Sentara

Policy:	Research Financial Conflict of Interest		
Manual:	Research	**Original Date:**	4/23/2014
Section:	Research Compliance	**Revision Date:**	12/16/2025
Location(s):	SAMC, SCH, SHRH, SLH, SMJH, SNGH, SNVMC, SOH, SPAH, SRMH, SVBGH, SWRMC, SASD	**Approved By:**	Research Leadership Committee; Compliance
		Process Owner:	Director of Clinical Research

Revision Description (Most Recent): Updated to comply with current federal regulations and guidance

Policy Statement:

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1. Purpose:

Sentara Health is committed to ensuring research integrity to maintain the public trust and the scientific credibility of Sentara's research programs. Sentara Health acknowledges that investigators may have productive relationships with outside commercial entities; however, these relationships can involve financial incentives that may conflict with the primary mission of caring for patients and conducting research responsibly. Sentara Health is committed to ensuring that real or apparent conflicts of interest are properly disclosed and appropriately managed to assure that conflicting interests do not interfere with the responsible conduct of research.

The purpose of this policy statement is to maintain the integrity and objectivity of Sentara's research programs by establishing standards and a framework for conflict of interest (COI) compliance to ensure that the design, conduct, and reporting of research at Sentara Health is free from bias resulting from investigator financial COI. This policy statement provides an up to date, written, enforced, and publicly accessible policy on financial COI that complies with federal regulations (42 CFR Part 50.604(a)).

2. Persons Affected:

This is a Sentara-wide policy that applies to all investigators who conduct research at Sentara Health, whether or not the research is federally funded. The policy also applies to individuals who are involved in the design, conduct, or oversight of any research at a Sentara facility including Senior/Key personnel identified in a grant application, IRB application, or any report related to research at Sentara.

3. Definitions (adapted from 42 CFR 50.603):

3.1. *Conflict of interest* in research may arise when an investigator's personal, financial, or other interests could affect, or appear to affect the conduct of their research activities. Having a COI does not imply improper conduct of research but rather refers to activity that must be identified and managed, reduced, or eliminated so that the conflict does not threaten the integrity of Sentara's research and the public's trust in research.

3.2. *Designated Official* means an official appointed by Sentara Health to review financial disclosures from research personnel to determine if significant financial interests are related to an Investigator's or Senior/key personnel's research and if the relationship could directly and significantly affect the design, conduct, or reporting of the research. For this Policy, the designated officials at Sentara Health are the Research Compliance Monitor, the

Chief Research Officer and the Senior Administrative Director for Research and the designated Sentara Corporate Compliance Manager.

3.3. *Financial COI (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

3.4. *Institutional responsibilities* is a term that means an Investigator's professional responsibilities on behalf of Sentara, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

3.5. *Investigator* means 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 research funded by the PHS, (as well as other funding sources) or proposed for such funding, which may include, for example, collaborators or consultants.

3.6. Leadership Role: Employment, consulting in any administrative or executive capacity, or serving as: (i) a member of a board of trustees or board of directors, (ii) an officer or (iii) a member of an advisory committee, advisory board, or subcommittee of a board of trustees or a board of directors, whether remunerated or non-remunerated, in a research sponsor or research-related organization.

3.7. *Manage:* Taking action to address a real or perceived FCOI, which can include reducing, eliminating, or managing the FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free of bias.

3.8. *Research:* Any systematic investigation designed to develop or contribute to generalizable knowledge, including basic, applied, and demonstration research in all fields of knowledge. This document pertains to research activities that are:

- Conducted because of an agreement between Sentara Health and a third party
- Supported by funding that is administered through Sentara Health, or
- Requires review by Sentara Health or its affiliated Institutional Review Board(s).

3.9. Research Compliance Monitor means Sentara's designated official who will work with the Chief Research Officer to monitor financial disclosures and to determine the relatedness of any significant financial disclosures with an Investigator's or Senior/key personnel's research to determine whether the relationship requires further review.

3.10. *Senior/key personnel*: The project director or principal investigator or any other person identified as Senior/key personnel by the institution in a grant application, progress report, or any report submitted to the Public Health Service of the US Department of health and Human Services by Sentara Health.

