CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Title: Financial Conflict of Interest in Research	**Current Effective Date:** 02/29/2024

Purpose: The purpose of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from an Investigator's (and/or the Investigator's spouse and/or dependent children) financial conflicts of interest. This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought.

Audience: Physicians, Allied Health, Staff, Residents, Students with PHS Funding

Departments: All Hospital Departments

Keywords: Research, Human Subject, Conflict of Interest, Disclosure, Compliance

Definitions:

Disclosure means an Investigator's disclosure of financial interest to the Health System related to his or her institutional responsibilities.

Entity means a non-Health System organization, whether public or private. Examples include the following: a company, partnership, professional association, voluntary health organization, etc.

Financial Conflict of Interest (FCOI) means a significant financial interest related to proposed Heath System research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children, regardless of whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Health System, including, but not limited to, activities such as research, research consultation, teaching, professional practice, and institutional committee memberships.

Investigator means the principal investigator or project director and any other person, whether faculty, staff, resident, or student and regardless of title or position, who has

the authority to make independent decisions related to the design, conduct or reporting of Health System research. It also includes subgrantees, contractors, collaborators, or consultants to the Health System.

Manage means to take action to address a financial conflict of interest which includes reducing or eliminating the financial conflict of interest, to the design, conduct, and reporting of research are free from bias or the appearance of bias.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge and encompasses basic and applied research and product development.

Significant Financial Interest (SFI) means

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the **twelve months preceding the disclosure and the value of any equity interest in the entity as** of the date of disclosure, when aggregated, exceeds $5,000. For purposes of the definition of Significant Financial Interest, 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.
    b. Regarding any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (and/or the Investigator's spouse and/or dependent children) hold any equity interest (e.g., stock, stock option, or other ownership interest); or
    c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For Public Health Services (PHS)-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
3. The term *significant financial interest* **does not include** the following types of financial interests:

a. Salary or other remuneration paid by the Health System to the investigator if the investigator is currently employed or otherwise appointed by the Health System.
b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
c. Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of high education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
d. Travel by a PHS-funded Investigator that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of high education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Policy: Any Health System agent or employee who is engaged in research shall be responsible for disclosing any potential conflict of interest (COI) as outlined in the policy. Additionally, Health System agent or employee engaged in research are responsible for complying with other applicable laws and Health System policies, including Cape Fear Valley Health System Policy-Procedure: Conflict of Interest – 808.

A conflict of interest exists when significant financial interests or other personal considerations may compromise or appear to compromise professional judgment or integrity in the conduct or reporting of research or performance in administration, management, instruction, and other institutional obligations. Federal regulations require full disclosure of significant financial interests, as defined by the Department of Health and Human Services (HHS), in externally sponsored research. The existence of such conflicts does not in any manner indicate wrongdoing on the part of the individual. In, fact, in today's research environment, it is understood that conflicts of interest can occur. However, if a conflict of interest exists, it must be reduced, managed, or eliminated as soon as one becomes aware of it.

The key to handling potential conflicts is to fully disclose significant financial interests and, if a conflict of interest is identified, to participate in the development and implementation of an appropriate management plan. The Health System is committed to advancing research and fostering an entrepreneurial spirt at Cape Fear Valley Health (CFVH) while maintaining objectivity and integrity in research.

Notwithstanding all other language in this Policy-Procedure, the Health System prohibits any arrangement where the amount of compensation, or potential compensation, will be directly affected by the outcome of the research (e.g., an

arrangement has been made where the value of the compensation will change depending on the outcome of the research).

Procedural Guidelines:

1. **Investigator Responsibilities**
   - An investigator is responsible for disclosing all significant financial interests by completing and submitting a Financial Conflict of Interest Disclosure Form ("Disclosure Form") to the Human Resources Department.
   - Submitting a Disclosure Form annually even if they have no new financial interests to report.
   - Providing updates to the Disclosure Form within thirty (30) days of discovering or acquiring a new significant financial interest or after a financial conflict of interest has been eliminated.
   - Disclosing conflict of interest information upon submittal of applications for externally funded research or other externally funded activities. If there is any doubt about the existence of an actual or apparent conflict of interest, the investigator should err on the side of disclosure.
   - Principal Investigators are responsible for informing any co-investigators, staff, residents, or students involved in the design, conduct, or reporting of the externally sponsored research project that they are required to complete a Disclosure Form.
   - Principal Investigators are responsible for completing all required training and education.
   - Principal Investigators are responsible for ensuring updated Disclosure Form(s) is on file at the time of Institutional Review Board (IRB) approval for any new research proposals.

