A. **Policy:** All investigators, as defined in this policy, which engage in clinical research, will disclose all significant financial and fiduciary interests to Saint Alphonsus Regional Medical Center (SARMC) on an ongoing basis.

B. **Purpose:** Saint Alphonsus Health System (SAHS), its physicians and associates are committed to conducting their institutional activities in accordance with the highest standards of integrity and ethics and in compliance with all applicable laws and regulations related to conflicts of interest and objectivity in research. To promote the ethical conduct of research, SARMC has established this policy and related forms and procedures to identify and address conflicts of interest in the context of human subject research.

Financial interests in human subjects research are distinct because financial interests are discretionary, and because the perception is widespread that they may entail special risks. Specifically, 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 the subjects, and even the proper use of subjects’ protected health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, review, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. The purpose of this policy is to set forth information about and procedures to identify and address conflicts of interest in the context of human subject's research.

C. **Definitions:**

1. **Conflict of Interest** means a situation in which a Significant Financial Interest may compromise, or have the appearance of compromising, an Investigator’s judgment in conducting, reviewing or reporting research.

2. **External Entity** means any natural person, corporation, partnership, sole proprietorship, association, organization, holding company, joint stock company, receivership, trust, governmental agency or subdivision regardless of whether organized for profit, nonprofit or charitable purposes.

3. **Equity Interest** means any stock, option or other ownership interest in an External Entity.

4. **Family Member** means the Investigator’s spouse and dependent children.

5. **Financial Conflict of Interest (FCOI)** means that SARMC has determined the conflict could directly and significantly affect the design, conduct or reporting of research.

6. **Institutional Responsibilities** means an investigator’s professional responsibilities on behalf of the institution including research, research consultation, teaching,
clinical practice, institutional committee memberships, and serves on panels such as Institutional Review Boards (IRB) or Data Safety Monitoring Boards.

7. Investigator means the Principal Investigator (PI) and any other personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which includes, co-investigators and research coordinators.

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

9. PHS means the Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Examples of PHS funding mechanisms include:
   a. Grants
   b. Cooperative agreements
   c. Career Development Awards
   d. Center Grant of Individual Fellowship Awards
   e. Any activity where funding is provided by PHS

10. Research means a systematic investigation, study or experiment designed to develop or contribute to general knowledge relating broadly to public health, including behavioral and social-sciences research.

11. Significant Financial Interest (SFI) means an Investigator’s (and/or his/her Family Members’):
   a. Remuneration (any monetary or other financial benefit such as salary, consulting fees, honoraria or paid authorship) from any External Entity (not those paid by SAHS) that is related to the Investigator’s research activities and exceeds $5,000 during the 12-months prior to the disclosure when aggregated for the Investigator and their Family Members;
   b. Equity Interest in any External Entity that is related to the Investigator’s research activities (for publicly-traded External Entities an SFI exists only if the Equity Interest exceeds $5,000 in value when aggregated for the Investigator and their Family Members);
   c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
   d. Reimbursed or sponsored travel that is not related to the Investigator’s Institutional Responsibilities, such as travel required for awarded Grant activity. Note: travel may be paid on behalf of the Investigator and not directly reimbursed to the Investigator so that the exact monetary value may not be readily available but still must be estimated.
   e. An SFI does not include the following:
      i. Salary, royalties or other remuneration paid by SAHS to the Investigator and intellectual property rights assigned to SAHS;
ii. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);

iii. Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001 (a).

iv. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

D. Procedure: Successful implementation of this policy assumes a shared responsibility by the Investigator and SARM C.

1. Investigator Responsibilities
   a. All Principal Investigators, co-Investigators, and research coordinators who consent research participants must completely and accurately disclose all SFIs on an annual basis or as changes occur. Examples include SFIs in any External Entity that:
      i. Sponsors the Investigator’s research;
      ii. Has made or pledged a gift to SAHS that benefits the Investigator’s research;
      iii. Has products, services or research interests that could reasonably appear to be affected by Investigator’s research; or
      iv. Sells goods or services to SAHS that will be used in Investigator’s research.
   b. The Investigator is required to submit an updated disclosure within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
   c. All Investigators must complete training on FCOI prior to engaging in research. Re-training must be completed at least every three years and immediately when any of the following circumstances apply:
      i. An Investigator is new to SAHS;
      ii. SARM C revises its conflict of interest policies or procedures in any manner that affects the requirements of Investigators; or
      iii. SARM C finds that the Investigator is not in compliance with this policy or Management plan.

