authorized designee shall review the disclosures according to the review process set forth below.

Review Process

1. The RIO and/or authorized designee shall review all disclosures that meet the SFI threshold or criteria and may reasonably appear to be related to the proposed research project and may request the Investigator to submit additional documents, statements, or information (e.g., copies of any contracts, sponsor agreements, grants, leases, licensing agreements, corporate organization documents, equity subscription agreements, equity option agreements, warrant agreements, stockholder agreements, and/or documents setting forth the current or potential terms of any disclosure) and/or to answer questions relating to the disclosure. A SFI in/with an Entity would reasonably appear to be related to an Investigator's research study in circumstances such as, but not limited to, the following:

a. Entity is provider of materials or products for the research or is a licensee with improvement rights to technology likely to arise out of the research
b. Investigator or Entity has financial interests that could reasonably be considered to have potential influence on the design, conduct or reporting of the research
c. Entity has reasonable possibility of being financially affected by the research
d. Entity sponsors research at Atlantic Health in which the Investigator is involved
e. Entity makes gifts to Atlantic Health that benefit Investigator's research

2. The RIO and/or authorized designee shall review all relevant documents, statements and information for each disclosure and determine, within thirty (30) days after receipt of disclosure information: (1) whether a FCOI exists, and (2) if so, what is the appropriate action that must be undertaken to manage, reduce or eliminate the FCOI.

Actions and Recommendations to Manage, Reduce or Eliminate Financial Conflicts of Interest

1. If the RIO determines that an Investigator has a FCOI, the RIO may impose conditions or restrictions to eliminate the FCOI or develop and implement a management plan that specifies actions to be taken to manage such FCOI, which plan may include the following:

    a. Require public disclosure of the FCOI, including a disclosure to the human subjects participating in the Study;
    b. Monitor the study with independent reviewers including transferring oversight jurisdiction of the study to another IRB;
    c. Require modification of study plan;
    d. Require elimination of Investigator's FCOI;
    e. Require severance of the arrangement between the Investigator and the party(ies), including the Sponsor, that created the actual or potential FCOI; and/or
    f. Take such other action that the RIO determines to be appropriate.
2. The RIO shall communicate the findings and recommendation in writing (typically referred to as the "Management Plan") to the IRB and to the Investigator within fifteen (15) days following the RIO's determination.
3. For PHS funded research, if the RIO determines that an Investigator has a FCOI (i.e., SFI that relates to PHS-funded research and could directly and significantly affect the design, conduct or reporting of the PHS-funded research), then PHS agencies will be notified of the Management Plan according to the procedures described below.

Reporting Financial Conflicts of Interests to PHS Agencies

1. For research funded under a PHS award or cooperative agreement, if the FCOI has not been eliminated prior to expenditure of funds, the RIO shall provide the Management Plan to the appropriate PHS agency regarding any Investigator's SFI found to be a FCOI as follows:

a. prior to expenditure of funds
b. within sixty (60) days after identifying a new disclosed FCOI
c. at the same time as when the grantee submits an annual progress report, (i.e. report annually for the duration of the project period (including extensions with or without funds)), addressing the status of the Financial Conflict of Interest and any changes to the Management Plan and whether the disclosed FCOI is still being managed, or explain why the disclosed FCOI no longer exists
d. upon determinations of Investigator non-compliance with requirement to disclosure SFIs
e. upon the failure of the institution to review an existing SFI

2. Should a FCOI be discovered while research is ongoing, then for PHS funded research, Atlantic Health must, within sixty (60) days, submit a report to the PHS entity, describing the conflict and the Management Plan implemented. Atlantic Health must complete and document a retrospective review within one hundred twenty (120) days to determine if any research conducted prior to the discovery of the conflict was biased and, if such research was biased, Atlantic Health must submit a mitigation report to PHS. The mitigation report must include elements a-c of the Management Plan components below, plus reasons for the retrospective review, methodology used for the retrospective review, findings of the retrospective review, conclusions of the retrospective review, and a description of the impact of the bias on the research project and Atlantic Health's plan of action to eliminate or mitigate the effect of the bias.
3. The Management Plan which must be sent to PHS pursuant to this policy must include, at a minimum:
    a. Project number and project title;
    b. Project Director or Principal Investigator contact;
    c. Name of the Investigator and name of the Entity with which the Investigator has the FCOI ;
    d. The nature and approximate value of the Financial Interest; or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
    e. A description of how the Significant Financial Interest relates to the PHS-funded research and the basis for the Institution's determination of existence of the FCOI; and
    f. A description of the key elements of Atlantic Health's Management Plan, including:
        i. Role and principal duties of the conflicted Investigator in the research project
        ii. Conditions of the Management Plan
        iii. How the Management Plan is designed to safeguard objectivity in the research project
        iv. Confirmation of the Investigator's agreement to the Management Plan
        v. How the Management Plan will be monitored to ensure Investigator compliance

