Title:  **SARMC Institutional Review Board: Permanent Study Closure**

**Policy Statement:** The SARMC IRB considers a study to be active until a study close-out form (available on the SARMC research web site) is reviewed and approved by the IRB at a full-board convened meeting. A study can be considered for closure when all the participants have fulfilled protocol requirements including follow-up visits and the data analyses are complete; or if requested by sponsor. It is the continued responsibility of the study team to maintain confidentiality of the collected and stored data after closure. The Office of Research Integrity (IRB) must be contacted if stored data is accessed for research purposes other than the original intent.

**Procedure:**

I. **Permanent Study Close-Out Form**

The Permanent Study Close-Out Form must be completed and submitted to the Office of Research Integrity. This form can be found at:

[http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources)

All fields in this form must be completed or it will be returned with a request for additional information. Included with this form should be a copy of the current consent, a summary of any protocol revisions since the last annual approval, and a current copy of the study protocol.

II. **IRB Administrative Closure**

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB Policy and Procedures such as but not limited to:

- late continuing review report,
- failure to complete the study close out form when study complete,
- investigator has left the institution and did not notify the IRB,
- confirmed documented scientific misconduct,
- unexpected serious harm to participants.

Any suspension or termination of approval shall be documented and include a statement of the reason for IRB action. It shall be reported promptly to the principal investigator, appropriate institutional officials and appropriate regulatory authorities such as the Food and Drug Administration (FDA) or Department of Health and Human Services (DHHS), if necessary.

Further information regarding the IRB Authority can be found in the SARMC policy: **Institutional Review Board: Purpose, Principles and Authority.**
III. Reactivation after Permanent Closure

Once a study is permanently closed it may not be reactivated unless a New Project Application is submitted and reviewed by the IRB. The investigator will be notified in writing of the determination by the IRB. In the event of an administrative closure, the PI has 30 days to notify the IRB of reactivation.

Related Policies: Institutional Review Board: Purpose, Principles and Authority

Related Forms: Study Close-Out Form

http://www.saintalphonsus.org/forms-and-resources

References:


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