Policy Statement: It is the policy of Saint Alphonsus Regional Medical Center that all research involving human participants conducted within the institution or utilizing SARMC patients or patient information be reviewed and approved by the Institutional Review Board prior to the start of such research. Additionally, the IRB will conduct continuing review of this research to ensure the ongoing protection of human participants. Furthermore, IRB oversight will be guided by the ethical principles described in the "Belmont Report" as well as the policies set forth by all applicable federal and state regulations related to research involving human participants.

Procedure:

I. Functions and Operations of the IRB

A. Meetings:

The IRB meets monthly. The schedule is set annually, and published with associated submission dates on the internal and external SARMC websites.

B. Pre-meeting materials are generally distributed at least 10 days in advance of the monthly meeting and shall include, but are not limited to:

1. Agenda
2. Minutes of prior month’s meeting
3. SARMC initial, continuing review and amendment applications
4. Previously reviewed expedited review submissions
5. Protocols
6. Informed consents
7. Investigational Brochures that have resulted in protocol and/or consent amendments for trials conducted at SARMC
8. Data collection tools, including surveys
9. Internal unanticipated problems and adverse event reports
10. External adverse event reports that have resulted in protocol and/or consent amendments for trials conducted at SARMC
11. Close-out documentation (closure to accrual or permanent closure)
12. Death notices
13. Data monitoring committee meeting minutes
14. Education materials
15. Administrative and miscellaneous items

C. Review Process:

1. Description of the review process for a new study:
A primary and secondary reviewer, typically one scientific and one non-scientific member, will be appointed in advance of the meeting for each new study. All members will be provided the full protocol, informed consent, data collection forms, advertisements, reference lists, and product or drug brochures. All review assignments are documented in the IRB agenda and meeting minutes.

2. Emergency use notification and reporting procedures:

   a. Please refer to the SARMC policy Emergency Use of a Test Article (Drug, Device, Biologic) at:


   1) Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB. The exemption may not be used unless all of the conditions described in 21 CFR 102(d) exist. FDA regulations recommend that any subsequent use of the investigational product at the institution have prospective IRB review and approval; however, the FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

   b. In the event that an experimental product or procedure must be used on an emergency or compassionate basis, the investigator must contact the IRB Chair immediately and write a letter within twenty-four hours describing the nature of the situation and requesting approval.

      1) The IRB Chair has the right to determine whether or not the request is an emergency and to determine whether the investigational drug, biologic and/or device may be used prior to full IRB committee review.

      2) The protocol governing the use of an investigational agent for treatment must then be presented at the next IRB meeting. Granting emergency review powers to the IRB Chair does not waive the IRB’s
responsibility nor abrogate the IRB’s right to approve or deny such a request subsequently.

a. If subsequent use of the investigational drug, biologic and/or device in conjunction with a research protocol is anticipated, a protocol and informed consent must be presented before the full IRB for review and approval.

4. Expedited Review

a. Expedited review may be carried out by the IRB Chairperson or by one or more experienced members of the IRB designated by the Chairperson (48 CFR 46.110; FDA 21 CFR 56.110). The reviewer(s) have all the rights and privileges of the full IRB.

b. This expedited review process may be used to review minor changes in previously approved research, as well as for certain kinds of research involving no more than minimal risk as detailed in 45 CFR 46.110; 21 CFR 56.110.

c. A research project may not be disapproved by the expedited review process. In this case the expedited reviewer will then recommend full board review.

d. Members of the IRB shall be kept informed of expedited reviews approved under this procedure at the next regularly scheduled meeting. The expedited reviews will be recorded in the meeting agenda and meeting minutes. The information recorded will include the title of the research project, details of what was reviewed, and identification of the expedited reviewer.

D. Criteria for IRB approval:

1. Risks to subjects are minimized:
   a. by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk;
   
   b. whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes;
   
   c. in relation to anticipated benefits, if any, and the importance of the knowledge that may result from the research.

2. Selection of subjects is equitable:
The IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant
women, handicapped, or mentally disabled persons, as well as economically or educationally disadvantaged persons.

3. Written informed consent will be sought from each prospective participant or the participant’s legally authorized representative:
   a. An investigator shall seek such consent only under circumstances that provide the participant or the participant’s authorized representative with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence;
   b. Information contained in the informed consent shall be in a language understandable to the participant or the representative;
   c. The informed consent may not include any exculpatory language through which the participant or representative is made to waive or appear to waive any of their legal rights, or releases or appears to release the investigator, the sponsor, Saint Alphonsus, or its agents from liability for negligence.

