Title: SARMC Institutional Review Board: Administration of the Institutional Review Board (IRB)

Policy Statement: The SARMC IRB was established by the hospital to comply with existing regulations for the protection of human participants involved in research. The purpose of the IRB is to help protect the participant, the researcher and the hospital by ensuring that ethical and moral principles are adhered to in research. The Office of Research Integrity is responsible for facilitating communication between investigators and the IRB, serving as a resource for both on general regulatory information and assisting in evaluation, auditing, and monitoring of human subject research as directed by the IRB.

Procedure:

I. Management of the IRB

A. Chairperson

The IRB will have a Chairperson appointed by the President of the Medical Executive Committee. The ideal candidate will exemplify the Guiding Behaviors of SARMC, will be knowledgeable in regulations governing the involvement of human subjects in research, and will have the ability to manage the business of the IRB in an efficient and effective manner. The President of the Medical Staff shall have the authority to remove an IRB Chairperson for cause, including, but not limited to, failure to consistently meet the obligations of the position. The IRB Chairperson has the following duties:

1. Chairing the meeting, conducting business so that each proposal is fairly and completely reviewed, seeing that the Board reaches a decision on the disposition of each proposal, and ensuring that these decisions are communicated to the individuals who submitted the proposal.

2. Identify and address conflicts of interest as they apply to researchers and IRB members.

3. Review all new IRB policies and procedures and any significant changes and updates to existing IRB policies, meeting regularly with Research Integrity staff to ensure continued compliance with all federal, state, local, and institutional requirements for the protection of human subjects.

4. Review all submitted materials for each convened IRB meeting.

5. Review and approve meeting minutes prior to distribution.

6. Review, approve and sign all non-routine correspondence related to decisions made directly by the Chairman and/or the IRB.
7. Review and determine approval of all expedited studies, renewals, amendments, protocol deviations, and study closures. The Chairman may identify designee(s) for this responsibility, to be documented in the IRB meeting minutes.

B. IRB Members
Potential members may be nominated by the IRB Chairperson, IRB members, IRB administrative staff, or Department Chairpersons. Members must be approved by unanimous vote of the IRB and are appointed for an unlimited number of terms. Members may vote to approve (with or without modifications), disapprove, or defer research submitted to the IRB. Members are expected to complete an orientation, attend IRB meetings on a regular basis, review research protocols assigned to them in advance, and serve as general reviewers on all research discussed at convened meetings.

The Chairman of the IRB shall have the authority to remove an IRB member for cause, including, but not limited to, failure to consistently meet the obligations of the position.

1. Alternate Members
Alternate members meeting the same qualifications and backgrounds of regular IRB members may be appointed by the IRB. Alternates are invited to attend IRB meetings to become familiar with the practices and proceedings of the IRB. Alternates may participate as voting members only when substituting for regular member at IRB meetings.

2. Attendance
IRB members are required to attend at least seventy-five percent (75%) of all scheduled meetings throughout the course of a calendar year. Members who are unable to attend shall notify the Office of Research Integrity in advance, and shall arrange for their designated alternate member to attend the meeting in their absence.

IRB Members can attend the meetings in person or via teleconference. Any members who participate in the convened meeting via telephone will be provided the opportunity to actively and equally participate in the discussions of all protocols. Such attendance will be documented in the meeting minutes.

C. Training of the IRB Chair and Members
1. Orientation may include but need not be limited to the following:
   a. meetings with the IRB Chairperson, Members and Staff
   b. review of IRB orientation materials, including policies and procedures
   c. completion of human research ethics training

2. Education - The Office of Research Integrity will provide continuing education opportunities for all IRB members. This education should include information on research ethics and human subject research. IRB members and Research Integrity staff are expected to renew their human research ethics training every two years.

D. Use of Consultants
There may be times when the IRB requires a consultant to provide additional expertise. The chairperson of the IRB will determine when such assistance is
needed. Use of a consultant will be documented in the meeting minutes.

E. Administrative Support
Administrative support, provided by the Office of Research Integrity, may include, but is not limited to, the following:

1. Maintaining the official roster of the IRB. This includes prompt reporting of changes in IRB membership to the OHRP.

2. Assisting new IRB members in completing orientation procedures and meeting required education standards; and maintaining training and reference materials related to human subject protection requirements.

3. Drafting and issuing all correspondence and reports related to IRB business, as well as any reports and correspondence directed to research officials, federal officials, and others on behalf of the IRB or IRB Chairperson.

4. Maintaining and updating the IRB policies and forms.

5. Receiving and reviewing new study applications and checking them for completeness; and then assigning unique identifying numbers to, and tracking the progress of, all research applications submitted to the IRB.

6. Scheduling IRB meetings and distributing pre-meeting materials to IRB members.

7. Compiling the minutes of IRB meetings in compliance with regulatory requirements.

8. Maintaining all IRB documentation and records in accordance with regulatory requirements; securely and properly archiving all IRB records; and issuing reports and correspondence to research investigators on behalf of the IRB or IRB Chairperson.

9. Facilitating communication between investigators and the IRB, including serving as a resource for investigators on general regulatory information, and providing guidance about submission procedures and completion of forms.

10. Assisting in evaluation, auditing, and monitoring of human subject research as directed by the IRB and/ or the CEO or designee.

11. Research Integrity staff are the designated signatories on all routine correspondence originating from the IRB Office.

II. Organizational Responsibilities

It is the responsibility of SARMC to provide written assurance to federal agencies that
it will comply with regulations governing the protection of human subjects. As part of its written assurance to the government (Federalwide Assurance), SARMC must develop policies and procedures for conducting human subject research in a responsible and ethical fashion, including how research will be reviewed by the IRB, the reporting of unanticipated problems to the IRB and appropriate regulatory bodies, and other issues.

The CEO serves as the Institutional Signatory Official (ISO) for SARMC’s Assurance and is ultimately responsible for overseeing the protection of human subjects within SARMC. The ISO must ensure that open channels of communication are maintained between the IRB, research investigators, staff, and administration. The ISO must also provide the IRB with sufficient meeting space and staff to support its substantial review of human subjects research and record keeping responsibilities.

The Research Administrator is designated as overall administrator for the IRB and is responsible for ensuring that it functions and operates in compliance with all Federal, State, and local laws and regulations that govern human subject protection in the conduct of research. The Administrator may delegate IRB administrative duties as the Administrator deems appropriate.

The Administrator is responsible for immediate notification of the SARMC ISO regarding any injury, breach of trust, unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with IRB requirements by research investigators, or suspension or termination of IRB approval. The Administrator is responsible for assuring that OHRP and FDA are notified of such incidents, in accordance with applicable laws and regulations.

**Related Policies:** Functions and Operations of the IRB; Purpose, Principles, and Authority of the Institutional Review Board (IRB); Education and Training on Human Research Subject Protections

**Related Forms:** None

**References:**
