Policy / Procedure:

Financial Conflict of Interest in Research

KEY TERMS: Research, Financial, Conflict of Interest, Financial Interest, Disclosure

I. PURPOSE:

The purpose of the Conflict of Interest in Research Policy is to protect the rights of human research subjects and to preserve Carilion Clinic's integrity, reputation and objectivity whenever Research is conducted by its employees or any other individual covered by this Policy. Objectivity is an essential value in research and the basis for public trust. Yet financial interests in Research can create special risks that undermine trust. Opportunities to profit from research may affect – or appear to affect – a researcher's judgments about which subjects to enroll, the clinical care provided to subjects and the proper use of subjects' confidential health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, data collection and analysis, adverse event reporting or the presentation and publication of research findings.

This Policy does not assume that financial interests in Research are categorically improper. However, this Policy recognizes that research is a privilege that imposes unique obligations. Therefore, this Policy establishes a Rebuttable Presumption that an individual who holds Significant Financial Interests in Research may not conduct such research. This Rebuttable Presumption applies when the research is funded by a public agency, a non-profit entity, or a commercial sponsor. This Policy does provide for a process to allow an individual who holds Significant Financial Interests in Research to conduct the research in the event of Compelling Circumstances.

II. SCOPE:

This Policy covers all persons who are employed by Carilion, and includes but is not limited to contracted staff, volunteers, and/or students. This Policy also covers principal investigators and their staffs who conduct research at Carilion (see the definition of Investigator). Carilion will strive to avoid financial conflicts of interest which present the potential to directly or indirectly compromise Research, unless such conflicts are managed in accordance with this Policy.

III. DEFINITIONS:

Capitalized terms in this Policy shall have the meanings set forth below. Other capitalized terms are defined when used within the Policy.

A. Carilion: Carilion Clinic and all affiliated or related entities.

B. Compelling Circumstances: Those facts that convince the Carilion Clinic Conflict of Interest and Organizational Ethics (COIOE) Committee that a Financially Interested Individual should be permitted to conduct Research. When considering a request by a Financially Interested Individual to conduct Research, the circumstances that the COIOE Committee should evaluate include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to the human subjects involved that is inherent in the research protocol. The COIOE Committee should also consider the extent to which the interest is amenable to effective oversight and management and how and to what extent the interest should be disclosed to research subjects or to the public.

C. Conducting Research: With respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, collecting, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

D. Conflict of Interest and Organizational Ethics (COIOE) Committee: The committee appointed by the Senior Vice President for Legal Services that has authority to review and manage conflicts of interest per the Carilion Clinic Policy on Conflicts of Interest.

E. Disclosure: A release of relevant information about Significant Financial Interests in Research to parties outside Carilion's review and management processes (e.g., to research subjects or journal editors).

F. Family: Spouse, domestic partner (defined as a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations) and dependent children.

G. Financially Interested Company: A commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research. This term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the Investigator actually knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a Financially Interested Company (e.g., a contract research organization).

H. Financially Interested Individual: An Investigator who holds Significant Financial Interests in Research as described below that would reasonably appear to be related to the individual's institutional responsibilities and could directly or significantly affect the design, conduct or reporting of research.

I. Investigator: Includes a project director or principal investigator or any other person, regardless of title or position, who, under the aegis of Carilion or pursuant to the review and approval of the Responsible IRB or any other applicable oversight committee, conducts

Research as well as the spouse and dependent children of anyone who conducts Research. This includes employees, medical staff members, fellows, students, trainees, administrators, contractors, collaborators, consultants, agents and sub-grantees.

J. Investigator's Institutional Responsibilities: Those responsibilities an Investigator has by virtue of being a Carilion employee, contractor or agent, staff, student, fellow, trainee, administrator, medical staff member, principal investigator or research staff. These may include, for example: teaching, professional practice, service on committees, research and research consultation.

K. Policy: This Financial Conflict of Interest in Research Policy.

L. Research: Means a systematic investigation 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 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 regulation. For the purposes of this policy, the research must be funded or supported by entities external to Carilion.