Violations of the Financial Conflict of Interest Policy

1. If the RIO has reasonable cause to believe that an Investigator has failed to disclose information on an actual or potential FCOI, or that for whatever reason a SFI was not timely reviewed during an on-going research project, the RIO shall inform the Investigator of the basis for such belief and, as applicable, afford the Investigator an opportunity to explain the alleged failure to disclose or comply.
2. If the RIO determines that the Investigator has failed to disclose meaningful information on an actual or potential FCOI, then the RIO shall notify the Institutional Official ("IO") and IRB Chair and/or designee and convene a meeting to evaluate the situation.
3. If the RIO determines that the Investigator has failed to comply with this policy, including with the RIO's instructions on managing, reducing or eliminating the FCOI, the RIO shall:
    a. Notify the IO and IRB Chair or authorized designee;
    b. Take such actions necessary to protect the integrity of the data and the safety of the human subjects participating in the study in a manner consistent with this policy; and/or
    c. Notify the Sponsor of the study, if applicable.

Subrecipient Requirements

When Atlantic Health is the primary awardee of a Public Health Service ("PHS")-funded project, it must assure that the Financial Interests of all subrecipients are reviewed and that FCOIs are eliminated or managed properly. During the proposal stage and during the negotiation of a subaward, all subrecipients/potential subrecipients of PHS funding will be required to certify that:

- The subrecipient institution has a policy in place to review and manage FCOI that meets regulatory requirements, and
  The subrecipient's policy applies to the sub-awarded portion of the research project and all subrecipient's investigators.
- The subrecipient agreement will require subrecipient to timely identify and create a management plan for any FCOI identified and submit to Atlantic Health for required reporting purposes.

If the sub-awardee institution does not have a FCOI program in place, the agreement must indicate that the subrecipient will follow this policy, including the pre-award and annual submission of a "A-133 Audit Certification" (and disclosure, if applicable) to Atlantic Health.

Education Requirements

All investigators participating in research are informed of this policy and their responsibilities regarding disclosures of Financial Interests. Additionally, each Investigator will receive information about applicable regulations and will participate in training on this policy. Prior to engaging in research at Atlantic Health, all investigators must complete CITI Training Modules and training must be repeated periodically as required by Atlantic Health.

Recordkeeping and Record Retention

1. Financial Interest disclosure forms and any other documents submitted by the Investigator and copies of the documents setting forth the determination and actions taken by the COI Committee must be maintained.
2. The records are maintained as required by the Atlantic Center for Research Policy, POL-CO-001, Research Records Retention, Archiving and Destruction
3. These records shall be made available, upon request from a properly authorized officer or employee of PHS or FDA, at reasonable times, to permit such officer to have access to and copy and verify these records.

IV. Specific Responsibilities

The following individuals have roles in this policy:

1. RIO and authorized designee
2. IO
3. IRB Chair and authorized designee

V. References

45 C.F.R. 94 Responsible Prospective Contractors
42 C.F.R. 50 (Subpart F): Promoting Objectivity in Research
21 C.F.R. 54: Financial Disclosure by Clinical Investigator
Atlantic Health Legal/Ethical Compliance Policy 2-07, Conflicts, Gifts & Endorsements
Atlantic Center for Research Policy, POL-ADM-002, Research Records Retention, Archiving and Destruction

VI. Revision History

4/1/2025
4/1/2024
4/1/2023
4/1/2022
4/1/2021
5/1/2020
4/1/2019
6/1/2018
Replaces Corporate Compliance Policy, 5-04 Financial Conflict of Interest, effective 12/1/2010, revised 4/1/2017
4/1/2016
4/1/2015
4/1/2014
5/20/2013
7/1/2012
10/1/2011
12/1/2010, New Policy


4/8/2026

Wayne A. McNulty, JD
Vice President, Compliance & Internal Audit
Chief Compliance, Privacy, Internal Audit & Research Integrity Officer