Policy / Procedure:

Identifying and Managing Investigator Conflicts of Interest in Research

KEY TERMS: Awardee, COI, Conflict of Interest, Collaborating Institution, External Investigator, FCOI, Financial Conflict of Interest, FDA, Financial Interest, Funding, Grant, IRB, National Institutes of Health, NIH, PHS, Principal Investigator, Public Health Service, Research, Subrecipient

I. PURPOSE:

This policy outlines the standards and procedures to ensure that the design, conduct, and reporting of research activities will not be compromised by any conflicting interest on behalf of the Principal Investigator(s), External Investigator(s), or other Key Research Personnel through implementing a system for the identification, disclosure, evaluation, management, reduction, and/or elimination of potential Conflicts of Interest in accordance with applicable local, state, and federal laws and regulations as well as Carilion Clinic Policy.

II. SCOPE/FACILITY/DEPARTMENT:

This policy applies to all members of Carilion Clinic workforce, or its affiliates, who conduct research on behalf of Carilion Clinic. Such personnel include, but are not limited to contracted faculty and staff, volunteers, and fellows. When Carilion conducts research with External Investigators from other institutions, the disclosure requirements of this policy will only apply in instances in which the non-Carilion institution does not possess a Public Health Service (PHS)-compliant Financial Conflict of Interest (FCOI) policy or Carilion Clinic, and the collaboration institution agree in writing to follow *Carilion's Conflicts of interest in Research Policy*.

III. POLICY STATEMENT(S)

I. The mission of Carilion Clinic is to improve the health of the communities we serve by providing patient-centered care, supporting excellence in medical education, and accelerating clinical and translational research. Consistent with this mission, Carilion Clinic and its affiliates will collaborate with partners in industry, government, academia, and other organizations to accomplish goals. Throughout these collaborations, an array of business ventures can occur, including employment opportunities, honoraria, equity interests, etc., to which a conflict of interest may arise. A conflict of interest may be actual, apparent, or potential. Conflicts of interest in research require careful navigation to preserve the integrity of research conducted and to ensure the safety of those participating in research at Carilion Clinic.

Carilion Clinic has adopted the Conflict of Interest standards of the Public Health Service (PHS) for all its research activities, committing to the highest ethical standards with respect to conflict of interest in research. Any potential conflicts of interest must be disclosed at the time any research is submitted to the Department Chair for review, or before funding is applied for or expended.

The disclosure of a potential conflict of interest does not, in itself, constitute an actual conflict of interest, nor does it imply that the disclosed interest is inconsistent with regulatory requirements.

IV. PROCEDURE:

1. Situations or Relationships in which a Conflict of Interest in Research May Arise:

Under this policy, potential conflicts of interest in research arise when an Investigator or Key Research Personnel has a financial or personal interest in a specific research study, sponsor, collaborating institution, company or individual. Examples include but are not limited to:

a. An arrangement between an Investigator or Key Research Personnel with a sponsor, company or institution including;
    i. Employment;
    ii. Holding executive positions or serving on advisory boards;
    iii. Receiving honorarium(-ia) for consulting, advising, or participating in speaker's bureaus;
    iv. Having Intellectual Property rights (e.g. patents, copyrights, royalties);
    v. Having equity interests, such as stocks, stock options, or ownership interests; or
    vi. Receiving any gifts, courtesies, or travel expenses paid on their behalf;
b. An Investigator's Financial Interest in agencies, organizations, and associations, which have the potential to influence or affect the applicable research study;
c. A loan between the Investigator and a sponsor of a research study;
d. A grant scholarship or other financial assistance between the Investigator and a sponsor of a research study; or
e. An Investigator's Family Member or business relationship interest in any of the above.

These examples are not exhaustive. Conflicts of interest in research may arise in other situations. The Compliance Office is available to discuss specific concerns.

2. Disclosure:

All individuals required to complete Carilion Clinic's Annual Conflict of Interest Questionnaire must disclose any potential conflicts of interest. Previously disclosed conflicts must be reaffirmed on the Questionnaire as well. Disclosures and reaffirmations via the Conflicts of Interest Questionnaire are required at the following times:

a. Within fourteen (14) days of starting work at Carilion Clinic;
b. At the time of joining a research study as Key Research Personnel;

c. At the time of an application for research funding;
d. At the time of an IRB application or amendment;
e. Within thirty (30) days of:
    i. A new potential conflict arising;
    ii. A change to a potential conflict;
    iii. The elimination of a previously disclosed conflict;

Information provided in the Annual Conflict of Interest Questionnaire will remain confidential to the extent allowable by applicable laws and regulations.