2. SAHS Responsibilities
   a. Maintain a written policy on FCOI that complies with applicable laws and regulations.
   b. Maintain the Institution’s FCOI policy publicly.
   c. Develop, provide and monitor FCOI training.
   d. Review each submitted “Financial Interest Disclosure Reporting Form” to identify any potential FCOI in accordance with applicable laws and regulations. At SARM C the Institutional Official and/or designee will carry out this function.
e. Any identified potential FCOI will be reviewed by the Research Administrator, which will then determine and document mitigation actions to manage the FCOI.

f. Establish adequate enforcement mechanisms and provide for sanctions or other administrative actions to ensure researchers are in compliance with the management plan.

g. If SARMC carries out research through a sub-recipient (e.g., subcontractors or consortium members), SARMC must take reasonable steps to ensure that the sub-recipient’s FCOI policy is in compliance with requirements for disclosure.

h. If the sub-recipient cannot provide such certification, a written agreement between SARMC and the sub-recipients shall state that sub-recipient investigators are subject to SARMC FCOI policy and specify time period(s) for the sub-recipient to report all identified FCOI to SARMC.

3. Management of FCOI
   a. To the extent possible and reasonable under the circumstances, the Research Administrator will work with the researcher to develop the means for the research to take place while protecting the objectivity of the research, its participants and uphold/maintain scientific integrity. Listed below are several possible resolutions for Management of the FCOI that may be recommended:
      i. Public disclosure of FCOI (e.g., when presenting or publishing the research, to staff members working on the project or to the IRB);
      ii. For research projects involving human subjects research, disclosure of FCOI directly to participants;
      iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
      iv. Modification of the research plan;
      v. Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or a portion of the research;
      vi. Reduction or elimination of the SFI (e.g., sale of an equity interest); or
      vii. Severance of relationships that create FCOI.
   b. Notify the IRB of the FCOI and the related Management plan.
   c. Determine the appropriate strategies to properly oversee and manage potential conflict(s), taking into consideration the possible remedies as outlined below.
   d. Inform the researcher of the actions taken and decisions made by the Research Administrator.

4. Reporting of FCOI
   a. If PHS is a funding source to any research activity, SARMC will provide to PHS all FCOI information prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
b. SARMC shall provide a written response to any requestors (within five business days of the request) information concerning a SFI that meets the following three criteria:
   i. The SFI was disclosed and is still held by the Investigator;
   ii. Institution determines that the SFI is related to the PHS-funded research; and
   iii. Institution determines that the SFI is a FCOI.

Such written response shall include the following information:
- Investigator’s name;
- Investigator’s title and role with respect to the research project;
- Name of the External Entity in which the SFI is held;
- Nature of the SFI; and
- Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) 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.

5. Sanctions
   a. Sanctions and penalties for non-compliance with this policy or Management plans arising from this policy will be determined by the Institutional Official with advice from the Research Administrator. Sanctions may include, but are not restricted to:
      i. Removal of Investigator from participation in research;
      ii. Letter of reprimand;
      iii. Termination of grant support;
      iv. Notification to funding agencies and/or professional journals and societies;
      v. Suspension; or
      vi. Dismissal.

6. Maintenance of records
   a. All records related to the implementation of this policy (e.g., disclosure forms and notifications to funding agencies) shall be maintained by the Research Integrity Official and designee. These records will be kept in a secured fashion for a period of at least three years following the termination or completion of the research activities.

E. References:
FDA regulations 21 CFR part 54
Federal Public Health Service reg. 42 CFR part 50, subpart F; and 45 CFR part 94

F. Related Policies or Forms:
- Financial Interest Disclosure Reporting Form