3.11. *Significant Financial Interest (SFI)* means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- Regarding any foreign or domestic publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- Regarding any foreign or domestic non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (see below).
- Investigators must disclose gifts, including equipment, given to them for research purposes. Investigators must also comply with Sentara Health's policy on gifts, as outlined in the Gifts and Other Business Courtesies Policy.

4. Applicable Federal Regulations regarding Institutional Responsibilities pertaining to Investigator financial conflicts of interest (42 CFR 50.604):

Through this policy, Sentara Health will comply with 42 CFR 50 Subpart F for research funded under Public Health Service (PHS) grants or cooperative agreements and all other applicable federal and state laws, regulations, and policies regarding financial COI. Specifically, Sentara will:

- Maintain an up-to-date written and enforced policy that is publicly accessible, on financial COI (42 CFR 50.604(a)).
- Inform each Investigator of the Institution's policy on financial COI and the Investigator's responsibilities regarding disclosure of SFI and require each Investigator to complete training (see below) (42 CFR 50.604(b)).
- Take reasonable steps to ensure that any sub-recipient complies with these responsibilities (42 CFR 50.604(c)).
- Designate an institutional official to solicit and review disclosures of SFI from each Investigator (42 CFR 50.604 (d)).
- Require each Investigator to disclose SFI to the Institution's designated officials (see below) (42 CFR 50.604 (e)).
- Provide guidelines for reviewing financial COI (see below) (42 CFR 50.604 (f)).
- Take actions as necessary to manage financial COI (see below) (42 CFR 50.604 (g)).
- Provide initial and ongoing financial COI reports to the PHS (42 CFR 50.604 (h)).
- Maintain records regarding financial COI (42 CFR 50.604 (i)).
- Establish adequate enforcement mechanisms, employee sanctions, or other administrative actions to ensure Investigator compliance with financial COI policies (42 CFR 50.604 (j)).
- Certify the above for each application for funding to which this applies (42 CFR 50.604 (k)).

5. Policy:

5.1. Sentara Health Research Compliance Office and COI Committee:

The Sentara Health Research Compliance Office is a subdivision of the Sentara Health Research Center consisting of the following Designated Officials: The Research Compliance Monitor, who works with the Chief Research Officer and the Senior Administrative Director for Research and closely coordinates with the designated Sentara Corporate Compliance Manager.

The Sentara Research COI Committee meets quarterly to supervise the reviews and management actions of the Sentara Research Compliance Office. The Sentara Research COI Committee is chaired by the Chief Research Officer and includes the designated Corporate Compliance Manager for research, the Senior Administrative Director for Research, the Chief Academic Officer, and the Sentara Medical Group Chief Medical Officer or designee.

5.2. Research COI Training:

Investigators and Senior/key personnel will complete the federally required COI training before engaging in any research activity at Sentara and will repeat the COI training at least every four years, and whenever there is a substantive change to Sentara's financial COI Policy.

The Collaborative Institutional Training Initiative (CITI) Program will provide the federally required COI training, which shall consist of a curriculum on Good Clinical Practice related to the Responsible Conduct of Research that includes an explanation of an investigator's responsibility to disclose Significant Financial Interests and of ways that financial conflicts of interest can be managed through Sentara's review and management procedures. The Sentara Health Research Center will emphasize and augment the CITI Program training through additional internal educational offerings and discussions at operational meetings.

Sentara Health Research Center will monitor the compliance of all Investigators and Senior/key personnel with this requirement and will maintain reports of compliance that will be made available upon request by the Sentara Compliance Department. The Sentara Health Research Center will work to maintain investigators' awareness regarding their roles and responsibilities in disclosing financial interests and in compliance with any required management plans. Additional training may be provided to specific investigators if warranted.

5.3. Research COI Disclosure:

All Investigators engaged in research at Sentara Health shall disclose any Significant Financial Interest (SFI) or those of any immediate family members if the SFI is related to any of the Investigator's Institutional Responsibilities.

All Sentara-employed Investigators and Senior/key personnel at the time of Sentara employment and annually will report a Sentara Disclosure Statement to the Sentara Compliance Department through the routine reporting using the Compliance Department's web-based COMPLIANCE 360 reporting platform. If an Investigator discovers or acquires a new SFI, he/she is required to make an ad hoc Disclosure Statement to report that SFI by accessing the reporting platform through the Compliance and Integrity SharePoint site in Sentara Source within 30 days of the discovery or acquisition. An investigator is also required to update the Disclosure Statement at the time of application for any

Public Health Service-funded research. The Research Compliance Monitor will regularly review the Disclosure Statements reported to the Compliance Compliance 360 platform (using platform access that is limited only to research investigators' Disclosure Statements).