2. **Financial Conflicts of Interest (FCOI)**

   A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of the research.

   Examples include, but are not limited to the following:
   - Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity having an interest in the Investigator's (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research;
   - Investigator (and/or an Investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

   This policy addresses individual financial conflicts of interest; however, the Health System may also have conflicts of interest in research whenever the financial interests of the Health System, or of a Health System official acting within their authority on behalf of the Health System, might affect-or reasonably appear to affect-the Health System processes for the conduct, review, or oversight of the research. If institutional conflicts of interest are

identified via the process describe below, they will normally be addressed in a manner consistent with this policy.

3. Review of FCOI's

The Human Resources Department conducts an initial review of all Disclosure Forms, and is responsible for determining whether an apparent or actual conflict of interest exists and thus whether further review and management is required.

If necessary, Human Resources will obtain additional information from the Investigator and may consult with other Health System officials including Department of Corporate Compliance to help determine whether the significant financial interest disclosed is related to a proposed or existing sponsored project or program.

When reviewing the collected information to determine whether a financial conflict of interest exists the following will be considered:

- Impact on integrity of research data;
- Risks to rights and safety of human research subjects;
- Risks to the rights of employees and trainees participating in research; and
- Appearance of conflict of interest.

4. Management of FCOIs

If the Department of Human Resources determines that an actual or apparent conflict of interest exists, the investigator may be required to comply with a management plan to ensure the reduction, management, or elimination of the conflict.

The Director of Corporate Compliance and Research Director will work with the investigator to resolve how the conflict should be managed, reduced, or eliminated. Other Health System officials may be involved in the management process if deemed necessary.

Conditions or restriction might be imposed by the Health System to manage, reduce, or eliminate actual or potential conflicts of interest including but are not limited to:

- Public disclosure of relevant significant financial interests (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of the research plan;
- Change of personnel or personnel responsibilities or disqualification from conduct in all or a portion of the research;
- Disqualification from participation in the portion of the activity that would be affected by the significant financial interests;
- Divestiture of significant financial interests; or
- Severance of the relationships creating actual or potential conflicts.

A draft of the plan will be provided to the Investigator for review and comment before it is finalized. The Investigator and Research Director must sign the approved plan to acknowledge their agreement to comply.

If the Health System identifies a significant financial interest that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim plan of action will be implemented when necessary.

5. **Training Requirements**

PHS-funded Investigators must complete FCOI training prior to engaging in research related to external funding, including PHS-funded grants and contracts, and at least every four years thereafter. Training must also be completed as soon as reasonably possible under the following circumstances:

- This policy changes in a manner that affects Investigator requirements;
- An Investigator is new to a subrecipient and will be working on the research;
- An Investigator is found to be noncompliant with this policy or their approved action plan.

6. **Monitoring**

Investigator compliance with management plans will be monitored by Human Research Protection Program Office. The frequency of monitoring will be dictated by sponsor/agency requirements and management plan provisions.

7. **Research Involving Human Subjects**

Specials consideration and scrutiny must be given to protect human subjects in research. Investigators with an identified financial conflict of interest or a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research shall not ordinarily participate in any research involving human subjects. This presumption against the participation in human subjects' research by financially interested individuals may be rebutted by compelling circumstances. Compelling justification may include factors such as unique investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level of risk to human subjects and the degree to which the financial conflict of interest and the research are related.

The compelling justification and the degree of risk to human subjects must be presented and reviewed by Institutional Review Board (IRB) on a case-by case basis. If compelling circumstances justify a waiver of this policy, the research will be subject to the development and implantation of management plan to ensure the safety of human subjects and the integrity of the research. The IRB must review the research with consideration given to the requirements of the management plan. The IRB may require additional safeguards to be implemented but may not determine less stringent financial conflict of interest management requirements.

8. Appeals

Investigators may appeal decisions in writing within 15 days of receipt of the finalized action plan or other decision of the Director of Corporate Compliance. The written appeal should include details regarding circumstances which support the request for a proposed revision to the decision.

An Ad Hoc Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Committee will be convened to review the significant financial interest information, the Management Plan, and additional information used to make the initial determination, to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions.

The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the Ad Hoc Appeals Committee is final and binding.

