Policy / Procedure:

Research Conflicts of Interest Committee

KEY TERMS: COI, Committee, Conflict, Conflict of Interest, FCOI, FDA, Funding, Grant, Interest, IRB, PHS, Principal Investigator, Public Health Service, Research

I. PURPOSE:

This policy establishes guidelines for the constitution, duties, and procedures of the Carilion Clinic Research Conflicts of Interest Committee in accordance with applicable local, state, and federal laws and regulations as well as relevant Carilion Clinic policy.

II. SCOPE:

This Policy applies to all members of the Carilion Clinic Workforce, or those of its subsidiaries, who conduct Research on behalf of Carilion. Such personnel include, but are not limited to contracted faculty and staff, volunteers, and fellows. When Carilion conducts research with external Investigators, such as faculty, staff, and students 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 Services-compliant Financial Conflicts of Interest Policy or Carilion and the collaborating institution contractually agree to follow Carilion Clinic's *Conflicts of Interest in Research Policy*.

III. DEFINITIONS:

COI Official: PHS-funded Institutions are required by Federal regulation to appoint a COI Official whose responsibilities are to solicit and review Financial Interests in PHS-sponsored Research. The Carilion Chief Compliance Officer serves in that capacity.

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.

Family Member: For the 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.

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 C.F.R. 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 in Human Subjects Research protections and who assumes the obligations of the Federalwide Assurance (FWA) for the protection of human subjects with the Office for Human Research Protection (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 Feeralwide 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 Food and Drug Administration (FDA) regulation or policy.

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 whole or in part at a Carilion facility.

Management Plan: A strategy developed by the Carilion Research Conflicts of Interest Committee (RCOIC) to mitigate, minimize and/or eliminate COI that could or could reasonably appear to affect a Research project.

Organizational Integrity and Compliance (OIC): The Carilion department responsible for advising on and auditing for institutional compliance with all relevant federal, state, local, and institutional regulations and Policies. The COI administrative staff is located in this department, and OIC's leader, the Chief Compliance Officer, serves as the COI Official and sits on the RCOIC.

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).

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 project, 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 C.F.R. 46 and 21 C.F.R. 56), regardless of the source of Research funding or whether the Research is otherwise subject to federal regulation.

Research Conflicts of Interest Committee (RCOIC): The body at Carilion responsible for reviewing disclosed COIs/FCOIs related to research activities and for creating management plans to mitigate or eliminate any identified conflicts.

Significant Financial Interest (SFI): For the purposes of this Policy, a Significant Financial Interest (SFI) includes an external Financial Interest consisting of one or more of the following interests 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 interests 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, an 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 does not include 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), 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.

vii. This definition does not include 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), 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.

viii. 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.

Workforce: Carilion Clinic employees and contractors, suppliers, volunteers, researchers, clinical and non-clinical students, residents and non-employed members of a 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.

IV. PROCEDURE:

A. Procedural Background:

The Research Conflicts of Interest Committee (RCOIC) strives to engage Carilion, Carilion Research stakeholders, and other relevant parties in the Carilion Research COI process in a collaborative manner. It functions to help protect the integrity of Carilion, its Investigators, and the Research conducted on its behalf. Since significant COIs pose a risk to the fulfillment of Carilion's mission and the maintenance of the public's trust, the RCOIC serves to help identify, manage, and minimize any potential or actual COIs associated with Carilion Research.
For more information regarding Carilion's Research COI process, please see Carilion Clinic Policy: *Conflicts of Interest in Research,* (Organizational Integrity and Compliance [OIC]). You may also contact OIC at researchcompliance@carilionclinic.org.

B. Committee Composition:

1. COI Official or designee, permanent member.
2. RCOIC Chair, appointed on an annual, renewable basis by the Institutional Official and COI Official in consultation with the RCOIC members.
3. HRPO/IRB Director or designee, permanent member.
4. General Counsel or designee, permanent member.
5. Research and Development Director or designee, permanent member.
6. Clinical faculty member(s) who serve as a PI, appointed on a three-year, renewable basis by the COI Official in consultation with the RCOIC members.
7. At the discretion of the RCOIC, additional *ad hoc* committee members may be requested for instances when potential COI considerations may require additional insight and guidance to establish appropriate Management Plans. For example, the Director of Carilion Innovation (or designee) may need to help review and navigate the COI management process for projects progressing through their pipeline. Another example could include *ad hoc* members from our external research partners to consult on COI relating to collaborative projects.