M. Rebuttable Presumption: The presumption under this Policy, in order to assure that all potentially problematic circumstances are reviewed, that a Financially Interested Individual may not conduct the Research in question. This rule is not intended to be absolute: a Financially Interested Individual may rebut the presumption by demonstrating facts that, in the opinion of the COIOE Committee, constitute Compelling Circumstances; or, the COIOE Committee or Vice President for Academic Affairs may, using procedures described in Section lV below, may develop a management plan. The individual would then be allowed to conduct the research, subject to any conditions specified by the COIOE Committee and, if human subjects research is involved, upon approval of the research by the Responsible IRB.

N. Reporting: The provision of information about Significant Financial Interests in Research by an Investigator to the COIOE Committee, the transmission of such information within institutional channels (e.g., from the COIOE Committee to the Responsible IRB) or the transmission of such information from the institution to the PHS or other relevant federal or state agencies or corporate entities.

O. Responsible IRB: The institutional review board (or boards) with jurisdiction over the research as specified in the Federalwide Assurance (FWA) that Carilion 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.

P. Responsible Institutional Official: The individual authorized to act for Carilion in Human Subjects Research protections and who assumes the obligations of FWA with the Office for Human Research Protections.

Q. Senior/Key Personnel: the project director/principal investigator and any other person *identified* as Senior/Key Personnel by the institution in a grant application, progress report, or any other report submitted to the NIH by Carilion Clinic under 42 CFR Part 50 Subpart F.

R. Significant Financial Interests (SFI) in Research: Include the following interests of the Investigator (and those of the Investigator's spouse and dependent children) or of any foundation or entity controlled or directed by the Investigator (or the Investigator's spouse and dependent children) that reasonably appear related to the Investigator's institutional responsibilities:

1. Any financial interest in a publicly traded entity where the value of 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). Equity interest includes any stock, stock option, or other ownership interest as determined through references to public prices or other reasonable measures of fair market value. (See exceptions below.)

2. Any equity interest (e.g. stock, stock option, or other ownership interest) in a non-publicly-traded entity, e.g. a start-up company, or remuneration from such entity with a value in aggregate exceeding $5,000 in the twelve months preceding the disclosure.

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

4. Travel related to an Investigator's institutional responsibilities that is either directly reimbursed or travel that is paid on behalf of an Investigator. The Investigator must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration and the monetary value. This does not include travel that is reimbursed or sponsored by a federal, state, or local government agency or institutions 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. Disclosure is required only by the Investigator and not the Investigator's spouse or dependent children.

Exceptions: Significant Financial Interests in Research *do not include* the following:

1) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment.
2) Income from seminars, lectures, or teaching engagements sponsored by, and service on advisory or review panels for, a federal, state, or local government agency or institutions

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.

3) Payments to Carilion, or via Carilion to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and Carilion. Payments must:
   a) Be reasonably related to costs incurred, as specified in the research agreement between the sponsor and Carilion.
   b) Reflect the fair market value of services performed; and
   c) Be commensurate with the efforts of the individual(s) performing the research.

4) Salary and other payments for services from Carilion.

IV. PROCEDURE:

A. Duty to Report Financial Information

1. Research Financial Disclosure Questionnaire

   a. All Investigators are required to complete a questionnaire ("Research Financial Disclosure Questionnaire") each time they are involved with a research project as defined in section III L of this policy. In the case of NIH-funded research, the questionnaire must be submitted no later than at the time of application for the research. The Research Financial Disclosure Questionnaire is required to be completed when an investigator submits an application to the Carilon Office of Sponsored Projects (OSP) for industry-sponsored clinical trials or research funded or supported by external grants or entities. It also is required when externally funded projects are submitted to the Carilion Clinic IRB for continuing review or changes to the research staff. The Carilion OSP and IRB will not approve externally funded research projects until appropriate disclosure questionnaires have been submitted and reviewed. The questionnaire will be available on the OSP and IRB web sites. The questionnaire shall include a statement which affirms that such person:
      - Is aware of the requirements of the policy,
      - Agrees to comply with the Policy, and
      - Has provided true and accurate information in the Research Financial Disclosure Questionnaire.
   b. A Research Financial Disclosure Questionnaire must be updated within 30 days of discovering changes that may:
      - Give rise to a potential conflict of interest or appearance of a conflict of interest;

- Eliminate a potential conflict of interest previously disclosed;
- Result in an affirmative answer to any question on the Research Financial Disclosure Questionnaire previously answered in the negative.

