Title: SARMC Institutional Review Board: Record Requirements

Policy Statement: All IRB records will be maintained by the Office of Research Integrity for at least three years after the closure of a study. The records shall be accessible for inspection and copying by authorized representatives of the FDA and the DHHS at reasonable times and in a reasonable manner.

Procedure:

I. IRB records shall be prepared and maintained for the following:

A. IRB membership: Curriculum Vitae/ resume for all IRB members, as well as the IRB roster. For each individual, the roster shall include:
   1. The name of the individual
   2. Credentials
   3. Scientific or nonscientific role on the IRB
   4. Institutional affiliation
   5. Contact information
   6. Meeting attendance and assigned reviewers

B. Written policies and procedures (SOPs). Please refer to SARMC Institutional Review Board: Standard Operating Procedure for IRB SOPs: Preparing, Maintaining and Distributing IRB Policies

C. Meeting minutes, including:
   1. Attendance at the meeting, including any consultants/guests/others, and the means of attendance (video/phone-conferencing)
   2. Actions taken by the IRB (approval, approval with contingencies, deferral, or disapproval), the order in which studies are reviewed, and the vote on these actions, including the number of members voting for, against, or abstaining
   3. The basis for requiring changes, deferring, or disapproving research
   4. A summary of discussion of risk/benefit ratios, informed consent, any other issues of concern, and IRB recommendations
   5. The recommended frequency of continuing review if less than 365 days and/or the time interval for submission of additional information
   6. The determination of significant/non-significant Risk decisions for medical devices, and the risk levels for pediatric studies
   7. List expedited reviews that are scheduled to be acknowledged at the meeting; the expedited will be identified with the dates of approval
   8. Primary and/or secondary reviewers for adverse events, addenda/
9. Educational presentation topics and presenters

D. Protocols, reviewed and approved consent documents, and scientific evaluations, if any, that accompany the proposals.

E. Copies of all correspondence between the IRB and the investigators.

F. Reports of adverse event or injuries to subjects.

G. Protocol deviation reports that indicate the nature of the deviation and the impact on participant risk.

H. Records of initial and continuing review and review of additions, revisions, and amendments to the protocol and/or informed consent form.

I. Emergency use reports.

J. Progress reports submitted by investigators and statements of significant new findings provided to subjects.

K. Conflict of interest reports.

L. Records of investigators’ completion of educational courses on human subjects research protection.

M. Any handwritten notes (additional to the meeting agenda) that were taken at the time of the meeting.


Related Forms: None

References:


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