3. Review of Conflict of Interest Disclosures:

PHS-funded Institutions are required by federal regulations to appoint a COI Official whose responsibilities are to solicit and review Financial Interests in PHS-sponsored research. The Carilion Clinic Chief Compliance Officer serves in that capacity, and the designated Compliance staff are responsible for reviewing relevant conflicts of interest and Financial Interests disclosed on the annual Conflict of Interest Questionnaire. Upon review, each disclosure will be categorized as either not a conflict which requires no further action, or as a conflict of interest which requires management.

Conflicts of interest requiring management that do not meet the regulatory threshold of a Significant Financial Interest (SFI) will be managed by the Compliance Office. Conflicts of interest that meet the regulatory threshold as a SFI will be referred to the Research Conflict of Interest Committee (RCOIC) for review and management. The Compliance Office reserves the right to refer non-significant conflicts of interest to the RCOIC for review at their discretion.

4. Managing Conflicts of Interest or Financial Interests:

After disclosure review and once a conflict of interest is categorized as requiring management, an appropriate Conflict of Interest Management Plan will be developed. A Conflict of Interest Management Plan outlines the specific actions that are to occur to mitigate, reduce, or eliminate the conflict to ensure research integrity and compliance with regulations. These actions may include but are not limited to:

a. Public disclosure of the conflict of interest (e.g. when presenting or publishing);
b. Disclosure of the conflict of interest to human subject participants in the informed consent form;
c. Appointment of an independent monitor;
d. Modification of the research study;
e. Change of personnel or personnel responsibilities, including exclusion of personnel form participating in some or all of the research;
f. Reduction or elimination of the Financial Interest (e.g. sale of equity);
g. Severance of relations that create conflicts of interests or Financial Interests; or
h. No administrative approval for a research study.

The Compliance Office will oversee adherence to Conflict of Interest Management Plans and reserves the right to modify plans as needed.

5. Reporting Requirements to the National Institutes of Health (NIH):

The National Institutes of Health (NIH) requires recipient institutions and their Investigators (except Phase I SBIR/STTR applicants and recipients) to fully comply with 42 CFR Part 50, Promoting Objectivity in Research (FCOI regulation). When submitting a federal grant application or receiving a grant, a signature of the Authorized Organization Representative (AOR) is required, certifying that Carilion Clinic is in full compliance with all FCOI regulations including:

a. Existence of institutional policy and process including up-to-date written and enforced administrative process and policy to identify and manage FCOI for all NIH-funded grants and cooperative agreements (excluding Phase I SBIR/STTR) applications and awards.
b. Accessibility of institutional policy and submission to NIH including this policy being available on Carilion's public facing website.
c. Institutional training of Investigators about FCOI regulations, the institution's policy, and the investigators responsibility to fully disclose all SFIs.
d. Investigator disclosing all SFIs related to their institutional responsibilities.
e. Carilion's designated official (Compliance Office) reviews each investigator's SFI disclosure to determine if SFI is related to NIH-funded research.
f. When Carilion determines that an FCOI exists, Carilion must report to the NIH awarding Institute an initial and annual FCOI report using the eRA commons.
g. Carilion maintains records related to Investigator disclosures of Financial Interests and the review of, response to and determination of an FCOI.

Prior to the expenditure of any funds under a PHS-funded research study, the Carilion Clinic Office of Research and Development and the Carilion Clinic Department of Medicine Clinical Research Unit will consult the Compliance Office to determine whether an FCOI exists. If an FCOI exists, the Compliance Office will provide an FCOI report for the conflicted Investigator(s) to include the applicable Conflict of Interest Management Plan to the PHS Awarding Component. The Compliance Office will provide additional FCOI reports to the PHS Awarding Component for any newly identified FCOIs during the PHS-funded research study including any new Conflict of Interest Management Plans within sixty (60) days of disclosure. Additionally, for ongoing PHS-funded research with an identified FCOI, annual FCOI reports will be made to the PHS Awarding Component by the Compliance Office that address the status of the FCOI and any changes to the Conflict of Interest Management Plan.

6. Subrecipients:

When Carilion Clinic is a primary awardee or subrecipient and engages a subrecipient to assist in funded research, a written agreement will be put into place identifying whether Carilion's Conflict of Interest Policy will be followed by the subrecipient, or if that of the subrecipients will apply to the subrecipients Investigators. This determination is made on a case-by-case basis. If a determination is made that the COI policy of the subrecipient will be followed, the subrecipient will certify as a part of the agreement that its policy complies with 42 CFR 50, Subpart F. 50.604. Additionally, as a part of the agreement, the subrecipient will report all identified COIs to Carilion in a timely manner. If the subrecipient agrees to follow Carilion's COI policy, the subrecipient

Investigators are responsible for reporting disclosures to Carilion Clinic via Carilion's Conflict of Interest Questionnaire. Any disclosures will be managed according to this policy.

