1.0 Policy:

The management of the membership of the IRB (Institution Review Board) and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the IRB Administrator.

2.0 Scope:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Department</td>
<td>This policy and procedure applies to IRB members and IRRC staff.</td>
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</tbody>
</table>

3.0 Responsibilities & Procedures

3.1.1 Term
Members, including the Chairperson, will serve on the IRB for a term of two years. Reappointment for additional terms may occur, by mutual agreement of the IRB Chairperson and the Institutional Official (IO). The IO and the Chief of Staff reappoint the IRB Chairperson for additional terms.

3.1.2 Appointments
The IRB Chairperson in consultation with the hospital leadership has the authority to appoint members to the IRB. Members will be solicited from Sparrow and greater Lansing-area communities.

3.1.3 Resignations and Removals
A member may resign with notice before the conclusion of his/her term. The vacancy will be filled as quickly as possible. A member may be removed by the IRB Chairperson.

3.1.4 Compensation
Participation by Sparrow faculty, staff, or students is considered a component of their job responsibilities as established by their supervisors. Regular members who are not affiliated with Sparrow will have their parking validated.

3.1.5 Liability Insurance
Regular and alternate members have liability insurance coverage as part of their membership in their capacity as agents of Sparrow.

3.1.6 Responsibility
The IRB Administrator is responsible for day-to-day management of the activities of IRB members.

The IRB Chairperson (or designee) is responsible for management of the activities of the IRB members relevant to meeting conduct and review of research.

3.1.7 Process Overview
The IRB Chairperson and the IRB Administrator provide administration and oversight of the IRB to ensure IRB membership has the expertise and commitment to meet its regulatory and institutional mandates.
### 3.1.8 Procedures Employed to Implement this Policy

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td><strong>IRB Administrator</strong></td>
<td>In consultation with the IRB Chairperson and other appropriate institutional parties, identify members of Sparrow Health System faculty and staff and members of the local community to serve on the IRB.</td>
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<tr>
<td><strong>IRB Chairperson and IRB Administrator</strong></td>
<td>Discuss the responsibilities and time commitment of IRB membership with the interested parties. If the individual states he/she is indeed interested in becoming a member, the dates of all IRB meetings are given to the individual for consideration. Request the Curriculum Vitae (CV) for review.</td>
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<tr>
<td><strong>IRB Administrator</strong></td>
<td>If Institutional Official and IRB Chairperson concur with the recommendation of the IRB Administrator, an Appointment Agreement Letter is sent out to the interested party, with copies to the institutional officials.</td>
</tr>
<tr>
<td><strong>IRB Administrator/IRB Coordinator</strong></td>
<td>Send the new member a list of the current members on the IRB, listing their areas of expertise and telephone numbers. The new member is also given the New Member Information Packet. Notify the new member of the next meeting, sending a packet of agenda materials to review. Inform the member that he or she will not be assigned specific protocols to comment on until their second full meeting.</td>
</tr>
<tr>
<td><strong>IRB Chairperson</strong></td>
<td>Meet with the new member and review the role and responsibilities of being an IRB member, as well as the expectations of the position.</td>
</tr>
<tr>
<td><strong>IRB Administrator or IRB Coordinator</strong></td>
<td>Document that the new member completed required training. If the new member has not completed required training within 90 days, remind the member to do so. If the member does not complete required training within the next 30 days, notify the IRB Chairperson.</td>
</tr>
</tbody>
</table>

### 4.0 Attachments

- OR 202-A New Member Information Packet Checklist
- OR 202-B New Member Welcome Letter
- OR 202-C IRB Appointment Agreement
- OR 202-D IRB Member Confidentiality Agreement
- OR 202-E Member Documentation Checklist
- GA 104-A IRB Member Recusal Agreement (Conflict of Interest)
NEW MEMBER INFORMATION PACKET CHECKLIST

□ Welcome Letter  OR 202-B

□ Documentation
□ Member responsibilities  OR 203-A
□ Reviewer duties (specific duties of IRB members)  OR 203-D
□ IRB Appointment Agreement  OR 202-C
□ IRB Member Confidentiality Agreement  OR 202-D
□ IRB Member Recusal Agreement  GA 104-A

□ Training & Educational Material
□ Belmont Report  Appendix A
□ Foundations of Human Subject Protection and Test
□ IRB SOPs
□ Bibliography & Resource List  GA 102-A
□ Training Checklist and Documentation – IRB Members  GA 102-B
To: (IRB Member)  
(Address)  
Date (today's date)  

Dear __________________:

Thank you for agreeing to serve as an Institutional Review Board member. We appreciate your willingness to assume a share of the responsibilities for human research oversight at this institution/organization during the next 3 years (insert desired term).

I have enclosed documents we will need signed and returned to the IRB Chairperson, as well as informational and educational material.

Please read and sign the following documents:

- IRB Appointment Agreement
- IRB Member Confidentiality Agreement
- IRB Member Recusal Agreement

As was discussed with you earlier, all IRB members must be trained and receive continuing education in topics germane to the protection of human research subjects. I have enclosed an independent study course titled "Foundations of Human Subject Protection," (or name equivalent). Please complete the course and submit your completed test within 3 months.

I look forward to seeing you on ___________________. Please arrive about an hour before the meeting and we will review the duties and responsibilities of IRB members.

Again, thank you very much for your participation in the IRB. Please do not hesitate to call me if you have any questions.