2. Carilion Clinic Conflict of Interest Questionnaire
   All Investigators who are required to complete the annual Carilion Clinic Conflict of Interest Questionnaire:

   a. Must complete a section on research activities if they are involved in externally funded research. The questionnaire includes a statement which affirms the Investigator:
      - Is aware of the requirements of the Carilion Conflict of Interest Policy
      - Agrees to comply with the policy
      - Has provided complete and accurate representation of all interests covered by the policy
   b. Are required to report within 30 days of discovering any potential conflict of interest situations that develop prior to completion of a new questionnaire.

3. Collaborators, subcontractors, subrecipients, and visiting scientists must either comply with the Policy or be subject to a written agreement that their institutions are in compliance with pertinent federal conflict of interest policies and that they in turn are in compliance with their own institutional policies. See IV G for more information.

B. Determining Whether a Conflict of Interest Exists

1. Research Financial Disclosure Questionnaire: The IRB Regulatory Affairs Administrator shall receive a copy of each Research Financial Disclosure Questionnaire and maintain a file of all questionnaires. If a potential conflict is identified on the Financial Disclosure Questionnaire, the IRB Regulatory Affairs Administrator, in consultation with the Human Protections Administrator, will, if necessary, contact the Investigator with the potential conflict and further document the details concerning any potential Significant Financial Interests in Research. If the IRB Regulatory Affairs Administrator and Human Protections Administrator determine that there are Significant Financial Interests in Research, those interests shall be reviewed in a timely manner with the Chair of the COIOE Committee and the Responsible Institutional Official. It will then be determined and documented whether:

   a. The Investigator is not a Financially Interested Individual, or
   b. The Investigator is a Financially Interested Individual but the conflict can be managed by full disclosure of the interest to the public or to research subjects in the informed consent document, or
   c. The Investigator is a Financially Interested Individual and the conflict should be referred to the COIOE Committee for further review

2. Carilion Conflict of Interest Questionnaire: Annual questionnaires or other documentation of about potential Significant Financial Interests in Research will be sent to the Carilion Internal Audit Department. Information about potential Significant Financial Interests will be referred to the COIOE Committee for further review.

3. The COIOE Committee will review the conflict. The COIOE Committee may confer with other officials as it deems appropriate, including the Responsible Institutional Official, who shall review and approve all findings of the COIOE Committee. The COIOE Committee will communicate its findings in writing to the investigator and the Responsible IRB. This communication will include one of the following opinions:

    1. COIOE Committee review revealed the Investigator is not a Financially Interested Individual;
    2. COIOE Committee review revealed the Investigator is a Financially Interested Individual and may not conduct the research;
    3. COIOE Committee review revealed Significant Financial Interests in Research but a plan has been approved (the "Plan") setting forth conditions for management and oversight of the research that will allow the Investigator to proceed with the research.

C. Notification and Approval

In cases where potential conflicts in research involving human subjects are identified on the Research Financial Disclosure Questionnaire or annual Carilion Conflict of Interest Questionnaire, the Responsible IRB will be notified by the IRB Regulatory Affairs Administrator that a) It has been determined the Investigator is not a Financially Interested Individual b) It has been determined that the Investigator is a Financially Interested Individual but that full disclosure of this to research subjects is sufficient to allow the research to continue or c) the potential conflict has been referred to the COIOE Committee for review and that IRB approval cannot be granted until the Committee has made a determination about whether the research can proceed. The IRB or Office of Sponsored Projects shall forward any information that they receive concerning Significant Financial Interests in Research to the COIOE Committee. The IRB may not minimize the Plan developed by the COIOE Committee but may require additional safeguards to ensure the optimal protection of research subjects.