7. Consequences of Noncompliance:

If a conflict of interest is not disclosed, identified or managed in a compliant and timely manner, the Compliance Office will initiate a retrospective review within 120 days of the discovery of noncompliance and report findings to any PHS Awarding Component as applicable. The COI Official or designee will conduct and document the retrospective review to include the following elements:

a. Reasons for the review;
b. Research study title number, and Principal Investigator;
c. Name of Investigator(s) with the COI;
d. Method for completing the review;
e. Nature and value of the COI;
f. Findings and conclusion of the review (including whether the research study is able to continue);
g. Conflict of Interest Management Plan to be implemented.

The Compliance Office may determine that interim measures are necessary regarding the Investigator's participation in the study. The Compliance Office may consult the RCOIC as necessary. The Compliance Office will update and previously submitted FCOI reports as necessary.

8. Training Requirements:

All Carilion Clinic Investigators participating in funded research are required to complete COI training via the CITI Program prior to IRB approval of the study and or prior to approval of the Investigator being added as key study personnel to an already IRB approved study. This training must be renewed every four (4) years. Investigators must make an account with the CITI Program, affiliate their account with Carilion Clinic, and add the COI modules to their account for completion. The CITI Program is accessible via Research, Ethics, Compliance, and Safety Training.

9. Public Accessibility Requirements:

42 CFR Part 50.604 mandates institutions maintain an up-to-date, written, enforced policy on FCOIs that complies with the subpart, and make such policy available via publicly accessible website. Members of the public can access this policy via Carilion Clinic's public facing website. Additionally, members of the public may contact Carilion Clinic's Compliance Office at researchcompliance@carilionclinic.org to request information concerning any related FCOIs that have been identified and are still held by PHS-funded Investigators. The Compliance Office will provide the following details pertaining to any identified FCOIs:

a. Investigator's name, title with respect to the involved research study;
b. Name of the entity in which the FCOI is held;
c. Nature of the FCOI (e.g. honorarium, travel reimbursement, equity, etc.);

d. And approximate dollar value range of the FCOI or a statement that the interest is one whose value cannot be readily determined.

V. OTHER ISSUES / CONCERNS:

N/A

VI. DEFINITIONS:

Conflict of Interest (COI): A situation in which an Investigator's, and/or their Family Member's financial, professional, or other personal considerations may directly or indirectly affect, or reasonably appear to affect, the Investigator's professional judgement in performing their Institutional Responsibilities. A Conflict of Interest may be actual, apparent, or potential.

***de minimis* Threshold:** The minimum threshold for which an Investigator must disclose Financial Interests.

Equity Interest: The ownership share of an individual in a public or private business.

Executive Position: Any position that is responsible for a material part of the operation or management of an organization, which includes but is not limited to, Chief Executive Officer, Chief Operations Officer, Chief Scientific Officer, Chief Medical Officer, Chief Information Officer, Chief Technology Officer, Scientific Director, or Medical Director.

Family Member: For purposes of this Policy, the Investigator's spouse/domestic partner and/or any individual who is related by blood or adoption (e.g., dependent children) to the Investigator.

FCOI Report: Carilion's report of a Financial Conflict of Interest to a PHS Awarding Component, to a lead institution if required under the terms of the sub-recipient agreement, or to a sponsor if required under contract.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect, or appear to affect, the design, conduct or reporting of research.

Financial Interest: Any monetary interest in a sponsor of research or other key party, held by the Investigator or the Investigator's Family Member within twelve (12) months of the proposal or awarding of research funding. Under 42 CFR 50.603, a Financial Interest is defined as anything of monetary value, whether or not the value is readily ascertainable.

Institutional Official: The individual authorized to act for Carilion Clinic in Human Subject Research Protections and who assumes the obligations of the Federalwide Assurance (FWA) for the protection of human subjects with the Office of Human Research Protections (OHRP).

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the institution, and as defined by the institution in its Policy on Financial Conflicts of Interest, which may include activities such as research, research consultation, teaching, professional practice,

institutional committee memberships, and service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

Institutional Review Board (IRB): An appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and is charged with the responsibility for compliance with federal regulations for the protections of human subjects in research. An Institutional Review Board (or Boards) has jurisdiction over the research as specified in the Federalwide Assurance (FWA) that the organization has provided to the U.S. Department of Health and Human Services (DHHS), or as otherwise established under DHHS or the Food and Drug Administration (FDA) regulation or policy.

Intellectual Property: Patents, copyrights, trademarks, trade secrets, technology, databases, software, and any other tangible or intangible intellectual property.

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 actual or proposed research, or proposed funding for research (e.g., co-Investigators, collaborators, consultants, medical staff members, fellows, students, administrators, or other Key Research Personnel).

Key Research Personnel: Any person, other than the Principal Investigator, who is independently responsible for the design, conduct, or reporting of sponsored research or educational activities conducted in who or in part at a Carilion Clinic facility.

