
Policy Statement: This policy describes the preparation, maintenance and distribution of the written procedures governing all Institutional Review Board (IRB) related activities at Saint Alphonsus Regional Medical Center (SARMC), in order to ensure compliance with all Department of Health and Human Services (DHHS) regulations, Food and Drug Administration (FDA) regulations and SARMC guidelines. This policy also describes the steps for revising and distributing policies and procedures.

Procedure:

I. Scope

This policy applies to the written policies and procedures to be used for all IRB activities conducted at SARMC.

II. Applicable Regulations and Guidelines

21 CFR 11 Electronic Records; Electronic Signatures
21 CFR 50 Protection of Human Subjects (FDA)
21 CFR 54 Financial Disclosure by Clinical Investigators
21 CFR 56 Institutional Review Boards
21 CFR 312 Investigational New Drug Applications
21 CFR 812 Investigational Device Exemptions
45 CFR 46 Protection of Human Subjects (DHHS)

III. References to Other Applicable Procedures

All SARMC IRB procedures are applicable to this policy.

IV. Responsibilities

Policies and procedures will be maintained utilizing the PPM software. The policy owner assumes ultimate accountability for all policies. It is the responsibility of all investigators and people supervising, managing, conducting, or supporting research activities at SARMC to follow the policies.

V. Procedures

A. Procedure for preparing new policies or revising previously issued policies

1. Based upon changes to FDA or other regulatory agency requirements, other guidelines, research practices, or the policies and procedures of SARMC, a new policy or a revised version of a previously-issued policy describing the new or revised procedures may be drafted. Training may
be conducted based on the changes.

2. The Office of Research Integrity will use a standard policy format.

   a) Each policy will include the following information:
      - Title of the policy
      - The Policy and Procedure Manual it resides in
      - The date approved and any revision dates

   b) Each policy will include the following information in the text, if applicable:
      - Introduction and purpose
      - Scope
      - Applicable regulations and guidelines
      - References to other applicable policies and forms
      - List of attachments
      - Responsibility
      - Process overview
      - Procedures

3. Draft versions of policies will be reviewed by Research Integrity staff, the IRB Chairperson, and selected members of the IRB and/or hospital staff in accordance with their area of expertise to ensure accuracy and completeness.

4. Once a policy is approved, the Office of Research Integrity will notify IRB members and the research community in a written format. The policy will be posted on the SARMC internet and intranet Research Integrity page.

5. The Office of Research Integrity will also be responsible for:
   - Maintaining updated tables of contents and lists of all policy titles, approvals, and expirations.
   - Maintaining an electronic version of all current and historical policies to be available in the event of an audit.
   - Documenting training, if necessary, based on the nature of the changes to the policy.
   - Maintaining accurate policy postings on the SARMC internet and intranet

B. **Procedure for reviewing policies**

1. Policies will be reviewed at least every 36 months from the date of the last revision. If revisions or additions are required, the procedure described above is to be followed.

2. If no changes are required, the policy review will be documented in the Policy and Procedure Manager system. The policy will be issued and distributed as described above.
C. Procedure for providing training on implementing policies

1. If needed, training will be provided to applicable staff prior to issuance of the policy.
2. New employees will be responsible for reviewing all applicable policies prior to undertaking any responsibilities.
3. All IRB members will receive orientation to the policies and procedures.
4. The Office of Research Integrity will be available to provide education and training to individuals and/or groups on research and IRB-related policies and procedures.


Related Forms: None

References:


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