D. Procedures to Allow a Financially Interested Individual to Conduct Research

1. The Investigator found by the COIOE Committee to be a Financially Interested Individual may make a presentation to the COIOE Committee to offer facts demonstrating that Compelling Circumstances exist that should allow the Investigator to conduct research. Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research and the degree to which the interest may be affected by the research. When the financial interest is directly related to the research and may be substantially affected by it, (e.g. an equity interest in a start-up company that manufactures the investigational

product) the risk is greatest and the presumption against conducting research must be high. However, even direct and potentially lucrative financial interests may be justified in some circumstances. For example, when the individual holding such interests is uniquely qualified by virtue of expertise and experience and the research could not be otherwise conducted as safely or effectively without that individual, he or she should be permitted the opportunity to rebut the presumption against conducting the research in spite of the Investigator's financial interests.

a. Early Stage Research: In addition to the prior example of Compelling Circumstances, experimentation to further develop an early stage discovery may similarly require the insights, knowledge, perseverance, laboratory resources, or special patient populations of the discoverer. The best interests of patients who could benefit from the discovery may justify further involvement of the discoverer as an investigator. If such circumstances are deemed compelling by the COIOE Committee, the committee's analysis should define the stages of the research and the specific activities for which there are compelling reasons for the conflicted discoverer/investigator's involvement and an approved management plan should be structured to restrict the investigator's roles to those stages and activities. The management plan should include a clear discussion of the time line proposed for elimination of the conflicted investigator from research participation and the strategy to restrict the time of involvement of a conflicted investigator to a minimum.

   Approval and management of the conflict may differ between experiments designed to promote further development on one hand and those designed to validate claims linked to the discovery on the other. Approval of such research when human subjects are involved should require particularly stringent analysis of the degree of risk to subjects and of the effectiveness of particular provisions of the conflict management plan to protect subjects and prevent the introduction of bias of the conflicted investigator.

b. Low Risk Research: In considering the degree of risk to human subjects, the COIOE Committee may encounter human subjects studies in which careful assessment finds risk to human subjects to be sufficiently low, so that the disposition of any associated conflict by the committee may be similar or identical to the disposition that would be made in non-human subjects research.

2. The COIOE Committee may, if appropriate, appoint a disinterested person or committee to investigate the Compelling Circumstances and to recommend conditions for management and oversight of the research. As a first principle, the COIOE Committee should encourage the Financially Interested Individual to minimize the potential for financial conflict of interest by eliminating the interest or the individual's direct involvement in the research.

3. If the COIOE Committee deems it appropriate, it shall develop a Plan that would allow a Financially Interested Individual to conduct the research. The terms of such Plan might include: full disclosure of the interest to research subjects, to the public or to others cited in this Policy; a requirement that informed consent be obtained by a clinician with no financial

ties to the research; modification of the research plan; disqualification from participation in all or a portion of the research funded by the PHS; or severance of relationships that create Significant Financial Interests in Research.

4. Approaches to be considered in a Plan might also include the following: regular audits of the research, including the informed consent and enrollment process; the involvement of a patient representative or ombudsman when subjects are recruited and informed consent is obtained; a requirement to escrow the financial interest until the investigational product has been approved and on the market for a specified time period; or the use of data safety monitoring boards. In some circumstances, monitoring boards might be composed wholly of Carilion representatives. However, when Carilion itself holds a financial interest in the research, disinterested monitoring might require the participation of objective individuals without conflict from outside Carilion.

5. When the COIOE Committee determines that a Financially Interested Individual should be permitted to conduct Research, a copy of the Committee's Plan describing the financial interest and any conditions to be imposed upon the research shall be provided to the head of the unit in which the Investigator resides administratively, and to the Carilion official who has responsibility for monitoring the activities of the Investigator. The Plan shall also be provided to the Principal Investigator on the research if he or she is not the conflicted individual.

E. Appealing a Determination of Significant Financial Interests in Research

An appeal of a determination of Significant Financial Interest in Research can be made directly to the COIOE Committee Chairperson who will call for reconsideration by the COIOE Committee if additional supporting information has become available since the initial review. The conflicted individual may be required to attend the reconsideration session. The decision of the COIOE Committee re-review may be further appealed to the Vice President for Academic Affairs by the conflicted individual. The conflicted individual must notify the Vice President of Academic Affairs of any intended appeal within 5 days of receiving notice of the management plan. The Vice President for Academic Affairs will form an *ad hoc* Appeal Panel comprised of three senior faculty or clinicians, and other consultants as needed, who will have 30 business days to review the relevant materials. The Appeal Panel's recommendation is made to the Vice President who will render a decision within 10 work days. The decision of the Vice President will be final and there shall be no further appeal within Carilion Clinic.