4. Informed consent will be appropriately documented:
   a. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or legally authorized representative at the time of consent. A copy of the consent shall be given to the person signing the form.
   b. When informed consent is obtained orally, an IRB approved short form written consent document (stating that the elements of consent have been presented orally) is required, and this document needs to be signed by a witness. The witness must observe the oral presentation of informed consent information to the subject, sign the short form written consent document, and sign a copy of the summary of the oral presentation approved by the IRB. The summary must also be signed by the person performing consent, and the short form consent document must be signed by the subject or the subject’s legally authorized representative.

E. Voting requirements:

1. Quorum is required to transact business:
   a. A quorum of the IRB, duly convened, shall be more than half of the total voting membership, provided that such quorum includes at least one non-scientific (lay) member.
   b. When the Board is not physically convened in the same location, reviews and votes will be conducted via teleconference, provided that each participating IRB
member has received all pertinent material prior to the meeting and can actively and equally participate in the discussion of the research projects. Minutes of such meetings will clearly document that these two conditions have been met.

2. **Percentage needed to approve or disapprove a research project:**
   It takes a majority of quorum to approve or disapprove a research project (over 50%). Those members in attendance who abstain from voting are considered a part of quorum.

3. **Voting rights of membership:**
   All members of the IRB have full voting rights to approve or disapprove a research project, taking into account the prohibition of conflict of interest.

5. **Proxy votes:**
   Proxy votes from absent IRB members will be accepted but will not count towards the recognition of a quorum.

6. **Prohibition of conflict of interest voting:**
   No IRB member may participate in the IRB’s initial or continuing approval of any project if the member has a conflicting interest, except to provide information requested by the IRB. If a conflict of interest exists, the IRB member affected will abstain from voting. This abstention will be recorded in the meeting minutes.

F. **Communication from the IRB:**

1. **To the investigator for additional information:**
   The IRB will notify the Principal Investigator, in writing, of the results of its deliberation, including requests for additional information. If the IRB determines that the investigator has not provided the required information, it will be the responsibility of the investigator to provide the necessary information before the IRB considers that aspect of the research project further.

2. **Investigator notification of IRB decisions:**
   The IRB shall notify the Principal Investigator in writing of its decision to approve, disapprove, or defer a decision regarding the proposed research project/activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in writing or in person at the next regularly scheduled IRB meeting.
3. Sponsor notification of IRB decisions:
The IRB delegates the responsibility to the Principal Investigator of informing the sponsor of all IRB related decisions with regard to the research protocol.

G. Reporting findings and actions to the Institution:
IRB meeting minutes will be submitted monthly to the IRB committee members (including the Chair) and a quarterly report will be submitted to the Office of Medical Affairs. The report will include at a minimum the date of IRB action, the protocol title, and a description of the action taken by the IRB.

H. The IRB reserves the right to request progress information from the Principal Investigator at more frequent intervals as it may deem appropriate. The IRB will determine if the protocol requires review more than once a year. This determination will be documented in the meeting minutes and communicated to the investigator through written correspondence.

I. During review, the IRB may determine that a research project requires verification from sources other than the investigator. The IRB may contact those sources, and any such contact will be documented.

J. Changes in the protocol may not be initiated without IRB approval except where necessary to address apparent immediate hazards to human subjects. Each investigator shall be required to report any proposed changes and/or unanticipated complications to the IRB immediately, using the Request for Amendment or Modification form.

K. Failure to comply with the procedures in the approved protocol, including the approved requirements for informed consent, may result in the immediate suspension or termination of the research, and may be reported to the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and other appropriate agencies by the Chairperson of the IRB.

L. The IRB has the authority and obligation to promptly notify the appropriate federal department or agency (when applicable) of any significant or material findings or action, including:
   a. serious unanticipated injuries or death, or any other unanticipated problems involving risks to subjects or others;
   b. any serious or continuing noncompliance with regulations or requirements of the IRB;
   c. any suspension or termination of IRB approval. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action.

Related Policies: SARMC Institutional Review Board: Purpose, Principles,
and Authority of the IRB

Related Forms: None

References:


Title 45A – Department of Health and Human Services; Part 46 – Protection of Human Subjects; Subpart A, Section 108 – IRB Functions and Operations.

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