All travel expenses that are reimbursed by an outside company must be reported through an ad hoc Disclosure Statement that includes the purpose, destination, and duration of travel within 30 days of receiving payment. This disclosure requirement does not apply to travel that is reimbursed or sponsored by Sentara Health, a federal, state, or local government agency located in the United States, a United States institution of higher education, an academic teaching hospital or medical center, or a research institute that is affiliated with a United States Institution of higher education.

Investigators not employed by Sentara (excluding VHS/ODU employed investigators) whose research is funded through Sentara will report a Sentara Disclosure Statement to the Sentara Compliance Department. Sentara Research will provide a list of these affiliated Investigators to Sentara Compliance, who will facilitate the Investigator's access to the web-based Compliance 360 reporting platform. These affiliated Investigators will file a report at the time of their first study start-up and annually thereafter and will file ad hoc Disclosure Statements when appropriate. The Research Compliance Monitor will regularly review these Disclosure Statements in communication with the compliance officials at the affiliated institution. In addition to Sentara's oversight, investigators employed by affiliated institutions will be governed by the relevant policies and procedures at their affiliated institution and their disclosure, review, and management of financial COI will be under the direction of the affiliated Institutional Official.

All Investigators and Senior/key personnel will work with the Sentara Health Research Center to complete any additional financial COI forms that are required by specific study sponsors at the time of study start-up.

Sentara Compliance Department and the Research Compliance Monitor will maintain confidential records of disclosures of all Investigators and Senior/key personnel.

An Investigator's or a Senior/key personnel's cumulative disclosures of financial interests will be intermittently audited by cross checking the disclosures with reporting through openpaymentsdata.cms.gov. Failure to disclose financial interests will be considered a violation of Sentara policy and subject to disciplinary action and possible reporting to federal funding agencies.

5.4. Research COI Review:

The Research Compliance Monitor will access the Disclosure Statements in Compliance 360 on a regular basis at a frequency that is needed to assess accumulated financial disclosures. The Research Compliance Monitor will determine if any SFI disclosures involve companies that are sponsors for active studies involving the Investigator to assess whether a financial conflict of interest exists. If any accumulated SFI disclosures are related to any of an investigator's active research activity, the Research Compliance Monitor will work with the Chief Research Officer to develop an appropriate management plan. The Research Compliance Monitor will report the review results on a quarterly basis to the Sentara Research COI Committee, including the Sentara Corporate Compliance Manager, and more frequently if needed. The Research Compliance Monitor, Chief Research Officer, and the Sentara Corporate Compliance Manager will also review any non-financial interests, such as leadership roles, that could raise conflict of interest concerns requiring a management plan.

All Disclosure Statements will be maintained confidentially by the Research Compliance Monitor and the Sentara Corporate Compliance Manager and will only be shared with authorized individuals acting in their official capacity. This information will not be shared outside of Sentara Health unless required by legal or contractual obligations, audits, investigations, or when financial COI notifications are required by the IRB or research sponsors.

5.5. Research COI Management:

The Research Compliance Monitor will develop a proposed management plan for all research financial conflicts of interest, working with the Chief Research Officer and the Sentara Corporate Compliance Manager. The drafted management plans will be reviewed quarterly by the Sentara Research COI Committee, and more frequently if warranted. This process will also be periodically reviewed by the Sentara Conflict of Interest Review Committee, a standing system-wide committee appointed by the Sentara Health Chief Compliance Officer that is responsible for setting financial COI standards and for reviewing and directing management of financial COI.

Full disclosure is a key part of any management plan. This action may be the full and open disclosure of the SFI to all personnel whom the Investigator directly supervises and to relevant members of the research team. Investigators are required to disclose all financial COI in all publications and presentations of research related to the SFI, and to human subjects participating in a study, which could be affected by the Investigator's SFI via communication (usually in the informed consent form) that is approved by the appropriate Institutional Review Board. If revisions to an informed consent form is required, the Research Compliance Monitor will work with the SHRC Regulatory Specialist to ensure that the appropriate IRB is properly engaged to revise the informed consent form.

