Policy & Procedure	ID No.	CR - 0331
Subject: AtlantiCare Research Conflict of Interest Policy	*Category:*	General
Policy Scope: AtlantiCare	*Department:*	Provision of Care

PURPOSE:

The AtlantiCare IRB is committed to the integrity of the research process and maintaining public trust. This policy provides the framework whereby the IRB can ensure compliance with applicable laws and regulations regarding financial and other interests that may present a real or perceived conflict of interest (financial or otherwise) with integrity of the research process. The AtlantiCare IRB encourages relationships between Investigators and outside organizations, recognizes the value these add to the research process, and aims to mitigate any real or apparent bias.

DEFINETIONS:

This policy seeks to define and delegate responsibilities regarding the following occurrences:

Conflict of Interest "COI": any circumstance in which professional judgment regarding a primary interest threatens, or appears to be threatened by a secondary interest

Financial Conflict of Interest "FCOI": a significant financial interest that could directly and significantly affect the design, conduct or reporting of Public Health Service (PHS)-funded research.

Significant Financial Interest "SFI": a financial interest consisting of one more of the following interest 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. Significant financial interest occurs in any of the following scenarios:

- With regard to any publicly traded entity, gains of < $5000 in a 12-month period for salary and non-salary services, stocks or other ownership interests.
- With regard to non-publicly traded entity, gains of > $5000 in a 12-month period when the investigator (or spouse or dependent children) holds an equity interest.
- Intellectual property rights and interests upon receipt of income relate to such rights and interests.

POLICY:

The AtlantiCare IRB will comply with all applicable federal and state laws, regulations and policies regarding promoting objectivity in research. These include, but are not limited to:

- Publishing the AtlantiCare IRB COI policy on the research portal.
- All providers involved in research complete a COI questionnaire annually, and upon opening a new study.
- Validate CITI Training prior to providers' participation in research activities and every three years as part of the requirement. COI modules are included in CITI Training (Biomedical Research ID #17464 & Responsible Conduct of Research ID #16599).
- Review of the AtlantiCare COI policy will take place for providers found to be non-complaint with the policy or the management plan.
- Taking reasonable steps to ensure any Sub-Investigators of PHS-funded research complies with this policy, if Sub-Investigator's institution does not have a FCOI policy consistent with 42 CFR Part 50.601.
- Providing guidelines for determining type of COI that may exist (item #4 below).
- Developing a management plan with providers who have a COI.
- Providing the PHS Awarding Component with FCOI reports.
- Keeping records of COI disclosures.
- Ensuring provider compliance with COI policies with enforceable actions.
- Responding in writing within FIVE (5) business days of any public request by providing investigator name, title, research role, name of entity in which SFI is held, nature and vague ranges of SFI that meets the following criteria:
  - SFI was disclosed and is still held by Investigators/Senior/key Personnel for PHS-funded research projects
  - AtlantiCare determines the SFI is related to the PHS-funded research
  - AtlantiCare determines the SFI is a FCOI
- Providing all FCOI reports to research sponsors as required by federal FCOI regulations, sponsor terms and conditions, and/or as outlined in FCOI management plan.
- Maintaining records relating to investigator SFI disclosures, including review and determination for at least THREE (3) years

1. **Conflicts of Interest and IRB Members**
   - AtlantiCare IRB members are required to complete a COI questionnaire annually, or whenever a new interest requiring disclosure arises.
   - AtlantiCare IRB members must declare an actual, perceived or potential COI prior to, or at the opening of a meeting. Members.
   - Members with COI must recuse themselves, and are not permitted to participate in the review, discussion, or voting process for any research study in which they have a COI.

2. **Conflicts of Interest and Investigators**
   - Any investigator who thinks they may have an actual, potential, or perceived COI must report relevant facts promptly to the IRB chair or designee to determine if a COI exists and devise a management plan as needed.
   - An investigator cannot begin a research study until any real or perceived COI related to the research has been addressed by the IRB chair or designee and has been reduced, managed or eliminated.
   - Investigators should be mindful it can take time to reach decisions and devise adequate management plans, and therefore should be proactive in reporting to allow sufficient time.

3. **Disclosure of CIOs by Investigators**
   - Investigators, Sub-Investigators and study staff are required to complete the COI questionnaire before beginning the research process annually. The IRB Chair or designee may request additional information and supporting documentation of any actual or potential COIs.
   - An investigator must update his/her COI disclosure for within 30 days of discovering or acquiring a new COI.
   - COI management plans are developed through the IRB chair or designee and may include an investigator divesting himself/herself from a research study. In this case, it is not necessary for the IRB Members to be informed of the COI.
   - Research informed consent forms must include a description of any relationship that might be perceived as a potential conflict of interest.

4. **Examples of Conflict of Interest**
   - An investigator or member of the research team or family member of either participates in research on a technology, process or product owned by a business in which they hold a financial interest
   - An investigator or member of the research team or family member has a financial interest in an entity with is supplying funding, materials, products or equipment for the current research project
   - An investigator or member of the research team or family member serves on the Board of Directors of a business which is supplying funding, materials, products, or equipment for the current research project
   - An investigator or member of the research team or family member receives consulting income from an entity that is funding the current research project.

5. **CIO Review Process**
   - The IRB Chair or designee will pre-review any Questionnaire with a potential COI indicated

- If a COI management plan has been approved through another IRB for a submission, the AtlantiCare IRB may not limit or reduce the conditions of that plan but may impose additional requirements to meet the regulatory criteria for approval.
- The IRB Chair or designee is responsible for reviewing all SFIs disclosed in order to determine whether the SFI is related to the research, and if so, refer to the AtlantiCare IRB to determine of the SFI is a FCOI.

6. **COI Outcomes**

- SFIs that could be affected by the research or is in an entity or individual whose financial interest could be affected by the research will be deemed RELATED TO RESEARCH. Additional input from the investigator and/or department heads may be used in the determination.
- The AtlantiCare IRB Chair or designee will determine is the SFI could directly and significantly affect the design, conduct or reporting of related research. If so, he/she will determine if the FCOI should be managed or eliminated before research funds are expended.
- If a new SFI arises during the course of a research project, the AtlantiCare IRB Chair or designee will review the SFI and made a determination. If the SFI is deemed a FCOI and a management plan is recommended, one must be implemented within 60 days of the date of disclosure.
- If human participants are involved in the related research, the AtlantiCare IRB will determine if the SFI will adversely affect the protection of participants. If so, then disclosure to potential participants or the public cannot be used as the sole method of FCOI management.

7. **FCOI Management Plans**

- Unless otherwise advised by the AtlantiCare IRB Chair or designee, or the AtlantiCare IRB, FCOI management plans will include disclosure of the FCOI in the research project's informed consent form.

AtlantiCare: AtlantiCare is defined as any and all affiliated companies of the AtlantiCare Health System, including its joint ventures operating under the AtlantiCare trademark, and captive professional services corporations such as AtlantiCare Physicians Group.

AtlantiCare affiliate: AtlantiCare affiliate is defined as an organization associated with another AtlantiCare organization as a subordinate, subsidiary, or member.