

DEPARTMENT: Research Compliance		Reference# IRB.006
Effective Date: 1/23/2006	Page 1 of 3	Replaces Policy Dated: 4/28/2003
Description:	Membership of the IRB	

A. Composition

The IRB is composed of at least 5 members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at the institutions. The membership includes individuals with the necessary experience and expertise and knowledge of the local research context to review the scope of biomedical and behavioral research conducted at Sunrise Health. Members include both men and women and members of minority groups. Designated alternates may be used. The membership includes:

- Physicians;
- Scientists;
- Nurses;
- Pharmacists;
- At least one member who is unaffiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- At least one member whose primary concerns are in nonscientific areas, such as lawyers, ethicists, and clergy.

The membership roster and IRB registration information are updated as needed when membership changes. The revised IRB registration is submitted to the Office for Human Research Protections (OHRP) as required by the institution's FWA.

The membership of the IRB is reviewed at least annually to determine if the membership includes individuals with varying backgrounds and the experience and expertise needed to review the scope of biomedical and behavioral research conducted at Sunrise Health. The Office of Research Compliance is responsible for compiling information about research protocols reviewed at convened meetings (full board review) to assess scope of biomedical and behavioral research reviewed by the IRB. The report includes institution, department and unit, as well as special populations, such as pregnant women and fetuses, prisoners, children, and individuals with impaired decision-making capacity.

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B. Recruitment and Selection of Members

Physician-scientist members are recruited by the IRB Chair through the chairs/chiefs of the hospital departments or units. Affiliated and non-affiliated individuals who are interested in serving on an IRB may self-refer or be referred by current IRB members. New members are recruited as needed to ensure that the membership of the IRB includes individuals with varying backgrounds and the necessary experience and expertise to review the scope of biomedical and behavioral research conducted at Sunrise Health. In addition, new members are recruited on an as needed basis to replace the experience and expertise of members who resign and to provide additional experience and expertise needed to review new research protocols. Members are selected based on reputations for fairness, objectivity and commitment to exercise faithfully their responsibilities for protection of human subjects in research according to the guiding principles and relevant federal and state regulations. There are no term limits placed on length of service.

C. Member Orientation/Education and Training

New members are required to complete a human research training program. The Chair of the IRB and the Manager of the Office of Research Compliance provide new members with an overview of the IRB review process and governing regulations. Once the member has completed the education program and orientation, the member is added as a voting member to the IRB. The IRB roster is updated and the updated IRB registration is then sent to OHRP. The new member is given an IRB Member Handbook, which includes IRB policies and procedures, IRB guidance documents, IRB review worksheets and other information relevant to IRB members, as well as links to the Belmont Report and federal and state regulations.

D. Responsibilities of IRB Members

Voting members are responsible for initial and continuing review of all research activities involving human subjects scheduled for review at the convened meeting of the IRB and for considering:

- Ethical and scientific issues;
- The appropriateness of the study population;

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- The appropriateness of the methods of recruitment and process for obtaining informed consent of subjects;
- The risks and anticipated benefits to subjects as well as the importance of the knowledge that may reasonably be expected to result;
- The adequacy of the study design and methods of data analysis;
- The adequacy of procedures used to monitor the data and subject safety;
- The adequacy of procedures used to protect confidentiality and privacy; and
- The accuracy and completeness of information in the consent form as well as the reading level and presentation of the information.

Voting members (or their alternates) are expected to attend at least 2/3 of the scheduled IRB meetings. Attendance records are reviewed annually. The IRB Chair will consider removal of voting members who have not attended one-half of the scheduled meetings during the past year, or addition of an alternate voting member with similar experience and expertise.

E. IRB Members and Conflicts of Interest

Voting members of the IRB are required to self-identify conflicts of interest and recuse themselves from participating in the discussion and vote on research activities with which they have a conflict of interest as defined in the *Sunrise Health IRB Conflicts of Interest Policy*. When members recuse themselves, they must leave the room for the discussion and vote on the research, except to provide information at the IRB's request prior to the discussion and vote. Recusals are documented in the Minutes of the meeting.