Additional actions may include, but are not limited to the following:

- Additional periodic review of an Investigator's research and SFI by the Sentara Health Research Compliance Office, along with input from Corporate Compliance as necessary.
- Modification of the research plan to ensure the integrity of the research.
- Independent oversight, including the appointment of an independent monitor from outside the Sentara Health Research Center who deemed qualified to provide additional periodic review of an Investigator's research and SFI.
- Involvement of an independent statistician to review the research results, data analysis, and interpretation.
- Change of personnel responsibilities.
- Prohibition to participate in research.
- Divestiture of the SFI.
- Severance of the relationship(s) that create the financial COI.

Sentara Health may also develop a management plan in situations that do not constitute financial COI, but where it is determined that there are COI concerns and action is needed to preserve the integrity of the research. Investigators who hold leadership roles in a company involved in research, such as serving on an advisory committee or a study oversight committee, whether remunerated or not, may be required to recuse themselves from taking on the role of site Principal Investigator at Sentara.

Sentara Health will establish adequate enforcement mechanisms and provide for employee sanctions and other administrative actions to ensure Investigator compliance as appropriate. For non-employed Investigators, Sentara Health will work with the affiliated institutional officials to ensure Investigator compliance.

5.6. Presumptively Prohibited Activities:

Conflicts of interest in Research involving human subjects:

Conflicts of interest in Research involving human subjects require enhanced considerations beyond preserving the integrity of the Research, to include risks to the rights and welfare of participants.

To protect research participants and preserve the integrity of the research study and data, Sentara Health has a presumptive prohibition against participation in human subject research by an Investigator in the following situations:

- The human subject research is funded by an Outside Entity in which the Investigator has a Significant Financial Interest.
- The human subject research involves a product or intellectual property from an Outside Entity in which the Investigator has an SFI.
- The human subject research is funded by an Outside Entity for which the Investigator serves in a Fiduciary Role (e.g., Board of Directors, Chief Executive Officer).
- Exceptions to the presumptively prohibited activities may be made in compelling circumstances on a study-by-study basis. Compelling circumstances could include the nature of the research, the risk level of the study (minimal risk vs. more than minimal risk, as defined at 45CFR 46.102(j)), the nature of the SFI, how closely the SFI is related to the proposed research, and the degree to which the interest may be affected by the proposed research.
- Investigators wishing to participate in a presumptively prohibited human subject research activity must present a written request for an exception to the Sentara Conflict of Interest Review Committee and the appropriate Institutional Review Board (IRB). This request must include a list of compelling circumstances and a proposal on how the conflict of interest could be effectively managed.

Conflict of Interest in Research Involving Sponsorship, and/or Products from a Privately Held Entity

An Investigator wishing to conduct research activities that involve sponsorship, including but not limited to funding or in-kind support, or products/intellectual property from a privately held outside entity, including a start-up, in which the Investigator has an SFI, should be aware that these situations may create conflicts of interest that can impact the scientific integrity of the research.

The following activities/situations are presumptively prohibited as they create, in almost all circumstances, conflicts of interest that cannot be effectively managed:

5.6...1. An Investigator's research at Sentara Health is sponsored by a privately held outside entity, including a start-up, in which the Investigator has an SFI or otherwise holds a Fiduciary Role or executive-level position.

5.6...2. An Investigator's research at Sentara Health is sponsored by a privately held outside entity, including a start-up, in which the Investigator's current research assistants, trainees, students, or

others over whom the Investigator has supervisory authority have an SFI or otherwise hold a fiduciary role or executive-level position.

5.6...3. The Sentara Conflict of Interest Review Committee may make exceptions in compelling circumstances, which will depend in each case upon the nature of the research, the status of the outside entity, the nature of the SFI, how closely the SFI is related to the proposed research, and the degree to which the interest may be affected by the proposed research. The Sentara Compliance Department may, within its discretion, consult other offices as necessary and appropriate in its evaluation of the compelling circumstances, such as the appropriate IRB or study sponsors, or it may refer a case to Sentara Health Research Center leadership or Legal for adjudication.

5.6...4. Investigators wishing to engage in a presumptively prohibited activity must present a detailed written request for an exception to the Sentara Conflict of Interest Review Committee. This request must include a full summary of the presumably prohibited activity in question, a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

Self-Funded Research

5.6...5. Investigators are presumptively prohibited from using their own personal funds or receiving funding from a Family Member or a Family Trust to support research efforts they are directing or conducting under the auspices of Sentara Health, including efforts that involve research personnel, such as, but not limited to, graduate students.