C. Committee Duties and Responsibilities:

1. Meetings:
    a. RCOIC meetings are held annually or as needed.
    b. Members are required to attend the annual meeting and at least 75% of any additional meetings each year.
    c. It is important that meetings, votes, and Management Plans are completed in a timely manner that allows Carilion (via the COI Official) to uphold its PHS FCOI reporting requirements (See Carilion's *Conflicts of Interest in Research Policy*).
2. To review materials relevant for meetings ahead of time in order to provide meaningful participation and deliberation. These materials will be provided to RCOIC members at least five (5) business days before the scheduled meeting by the COI staff in the Carilion Clinic Office for Organization Integrity and Compliance (OIC).
3. To treat all materials for review as confidential information as allowable by relevant laws and regulations. It should not be shared with others, should be stored securely, and should be disposed of properly.
4. To act in a professional and respectful manner while in deliberations. Information disclosed for review should not be treated as gossip or jokes.
5. A member must recuse themselves if there exists, or could reasonably exist, a COI with the subject under review. Examples of instances in which this could occur include, but are not limited to:
    a. The review is on someone from the same department;
    b. The RCOIC member has a personal interest due to interdepartmental relationships (e.g., collaborations); or
    c. The RCOIC member has a Financial Interest in the subject of review.
6. All members of the RCOIC are responsible for recommending and/or providing input on potential new members.
7. The RCOIC Chair is responsible for sending invitations out to newly appointed members.

8. If for whatever reason, a member of the RCOIC can no longer fulfill their member obligations, then they should notify the RCOIC Chair in writing as soon as possible to allow time for a new member to be selected and invited.

D. RCOIC Meeting Procedures:

1. A RCOIC member or OIC COI staff member will take minutes of the meeting that will be archived and distributed to the RCOIC members for their records.
2. RCOIC meetings are not open to the general public. Meeting attendance should include committee members and those invited by the RCOIC to help in the administration of the meeting and to consult on specific cases under review.
3. Each meeting must meet quorum, which is at least half of all voting members present. For example, if the RCOIC is composed of eight voting members, then at least four of those voting members should be present to meet quorum.
4. If the RCOIC finds that a disclosure does not constitute a COI via a majority of the vote, then the RCOIC will direct OIC COI staff to provide written notification of its decision and rationale to the Investigator. This information will also be available for the Carilion IRB.
5. If the RCOIC finds that a Disclosure does constitute a COI via a majority of the vote, and that the COI can be managed, then the RCOIC will propose a Management Plan (See Section IV. E.).

E. The RCOIC's Role in Management of Actual and Potential COI or FCOI:

1. When the RCOIC finds that an Investigator's disclosure is or could reasonably be perceived as a COI, a Management Plan will be developed and implemented to specify the actions that will be taken to manage the specific COI. Examples of conditions or restrictions to manage a COI include, but are not limited to:
    a. Public disclosure of the COI (e.g. when presenting or publishing the research or addendum to previously published presentations);
    b. For Research projects involving human subjects Research, disclosure of the COI directly to the participants;
    c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research;
    d. Modification of the Research study;
    e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
    f. Reduction or elimination of the Financial Interests (e.g. sale of an equity interest);
    g. Severance of relationships that create financial conflicts; or
    h. No administrative approval for a specific Research study.
2. Most cases of COI occur around common disclosures for which the RCOIC can develop standardized Management Plans. However, some cases of COI can be more complex, and customized Management Plans may need to be developed at the discretion of the RCOIC.

F. The RCOIC's Role in Instances of Non-Compliance:

1. If a COI is not disclosed, identified or managed in a compliant and timely manner, the RCOIC will be notified, and Carilion will complete a retrospective review within one hundred twenty (120) days of the discovery of noncompliance. The COI Official (or designee) will conduct and document the retrospective review (See Carilion's *Conflicts of Interest in Research Policy*).
2. Carilion may determine that interim measures will be necessary with regard to the Investigator's participation in the study between the date that the COI or the Investigator's noncompliance is determined and the completion of the retrospective review. Such a determination will be based on the recommendation of the RCOIC in consultation with Carilion leadership.
3. The COI Official (or designee) will present the findings of the retrospective review to the RCOIC to determine what additional measures, if any, are necessary.

The COI Official (or designee) in collaboration with the RCOIC and Carilion leadership will monitor Management Plans for Investigator compliance on an ongoing basis until the completion of the Research project.

V. OTHER ISSUES / CONCERNS:

References:

- 21 C.F.R. Part 54 Financial Disclosure by Clinical Investigators
- 42 C.F.R. Part 50, Subpart F, 50.601-50.607 and 45 C.F.R. Part 94, 94.1-94.6, as amended by the Finale Rule on Financial Conflict of Interest Regulations, revised regulations, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (76 FR 53288), dated August 25, 2011 and effective August 24, 2012.
- 45 C.F.R. 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: *Conflicts of Interest in Research*, (OIC)
- Carilion Clinic Policy: *Principal Investigator (PI) Eligibility*, (Research and Development)

Approvals

Name	Title	Dept./Committee	Date
Jeanne Armentrout	CAO and EVP	Administration	06-12-2020
Patrice Weiss	CMO and EVP	Administration	06-12-2020
Ralph E. Whatley	Research Liaison	Education and Research	06-02-2020