Management Plan: A strategy developed by the Carilion Clinic Compliance Office or the Carilion Clinic Research Conflict of Interest Committee (RCOIC) to mitigate, minimize and/r eliminate conflicts of interest (COI) that could or could reasonably appear to affect a research study.

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).

PHS Awarding Component: The organizational unit of the PHS that funds research that is subject to 42 CFR Part 50, Subpart F, 50.601-50.607 and 45 CFR Part 94, 94.1-94.6.

Principal Investigator: The project director or Investigator who meets the qualifications and requirements outlined in the Carilion Clinic Policy: “Principal Investigator (PI) Eligibility”, regardless of funding source, and who has the full and final responsibility for the conduct of the activities as described in the protocol as well as protecting the rights and welfare of participants involved in the research.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development when such research or product development is funded by the Public Health Service (PHS). It includes any such activity for which research funding is available from a PHS Awarding Component through a grant or 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 grant, or research resources award. It also includes all research meeting the definition of "research" performed with "human subjects" as these terms are defined in the Federal Common Rule, 45 CFR 46 and 21 CFR 56, regardless of the source of research funding or whether the research is otherwise subject to federal regulations.

Research Conflicts of Interest Committee (RCOIC): The body at Carilion Clinic responsible for reviewing disclosed COIs/FCOIs related to research activities and for creating management plans to mitigate or eliminate identified conflicts. For more information, see the Carilion Clinic Policy: *Research Conflict of Interest Committee Policy.*

Significant Financial Interest (SFI): For the purpose of this policy, a Significant Financial Interest (SFI) includes and external Financial Interest consisting of one or more of the following interest of an Investigator (and those of the Investigator's Family Member[s]) reasonably related to their Institutional Responsibilities, when combined for the twelve (12) months preceding the disclosure date, or reasonably known to occur in the twelve (12) months following the disclosure date, when combined from a single entity:

i. Renumeration, compensation, and/or other payments for services (e.g. consulting, speaking), which exceed $5,000.

ii. Equity interest in a single publicly traded entity, which exceeds $5,000 or 5% ownership.

iii. Equity interests, including stock options, in a non-publicly traded entity (e.g. a start-up company) of any amount.

iv. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

v. Sponsored or reimbursed travel for Investigators, which is paid on behalf of the Investigator and not reimbursed to the Investigator, related to their Institutional Responsibilities. This definition does not include travel that is reimbursed or sponsored by a Federal, state, or local government agency, and Institution of higher education as defined at 20 U.S.C 1001(a), a research institute that is affiliated with an institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, or a medical center

vi. This definition <u>does not</u> include salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.

vii. This definition <u>does not</u> include income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, and

Institution of higher education as defined at 20 U.S.C 1001(a), a research institute that is affiliated with an institution of higher education as defined at 20 U.S.C 1001(a), or an academic teaching hospital.

viii. This definition does not include income from service on an advisory committee or review panels for Federal, state, or local government agency, and Institution of higher education as defined at 20 U.S.C 1001(a), a research institute that is affiliated with an institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, or a medical center.

ix. This definition does not include 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 financial vehicles.

Subrecipient: A third-party organization that receives funding from a primary recipient or another subrecipient to collaborate in carrying out externally funded research or program. This may include subcontractors, subawardees, and cooperative/consortium members.

Trainee: An individual working as a mentee of a Principal Investigator. This can include residents, fellows, postdoctoral associates, and students.

Workforce: Carilion Clinic employees and contractors, suppliers, volunteers, researchers, clinical and non-clinical rotating students, residents and non-employed members of Carilion Clinic hospital medical staff only when their conduct, in the performance of work for Carilion Clinic, is under the direct control of Carilion Clinic.

VII. REFERENCES:

- 21 CFR Part 54 Financial Disclosure by Clinical Investigators
- 42 CFR Part 50, Subpart F, 50,601 – 50.607 and 45 CFR Part 94, 94.1 – 94.6, as amended by the Finale Rule on Financial Conflicts of Interest Regulations, revised regulations, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Contractors (76 FR 54288), dated August 25, 2011, and effective August 24, 2012
- 45 CFR Parts 160 and 164 as amended by the Privacy and Security Provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 (“HITECH Act”) and the rules promulgated thereunder (collectively referred to herein as the “HIPAA Rules”)
- Carilion Clinic Policy. (2023). *Principal Investigator (PI) Eligibility.* Systemwide. Research and Development.
- Carilion Clinic Policy (2020). *Research Conflicts of Interest Committee.* Systemwide. Compliance.

VIII. APPENDICES:

N/A

Approvals

Name	Title	Dept./Committee	Date
Kristin Meador	Chief Compliance Office	Privacy/Compliance	08/2025