9. Confidentiality

When disclosure of current review status or outcome is required for internal coordination of approvals for research or medical activities, limited, non-specific information from the investigator's disclosure form and/or management plan will be provided. The recipient of such information shall maintain confidentiality, except as required for the performance of Health System duties or as otherwise required by law.

Disclosure forms will be maintained by the Department of Human Resources. Management plans, and other related records will be kept by the Human Research Protection Program Office in locked file drawers and/or within electronic databases with firewall and password protection. Records will be maintained for at least three years from the date of submission of the final expenditures report or other time periods as required by law.

10. Non-compliance

Individuals are expected to comply with the policy fully and promptly, including the requirements of disclosure. Individuals who deliberately or repeatedly fail to disclose fully and truthfully conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict will be subject to the applicable Health System disciplinary processes, which could include suspension of project funding.

In addition to Health System sanctions, violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies. Individuals may also be subject to criminal sanctions or civil liberties under federal or state law.

In the event the Health System discovers a failure to comply with this policy has biased the design, conduct or reporting of the research in accordance with the process outlined above, the Health System will promptly notify the sponsor of the research as required by applicable law and describe the corrective actions(s) taken or to be taken.

11. Reporting

The Health System will provide initial and ongoing reports of its management plans and other records for at least three years from the date of submission of the final expenditures report, or as otherwise required by law.

12. Specific provisions applicable to PHS-funded research

The following additional requirements also apply to all research funded by the PHS of the U.S. Department of Health and Human Services and any PHS Awarding Component including the NIH.

- **Reporting**

  The Health System will provide to the PHS Awarding Component a FCOI report as outlined in the regulations:

  Initial Report: Prior to expenditure of any funds under the PHS-funded research project, the Health System will provide a FCOI report regarding any SFI found to be a FCOI. The Health System will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Health System identifies a FCOI not previously disclosed. This report will include the following information:
  - Grant/Contract Number
  - PD/PI
  - Name of Investigator with FCOI
  - Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
  - Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
  - Description of how FCOI related to PHS-funded research ant eh basis for the determination the financial interest conflicts with such research
  - Key elements of the FCOI management plan

  Annual updates to this research will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:
  - Status of the FCOI
  - Changes to the management plan
  - Justification an FCOI no longer exists

- **Subrecipients**

  For PHS-funded research that involves subcontractors, subgrantees or sub awardees (collectively subrecipients) at other Institutions, the Health System requires a written agreement that includes terms establishing whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must report identified financial conflicts of interests to the Health System in sufficient time to allow the Health System to report the FCOI to the PHS Awarding component.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Health System's FCOI in Research policy. A subrecipient's failure to promptly comply with the Health System's policy will be considered grounds for immediate termination by the Health System of any applicable subcontract or subaward. The written agreement terms required by the Health System will contain a provision that subrecipients will report to the Health System as the pass-through entity, any identified FCOI in sufficient time to allow the Health System to report and manage the FCOI and meet the reporting obligations described above.

- **Public Accessibility**
  This policy will be posted on Cape Fear Valley Health's public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestor via an email response within five business days from when the IRB receives the request.

  The written response will include:
  - Senior/key personnel name
  - Senior /key personnel's role in the research project
  - Name of the entity in which the FCOI is held
  - Nature of the FCOI
  - Approximate dollar value of the FCOI or a statement that the value cannot be readily determined.

  This information will remain available for three years from the date the information was most recently updated.

- **Investigator/Institutional Non-Compliance**

  If a significant financial interest is not disclosed or reviewed in a timely manner, the Health System will review the Investigator's financial interest, and determine if it is related to PHS-funded research; determine whether an FCOI exists, and if so:
  - Implement an action plan for ongoing research, at a minimum implement an interim action plan
  - Complete a retrospective review of Investigator's activities and the PHS- funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
  - If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report

If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the subrecipient's Indirect Cost Allocation portion. If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 a conflicting interest that was not managed or reported to the Health System, the Investigator must disclose the FCOI in each public presentation of the results of the
an addendum to previously published presentations.

- **NIH Reporting Requirements**
  If the Health System is unable to satisfactorily manage a conflict of interest involving NIH funding, it will appropriately notify NIH's Office of the General Counsel.

Related Documents/Policies:

CFVHS Policy-Procedure: Conflict of Interest - 808

References:

42 CFR Part 50 Subpart F
45 CFR Part 94
FDA Guidance for Industry – Financial Disclosure by Clinical Investigators