

SOP: OR 201 Version No: 1 Effective Date: 01/06/06	COMPOSITION OF IRB	Supersedes Document: 12/8/04
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1. POLICY

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, the IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women.

The institution will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

Specific Policies

1.1 Membership Selection Criteria

The members of the IRB shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas. (Resumes/CV's for IRB members are kept on file in the OROC Office.)

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution, either self or family member. For FDA-regulated research, there shall be at least one member who is a licensed physician.

1.2 Composition of the Board

Regular members: The backgrounds of the regular members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:

- A. Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the Sparrow Health System will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on IRB, and their services should be fully utilized by the IRB.
- B. Scientific members: Sparrow Health System's IRB shall include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a

consultant to assist in the review, as provided by 21 CFR 56.107(f). However, when FDA regulated products are reviewed, the convened meeting must include a licensed physician member, therefore, at least one (1) member of each IRB must be a physician licensed in the state of Michigan.

- C. Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.
- D. Representatives of special groups of subjects: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the IRB.
- E. Chairpersons: The individual IRB Chairperson should be highly respected individuals, from within or outside the Sparrow Health System, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.
- F. Special Consultants: The Chairperson may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the Board. These individuals may not vote with the regular and alternate members of the IRB and their presence or absence will not be used in establishing a quorum for a Board meeting. Consultants will be used at the Chairperson's discretion, or if requested by the full Board. All consultants will be asked to sign a Conflict of Interest Statement, and consultants with access to confidential information will be asked to sign a Confidentiality Agreement.

The consultant may be asked to participate via a teleconference or attend the Board meeting to lend his/her expertise to the discussions. Consultants will not vote.
- G. Co-Chairperson: The Chairperson may appoint a Co-Chairperson (or designee) 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. The Co-Chairperson shall have the authority as stated in the federal regulations and Sparrow Health System's SOPs.
- H. Alternate Members: The Chairperson may designate alternate members with similar expertise and knowledge for a regular member of the IRB.

2. SCOPE

These policies and procedures apply to all IRB members and the OROC staff.

3. RESPONSIBILITY

Institutional Official, with the assistance of the IRB Chairperson and IRB Administrator, is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.

IRB Chairperson, with the assistance of the IRB Administrator, is responsible for recruiting and installing new IRB members.

IRB Chairperson is responsible for evaluating IRB members semi-annually.

The Institutional Official will evaluate the IRB Chairperson semi-annually.

The IRB Chairperson and Institutional Official will evaluate the IRB Administrator yearly.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

FDA Information Sheets, FAQ section II, questions 14, 15.

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

The IRB Chairperson and the IRB Administrator assures that the composition of the IRB meets applicable regulations as stated in this SOP and the IRB members are sufficiently qualified through expertise and education according to Sparrow Health System’s policies and federal regulations. This ensures that the IRB promotes complete and accurate review of proposed research submitted to the IRB. An updated roster of all IRB members is kept on file with the IRB member’s CVs or resumes.

The IRB Chairperson, with the assistance of the IRB Administrator, is responsible for overseeing recruitment of members and evaluating existing IRB members semi-annually. The IO and Chief of Staff will evaluate the IRB Chairperson semi-annually.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator and IRB Chairperson</i>	Ensure the overall diversity of the IRB membership (gender, race, ethnicity, community affiliation and professional experience) through non-discriminatory selection methods.	
<i>IRB Chairperson, Institutional Official and Chief of Staff</i>	Following established criteria, select new members, and replace members who resign or otherwise leave IRB service.	
<i>IRB Administrator</i>	Maintain a roster of all regular and alternate members, for FDA inspection purposes. Maintain a file on all members, to include their curriculum vita, letters of nomination and other evidence of professional ability. Maintain a roster of available consultants who are eligible and qualified to attend meetings as invited consultants.	FWA IRB Roster