Title: SARMC Institutional Review Board: Purpose, Principles, and Authority of the Institutional Review Board (IRB)

Policy Statement: The Institutional Review Board’s primary responsibility is to protect the rights and welfare of human subjects in research. In doing so, the IRB monitors human subject research to determine that it is conducted ethically and in compliance with state and Federal regulations, the requirements of applicable law, Saint Alphonsus Regional Medical Center's Assurance (FWA-00007980), and Saint Alphonsus Regional Medical Center's policies and procedures. The IRB fulfills these responsibilities by conducting prospective and continuing review of human subject research, including review of the protocol, the informed consent process (including applicable HIPAA aspects), procedures used to enroll subjects, and adverse events or unanticipated problems reported to the IRB.

Procedure:

I. The Principles That Govern the IRB in Assuring that the Rights and Welfare of Subjects are Protected

A. Participation of a human subject in any research study must be voluntary and the information provided to gain subject consent must be adequate and appropriate. Potential participants must be informed that they have a right not to participate and that alternatives are available. The alternatives should be listed and the advantages and disadvantages of the alternatives should be explained.

B. The risks to the individual subject must be reasonable when measured against:
   (1) the possible benefit to the subject and
   (2) the importance of the knowledge to be gained.

C. Research activities involving human subjects must be conducted by qualified investigators and support staff who have had adequate human research ethics training (as discussed in the policy Education and Training on Human Research Subject Protections).

D. All research studies under the auspices of SARMC that involve human subjects must be reviewed by, and receive the approval of, the IRB, prior to initiation of the study. All research studies are subject to continuing review, which must be carried out on at least an annual basis.

E. The interpretation and implementation of this policy is the responsibility of the IRB.
II. The Role of the IRB

A. The IRB reviews the risks and potential benefits of the research study, appropriateness of methods used to obtain consent, and protection of the rights and welfare of the individuals involved.

B. Administratively, the IRB reports to the President of the Medical Executive Committee and the COO or his or her designee, who reports to the SARMC CEO and Board of Trustees. The IRB is authorized to do the following:
   1. Review and approve, disapprove, or cause to be changed before approving, all research studies.
   2. Require documentation of informed consent by all human subjects, parents, guardians, or legal representatives of human subjects, before participation in a research study.
   3. Review the consent process, the research in progress, or both, as the IRB deems appropriate.
   4. Suspend or terminate research studies when, in the opinion of the IRB, continuing such a study would harm or jeopardize the rights and welfare of the subjects involved.
   5. Require and monitor the maintenance of all appropriate records and policies as required by governmental mandate and SARMC.
   6. Require and monitor SARMC’s compliance with all federal, state, and local laws and regulations governing research.
   7. Breaches in scientific integrity, actions related to adverse events, or terminations of research determined to be serious by the IRB shall be reported to the COO or a designee and regulatory authorities in accordance with IRB policy.

Scope of the IRBs’ Authority

A. Research conducted within SARMC means:
   1. Research taking place in any facility owned or operated by Trinity Health doing business as SARMC, or utilizing equipment, materials, or other resources owned by SARMC.
   2. Research involving medical records or other information from patients registered at SARMC.
   3. Research conducted with the assistance of SARMC employees.
   4. Research conducted with the support of SARMC financial resources.
   5. Research otherwise involving SARMC; for example, research referencing SARMC in a grant application or in a research publication.

B. Independent or Central IRBs
   Except in circumstances described below under “Cooperative Review Agreements,” approval of a research proposal by another IRB does not substitute for the requirement for approval of the research proposal by the SARMC IRB, nor does approval by another IRB obligate approval of the research by the SARMC IRB. The SARMC IRB may, at its sole
discretion, rely upon approval by another IRB.

C. IRB Authorization Agreements
A current formal, signed agreement between SARMC and one or more other institutions may be established to provide for cooperative review by a single IRB for clinical research conducted at multiple study sites. In addition, reliance on the IRB of another institution or organization, or an independent IRB, must be documented by a written agreement that is available for review by the Office for Human Research Protections (OHRP) upon request. OHRP’s sample IRB Authorization Agreement may be used for this purpose:
http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf
or the parties involved may develop their own agreement.

Related Policies: Functions and Operations of the IRB; Education and Training on Human Research Subject Protections

http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf

References:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html