F. Reporting of Financial Conflict of Interest

1. The existence of Significant Financial Interests in Research of Investigators must be reported to PHS (Public Health Service) sponsors, and, as required, to other relevant federal agencies by the Carilion Office of Sponsored Projects.

2. For PHS-funded research, initial and ongoing Significant Financial Interests in Research of Investigators must be reported to NIH :

a. Prior to the expenditure of funds
b. During the period of award
c. Within 60 days of identifying a new FCOI for existing investigators
d. Within 60 days of identification for an investigator new to the project
e. Annually with the annual progress report or at time of extension.

3. The elements of the report to NIH include: project number, project director or principal investigator, name of the Investigator with the Significant Financial Interest, the entity with which the Investigator has the Significant Financial Interest, the nature of the Significant Financial Interest, the value of the financial interest and monetary ranges, how the financial interest relates to the funded research, and key elements of the management plan, including the role and principal duties of the conflicted individual in the research project, the conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the management plan, how the management plan will be monitored to ensure investigator compliance; and other information as needed.

4. Failure to report or review SFI in a timely manner: If such failure is identified by Carilion, the SFI must be reviewed for financial COI and an interim management plan implemented within 60 days.

5. Retrospective review and mitigation report for noncompliance: Upon a determination of non-compliance with this policy, the COIOE Committee is required to complete a retrospective review of the research project as well as the Investigator's activities within 120 days to determine if there was bias in the design, conduct, or reporting of the research. The COIOE Committee must document the methodology used for reviewing the SFI(s). A COI mitigation report must be sent to NIH if bias is found. The mitigation report must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effects of bias. It will be reviewed and approved by the Vice President for Academic Affairs. NIH may determine that further corrective action is needed.

6. If NIH determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with an SFI that was not managed or reported by Carilion as required by regulation, the COIOE committee shall require the investigator to 1) disclose the SFI in each public presentation of the research and 2) request an addendum to disclose the SFI in previously published presentations.

7. NIH has the authority to inquire at any time of any Investigator's reporting of Financial Interests and Carilion's review and response to the Financial Interests. NIH may impose special award conditions, suspend funding or impose other mechanisms if NIH decides that a particular FCOI will bias the objectivity of the research.

8. If the Investigator participating in a multi-center trial has been judged a Financially Interested Individual eligible to conduct Research, that fact will be reported to the principal investigator or sponsor.

G. Subrecipient Requirements

1. The Carilion Clinic Office of Sponsored Projects will establish via a written agreement with subrecipient institutions whether this Policy in its entirety or whether the financial Conflict of Interest policy of the subrecipient institution will apply to its investigators who are collaborating with Carilion investigators.

2. If applicable, Carilion will obtain a certification from the subrecipient institution that its FCOI policy complies with regulatory requirements in 45 CFR 50.604.

3. If applicable, Carilion will include in the written subrecipient agreement a requirement for the subrecipient to report identified SFIs for its investigators in a time frame that allows the awardee institution to report identified SFIs to the NIH as required by regulation.

4. Alternatively, if applicable, Carilion will include in the written agreement a requirement to solicit and review subrecipient investigator disclosures that enable the awardee institution to identify, manage and report identified SFIs to the NIH.

5. In all cases, the awardee institution is responsible for reporting all identified SFIs for subrecipient investigators to the NIH.

H. Training Requirements

1. Each Investigator must complete training prior to beginning research and at least every 4 years. Training is also required if the Policy changes substantially, if an Investigator is new to Carilion, and if an Investigator is found to be non-compliant with the Policy or management plan.

2. The training will be done through on-line modules developed by the Collaborative Institutional Training Initiative and Carilion. The modules will inform the Investigator about the institution's policy, the Investigator's disclosure responsibilities and the federal regulation governing conflict of interest.

I. Publicly Available Information about Significant Financial Interests

1. Prior to the expenditure of funds, Carilion must make available certain information about Significant Financial Interests in Research held by Senior/Key Personnel in NIH-funded research to any requestor within 5 business days of a request.

