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

Policy Statement: The SARMC Institutional Review Board (IRB) was established by the hospital to ensure compliance with the existing regulations of the FDA, the Department of Health and Human Services (DHHS), the Office of Civil Rights (OCR), and state and institutional regulations for the protection of human participants involved in research. The members of the IRB include medical, scientific and pharmacy staff, as well as risk management advisors, clergy and/or an ethicist, non-scientific members and lay members (affiliated and non-affiliated) from the community who have special interest in helping SARMC maintain a high standard of research.

Procedure:

I. Number of Members

The IRB must be composed of at least five (but no more than twelve) members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

II. Composition of Membership

The IRB should be composed of at least one member not otherwise affiliated with SARMC, a community representative, at least one scientific member, and at least one non-scientific member. In addition, there should be sufficient gender, racial, and vocational/professional diversity so as to ensure broad representation.

A. All candidates for IRB membership, including alternates, must provide a resume or CV prior to consideration by the Board. In addition to earned degrees, board certifications, licensure, and professional memberships, other indications of appropriate experience and competence, including required human research protection education/training, should be included. In order for candidates for IRB membership to be accepted to the committee, the IRB must vote unanimously in favor of the candidate’s membership.

B. IRB members may designate an alternate member who will attend an IRB meeting in the absence of the regular IRB member. Alternate members may be appointed by the IRB using the same process of appointment for primary members. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate’s qualifications will be comparable to the primary member to be replaced.

C. Alternates are invited to attend IRB meetings to become familiar with the practices and proceedings of the IRB, but may only participate as voting members when substituting for their designated IRB member.
D. All regular members, including non-affiliated member(s), will be voting members. No IRB member may participate in the IRB’s initial or continuing review of any study in which the member has a real or potential conflict of interest, except to provide additional information.

E. The IRB may use consultants when deemed appropriate to aid in the assessment of a new protocol, amending an ongoing protocol, or to provide relevant information by individuals familiar with the ethical standards of the local community. When consultants are used, documentation will be required and retained detailing the consultant’s education, experience, and qualifications. These individuals serve in an advisory capacity only and may not vote.

F. All members must attend a total of 8 meetings per calendar year. If an IRB member has missed 3 meetings, a letter of reminder will be mailed. If 4 meetings are unattended during the calendar year, the board will then be required to vote to keep or dismiss the current member. However, if the absences are due to medical conditions or other unavoidable instances, those circumstances will be taken into consideration.

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:


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