Sincerely,

IRB Chairperson

Enclosures
NAME (INSTITUTION/ORGANIZATION)  
ADDRESS  
CONTACT INFORMATION

To: (IRB Member)  
(Address)  
Date (today’s date)

IRB: _________________________________

Capacity: _______________________________

Term of Appointment: _____________________

Introduction and Purpose

The Institutional Review Board is a federally regulated entity with the mandate to review biomedical and behavioral research studies that take place within or under the authority of the __________________________(Name of Institution/Organization). The purpose of this review is to determine if the proposed research meets certain established regulatory, policy, and ethical criteria to protect the rights and welfare of the human subjects of such research. The criteria used by the IRB to determine the acceptability of such research is based upon principles discussed in the Belmont Report (attached), which are:

- The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.
- Legally effective informed consent will be obtained from each subject, unless the requirements for waiver of informed consent are met, by adequate and appropriate methods in accordance with the provisions of applicable state and federal regulations.
- The conduct of the study will be reviewed at timely intervals.

Scope of Work

The IRB will review protocol and informed consent forms, and review or delegate the review of Investigator and site qualifications for the purpose of approving, recommending modifications to, or disapproving proposed research involving human subjects as required by regulations of the U.S. Department of Health and Human Services and the Federal Food and Drug Administration. Criteria to be used in reviewing protocols include minimization of risk, equitability of subject selection, adequacy of informed consent and maintenance of subject confidentiality.

As regular member of the IRB, your presence will be used to establish a quorum; therefore you will be expected to attend regularly scheduled meetings, which generally occur once a month. All regular members receive a packet of material pertinent to the proposed research prior to the scheduled meeting. The packet contains the meeting agenda, expedited review information, the protocol(s) and informed consent form(s) and Investigator information submitted for review. You are expected to review this information prior to the meeting and participate in the review and ensuing discussion. You will be expected to serve as the primary reviewer for 1-3 protocols at each meeting.
The responsibilities of the primary reviewer are outlined in the description of reviewer duties (Attachment OR 203-D and SOP OR 203 section 1.3.2).

Requirements
Prior to assuming responsibilities of an IRB member, new appointees will be expected to observe a meeting, and complete the training course. IRB members are required to participate in continuing training and education during the term of their appointment.

Members are expected to agree to recuse themselves if they have a conflict of interest that could bias their consideration of research submitted for review, and to document this agreement at the time they accept appointment to the IRB.

Term
The term for IRB members is _____(insert desired term). This term is renewable. Members who are unable or unwilling to fulfill their duties as IRB members may be removed from the IRB at any time by the IRB Chairperson/Designee). See Member Responsibilities.

Liability Coverage
The ___________________________ (Name of Institution/Organization), maintains Insurance Warranty for all claims made against IRB members, alternates and consultants.

Please sign below if you agree to the terms described in the above.

__________________________________  __________________________
IRB Member                Date
CONFIDENTIALITY AGREEMENT

I understand and agree that information disclosed orally or in written form or discussed at the meeting may include confidential information that is proprietary to commercial entities sponsoring the proposed research and/or involves the privacy rights of individuals.

I agree that I will not disclose or divulge in any manner any confidential or private information revealed at the meeting in any form or manner to any third party for any purposes whatsoever. "Confidential or Private Information" as used in this Agreement shall not include:

1. Information or knowledge in my possession prior to disclosure at the IRB meeting, or from the _____________________________(Name of Institution/Organization);

2. Information generally available to the public or thereafter becomes generally available to the public through a source other than the _____________________________(Name of Institution/Organization/IRB);

3. Information that was rightfully obtained by me from a third party, who, I believe, is under no obligation of confidentiality to the _____________________________(Name of Institution/Organization/IRB) with respect to such information.

Acknowledged and Agreed:

Signature _____________________________  Date _________________

Printed Name _____________________________
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<tr>
<th>IN FILE</th>
<th>Item</th>
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<tbody>
<tr>
<td></td>
<td>CURRENT CV / RESUME</td>
</tr>
<tr>
<td></td>
<td>□ Year 1 □ Year 2 □ Year 3</td>
</tr>
<tr>
<td></td>
<td>Signed IRB Appointment Agreement</td>
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<td></td>
<td>Signed Confidentiality Agreement</td>
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<td>Financial Disclosure</td>
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<td>Training Checklist (GA 102-B)</td>
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<td>□ Year 1 □ Year 2 □ Year 3</td>
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</tbody>
</table>

Comments
IRB Member recusal agreement

NAME (INSTITUTION/ORGANIZATION)
ADDRESS
CONTACT INFORMATION

To: (IRB Member)
   (Address)
Date (today’s date)

IRB Member recusal agreement

I ____________________________ certify that I shall recuse myself from deliberation and voting on any study submitted to the IRB in which I have a potential or perceived conflict of interest concerning protocols reviewed by the IRB. This would include:

A. Service in any of the following categories with respect to the study in question:
   Principal Investigator (PI),
   Co-principal Investigator,
   Investigator receiving funding from the study, as listed in the study budget,
   In a supervisory or subordinate role with the PI of the study, or in a mentor/trainee relationship,
   Family member of PI.

B. I, my spouse and/or dependent children have a financial interest as follows:

1. Any financial arrangement with the Sponsor, Sponsor representative, or any other entity whereby the value of my compensation could be affected by the outcome of the study as defined in ____________________________(NAME of INSTITUTION/ORGANIZATION) Policies on financial relationships at 21 CFR 54.2(a); DHHS COI guidelines;

2. A proprietary interest in any products, intellectual property or any outcome of the study;

3. A significant equity in the Sponsor as defined in ____________________________(NAME of INSTITUTION/ORGANIZATION) Policies on financial relationships and 21 CFR 54.2(b);

4. I am the recipient of significant payments of other sorts (such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria), as defined in 21 CFR 54.2(f).

I will make known any conflict of interest prior to the beginning of the IRB’s discussion of the protocol under review.

Acknowledged and Agreed:

Signature: ___________________________________  Date: _________________

Printed Name: ________________________________