

SOP: OR 203 Version No: 4 Effective Date: 01/06/06	DUTIES OF IRB MEMBERS	Supersedes Document: 01/03
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1. POLICY

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the subjects of research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and the research subjects. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subjects protection, biomedical and behavioral research ethics, and the policies of Sparrow Health System germane to human subjects protection.

Specific Policies

1.1 Duty to Sparrow Health System

The IRB is appointed under the Medical Staff Bylaws of Edward W. Sparrow Hospital Association (referred throughout the SOPs as Sparrow Health System) as a standing committee that reports to the Medical Staff Executive Committee. As such, IRB members serve Sparrow Health System as a whole, rather than a particular department. Therefore, members must not allow their own interest or that of their department to supersede their duty to protect the rights and welfare of research subjects.

1.2 Term of Duty

Regular IRB members and Chairpersons are expected to commit to a 2-year term and, during that time, to fulfill certain duties. These duties will be described prior to appointment and each IRB member is expected to fully understand the duties of IRB members prior to accepting appointment as an IRB member.

1.3 Specific Duties

1.3.1 Regular Members:

- Non-affiliated member(s): Non-affiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- Non-scientific member(s): Non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
- Scientific members: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.
- Chairperson: In addition to the above responsibilities (germane to the member's capacity), the Chairperson chairs meetings of the IRB.

Chairperson performs or delegates to an appropriate voting IRB member expedited review when appropriate. They are empowered to suspend the conduct of a clinical trial deemed to place individuals at unacceptable risk, pending IRB review. The Chairperson is also empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an Investigator is not following IRB's requirements.

- The Chairperson may appoint a Co-chairperson to assist or act on behalf of the Chairperson in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Such documentation must be in writing and maintained by the IRB Administrator.
- The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of these individuals. The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

1.3.2 Primary Review Team: In addition to the duties described in section 1.3.1, each regular member will be expected to act as a Primary Reviewer for assigned studies at convened meetings. The Primary Review team will consist of three IRB members; one of which must be a physician. The Primary Review team members will present their findings resulting from review of the application materials and provide an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. Any one of the Primary Review team may lead the IRB discussion of the study. The Primary Review team may be required to review additional material requested by IRB for the purpose of study approval.

2. SCOPE

These policies and procedures apply to all IRB Members.

3. RESPONSIBILITY

IRB Chairperson, with the assistance of the IRB Administrator, is responsible for clearly articulating all IRB members' duties to potential and current IRB members.

IRB Members are responsible for fulfilling their duties as specified.

4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP IRB Guidebook

FDA Information Sheets FAQ, section II, question 17.

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

OR 203-A Member Responsibilities - Regular Member

OR 203-B Member Responsibilities - Chairperson

- OR 203-C Member Responsibilities - Alternate Member
- OR 203-D Member Responsibilities - Reviewer Duties

7. PROCESS OVERVIEW

The IRB Chairperson with the assistance of the IRB Administrator is responsible for recruiting and evaluating new and existing IRB members. In order for the IRB to conduct business and approve research projects, a majority (51%) of the IRB membership must be in attendance and of that 51% at least one of the members whose primary concern is non-scientific must be present. **All IRB members must complete the training and education programs described in SOP GA 102.**

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i> <i>IRB Chairperson</i>	Documents the expectations for members of the IRB. Meet with prospective members to discuss expectations. Answers questions from IRB members as needed. Periodically reviews members' duties.	Member Responsibilities - Regular Member (Scientific, Non-scientific or Non-affiliated Representative) - Chairperson - Alternate Member - Reviewer Duties
<i>IRB Administrator</i>	Maintain up-to-date descriptions of member responsibilities. Answer questions from IRB members as needed.	
<i>IRB Chairperson</i>	Ensure that members are carrying out their expected functions and that there is adequate staff support to ensure that members are able to function as documented.	
<i>Institutional Official</i>	Ensure that there is adequate staff and other institutional support so that IRB members are able to function as documented.	
<i>IRB Administrator</i>	As needed, make recommendations to the Chairperson regarding changes to descriptions, staffing, meeting scheduling, and other factors that affect members' ability to perform their roles.	