2. The written information shall include, at a minimum:

   a. Investigator's name
   b. Investigator's title and role with respect to the research project
   c. Name of the entity in which the Significant Financial Interest in Research is held
   d. Nature of the Significant Financial Interest in Research (e.g. equity, consulting fees, travel reimbursement, honoraria, etc. and
   e. Approximate dollar value of the Significant Financial Interest in Research Dollar ranges are permissible: $0-$4,999; $5,000-$9,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000. Alternatively, there may be a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measure of fair market value**.**

K. Disclosure of Financial Conflict of Interest

1. A condition of any Plan approved by the COIOE Committee shall be that research informed consent forms shall disclose the existence of any Significant Financial Interests in Research held by an Investigator who is conducting Human Subjects Research. The wording of disclosure in the consent form shall be determined by the Responsible IRB, but should include an explanation of the fact that the financial interest in question has been reviewed by the COIOE Committee, approved subject to compliance with the plan adopted by the COIOE Committee, and determined by both the COIOE Committee and the Responsible IRB not to pose any additional significant risk to the welfare of research subjects or the integrity of the research.

2. If the COIOE Committee has authorized a Financially Interested Individual to conduct Human Subjects Research, the disclosure statement in the research consent form should indicate that additional information (to include the COIOE Committee summary report describing the nature and amount of the financial interest and the approved Plan) will be provided to research subjects upon request.

L. Violations of the Policy

1. If the COIOE Committee has reasonable cause to believe that an Investigator has failed to disclose actual or possible conflicts of interest, it shall inform the Investigator of the basis for such belief and afford that person an opportunity to explain the alleged failure to disclose.

2. If, after hearing the response of the Investigator and making such further investigation as may be warranted in the circumstances, the COIOE Committee determines that the person has, in fact, failed to disclose an actual or possible conflict of interest, it shall recommend the appropriate disciplinary and corrective action. This will include, in cases of PHS-funded

research, prompt notification of the PHS Awarding Component of the corrective action taken or to be taken.

3. The Vice President for Academic Affairs or his/her designee is responsible for the implementation of this Policy, including the process and mechanism for Financial Interests reporting and management. The Vice President for Academic Affairs, or his/her designee, will oversee all identified breaches of Conflict of Interests reporting, review, and management processes, including:

    a. failure of Investigators to report financial Interests
    b. failure to update financial interests as required
    c. failing to respond to COIOE Committee or IRB inquiries or responding with incomplete or knowingly inaccurate information;
    d. failure to adhere to the management plan
    e. failure to comply with a prescribed monitoring plan, if applicable.

V. OTHER ISSUES / CONCERNS:

A. Maintenance of Records

Financial Disclosure Questionnaires submitted to the IRB Regulatory Affairs Administrator which do not reveal Significant Financial Interests in Research shall be maintained by the IRB Regulatory Affairs Administrator for a period of three years. Carilion Conflict of Interest Questionnaires which do not reveal any Significant Financial Interests in Research shall be maintained by the Internal Audit Department for a period of six years.

Financial Disclosure Questionnaires and Carilion Conflict of Interest Questionnaires reflecting a Significant Financial Interests in Research shall be stored with all documentation relating to the investigation of the conflict or appearance of a conflict and the recommendations for managing the conflict. These documents shall be maintained by the COIOE Committee or designee for a period of three years following the completion of the research.

B. Periodic Review

To ensure that the scientific research and the administrative processes involving research projects are conducted in an ethical and objective manner, periodic reviews shall be conducted. The content of these periodic reviews shall be reviewed by the COIOE Committee.

C. Potential Legal Sanctions

Investigators are reminded that there may be serious legal sanctions imposed for trading in the securities of publicly held companies based upon material non-public information which

could include data which they learn about in the course of their employment or affiliation with Carilion. Accordingly, all employees and other Investigators are strongly advised to consult their attorneys before trading in securities based upon non-public information.

This policy is based in part upon recommendations and language contained in a December 2001 report by The Task Force on Financial Conflicts of Interest in Clinical Research of the Association of American Colleges: "Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for Oversight of Individual Financial Interests I Human Subjects Research

Approvals

Name	Title	Dept./Committee	Date
		Conflict of Interest & Organizational Ethics Committee	7-16-12
Dan Harrington	VP Academic Affairs		7-25-12