5.6...6. Self-funded research can blur the boundary between funder and researcher, and may give rise to concerns regarding appropriate oversight, accountability, and conflict of interest.

5.6...7. As an exception to this presumptive prohibition, an Investigator may, in the normal course of conducting research, use personal funds to purchase low-cost, or routine research-related items (less than $100 per item). Review and prior approval by the Sentara Research Conflict of Interest Committee is required if an Investigator wishes to use personal funds to purchase major or capital research items or equipment.

5.6...8. Investigators and their Family Members wishing to support research projects at Sentara Health may donate in accordance with Sentara Health's donation guidelines and policies. However, Investigators cannot donate to a research account over which they or someone they directly supervise who has spending authority.

5.7. Other Obligations:

Reporting Requirements for PHS-Funded Research

For any Financial Conflict of Interest that Sentara Health identifies and that involves an award funded by PHS, prior to the expenditure of any funds under the award, Sentara Health, acting through its designated Institutional Officials and the Sentara Research Conflict of Interest Review Committee, will:

- Confirm that the Financial Conflict of Interest is managed or eliminated.
- For Financial Conflicts of Interest that will be managed, develop and implement a management plan that specifies how the identified Financial Conflict of Interest will be managed.
- Notify the PHS awarding agency of the existence of any Financial Conflict of Interest in accordance with PHS requirements.
- Monitor for compliance with implemented management plans.
- For any SFI that the Institution identifies as creating a conflict or potential conflict after the Institution's initial FCOI report that is related to ongoing PHS-funded research, Sentara Health shall provide PHS, within sixty days, an FCOI report regarding the SFI and implement a management plan in accordance with institutional policies.
- If there is an indication of noncompliance with Sentara's policy regarding SFI reporting, Sentara Health shall perform a retrospective review within 120 days to determine whether an investigator deviated from Sentara's FCOI policy. If the research involved PHS funded research, Sentara Health will report the determination to the appropriate PHS funding agency, including the funded project's project number, title, Principal Investigator, involved investigators, name of entity with which the investigator had a FCOI, reason for the retrospective review, methods for the review, findings of the review and conclusions of the review.

Public Accessibility

For PHS-funded research, Sentara shall ensure public accessibility by written response to any requestor within five business days of a request of information concerning any SFI disclosed to Sentara by senior/key research personnel who is conducting PHS supported research.

Non-Compliance with the Special Requirements under 42 CFR 50 Subpart F or the DoE interim COI Policy

In the event of non-compliance with special requirements under 42 CFR 50 subpart F or the DoE interim COI Policy, Sentara Health Research Center must conduct a retrospective review of the Investigator's activities on the PHS-or DoE-Funded Research project to determine whether any PHS- or DoE-funded research, or portion thereof, conducted during the time of non-compliance, was biased in the design, conduct, or reporting. Furthermore, the Sentara Health Research Center must, to the extent required by federal regulations or policy, submit a mitigation report to the PHS or to DoE.

- Non-compliance with special requirements includes the following:
  - 5.7...1. An Investigator failed to report a new SFI within the required time frame, or Sentara Health failed to review a new SFI within the required time frame, and that SFI, upon review by Sentara Health, is then determined to create a financial COI with a PHS- or DoE-funded research project.
  - 5.7...2. A Financial Conflict of Interest is not identified or managed in a timely manner.
  - 5.7...3. An Investigator fails to comply with a Financial Conflict of Interest management plan.

Exceptions:

None

Monitoring:

Outcomes Monitoring – The Research Compliance Monitor and Chief Research Officer will be responsible for monitoring financial conflicts of interest, developing management plans, and monitoring compliance.

Document Management – The contact listed will be responsible for developing, communicating, and maintaining this policy and related procedures and job aids necessary for the implementation and continuance of the policy. This policy shall be reviewed at least every 3 years for repeal or amendment as appropriate.

Related Documents:

Policy	List Related Policies.
Procedure	Financial Conflict of Interest
Job Aids	List Related Job Aids.
Regulatory References	42 CFR Part 50 Subpart F 21 CFR 54 45 CFR Part 94