1.0 **Policy:**

Each 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 member must understand that he or she is not serving on the Committee 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 germane to human subjects protection.

2.0 **Scope:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td>This policy and procedure applies to the Sparrow research community.</td>
<td>√</td>
</tr>
</tbody>
</table>

3.0 **Responsibilities & Procedures**

3.1 **Duty to Sparrow**

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

3.2 **Term of Duty**

Regular 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.

3.3 **Specific Duties**

3.3.1 **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. The 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.

3.3.2 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.

3.4 Responsibility
3.4.1 The IRB Chairperson, with the assistance of the IRB Administrator, is responsible for clearly articulating all IRB members’ duties to potential and current IRB members.

3.4.2 IRB Members are responsible for fulfilling their duties as specified.

3.5 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 who primary concern is non-scientific must be present. All IRB members must complete the training and education programs described in SOP GA 102.

3.6 Procedures Employed to Implement this Policy:

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>IRB Administrator/IRB</td>
<td>Documents the expectations for members of the IRB.</td>
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<tr>
<td>Chairperson</td>
<td>Meet with prospective members to discuss expectations.</td>
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<td>Answers questions from IRB members as needed.</td>
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<td>Periodically reviews members’ duties.</td>
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<tr>
<td>IRB Administrator</td>
<td>Maintain up-to-date descriptions of member responsibilities. Answer questions from IRB members as needed.</td>
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</table>
IRB Chairperson

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.

Institutional Official

Ensure that there is adequate staff and other institutional support so that IRB members are able to function as documented.

IRB Administrator

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.

4 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
GA 102    Training Checklist and Documentation – IRB Members
<table>
<thead>
<tr>
<th><strong>MEMBER RESPONSIBILITIES - REGULAR MEMBER</strong></th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Term</strong></td>
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<tr>
<td><strong>Responsibilities</strong></td>
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| **Time Commitments** | IRB: 10 hours per month |
|                     | Attend Continuing Education: 6 hours per year |
|                     | IRB members are advised to alert the IRB Administrator well in advance, if possible, if they cannot attend an IRB meeting, so they are not assigned protocols to review. If they cannot alert the IRB Administrator or in a timely manner, and are assigned protocols to review for the next upcoming meeting, then they are expected to deliver written comments to the IRB Administrator prior to the beginning of the meeting. |

| **Other Requirements** | The following financial relationships must be disclosed annually: any equity interests over $10,000 to commercial entities that sponsor or conduct research in this institution; significant payments of other types, including honoraria, consultant fees received from commercial entities that sponsor or conduct research in this institution. |
|                       | A potential for a conflict of interest must be disclosed prior conducting a review of research. Conflicts of interest could include close personal or professional relationship to an Investigator; interest, financial or otherwise, in the outcome of the research. |

| **Compensation** | Faculty: None |
|                 | Non-faculty: Reimbursement for continuing education and training related to IRB roles and responsibilities |
MEMBER RESPONSIBILITIES – CHAIRPERSON

Title
Chairperson

Term
2 years

Responsibilities
In addition to the duties of IRB members, the Chairperson of each IRB assumes the following duties:

Chairs convened meetings of the IRB.

Review all submitted Investigator reports and determine if there is reason for full IRB review. Perform or delegate expedited review of research applications and revisions.

Review reports of serious or unexpected adverse events.

Consult with Investigators as needed.

Conduct training sessions with Investigators and research staff.

Obtain continuing education germane to IRB responsibilities.

Chairpersons are empowered to suspend the conduct of a clinical trial deemed to place individuals at unacceptable risk pending IRB review.

The Chairperson may appoint a Co-chairperson or Associate 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.

Time Commitment
IRB: 5 additional hours per month

Attend Continuing Education: 6 hours per year

Instruction: 6 hours per year

Other Requirements
The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chairpersons. The IRB must be, and 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.

Compensation
Faculty: None

Non-faculty: Reimbursement for continuing education and training

Reimbursement for teaching expenses
MEMBER RESPONSIBILITIES - ALTERNATE MEMBER

Title: Alternate Member

Term: 2 years

Responsibilities
- Attend convened meetings of the IRB as needed.
- Review submitted research in place of regular member.

Time Commitments
- IRB: 20 hours per year
- Attend Continuing Education: 12 hours per year

Other Requirements
The following Financial relationships must be disclosed annually: any equity interests over $10,000 to commercial entities that sponsor or conduct research in this institution; significant payments of other types, including honoraria, consultant fees received from commercial entities that sponsor or conduct research in this institution.

A potential for a conflict of interest must be disclosed prior conducting a review of research. Conflicts of interest could include close personal or professional relationship to an Investigator; interest, financial or otherwise, in the outcome of the research.

IRB members are advised to alert the IRB Administrator well in advance, if possible, if they cannot attend an IRB meeting, so they are not assigned protocols to review. If they cannot alert the IRB Administrator in a timely manner, and are assigned protocols to review for the next upcoming meeting, then they are expected to deliver written comments to the IRB Administrator prior to the beginning of the meeting.

Compensation
- Faculty: None
- Non-faculty: Reimbursement for continuing education and training related to roles and responsibility of IRB member.
MEMBER RESPONSIBILITIES - REVIEWER DUTIES

Non-affiliated reviewer
Nonaffiliated 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 reviewer
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 reviewer
Scientific reviewers 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.

Primary reviewer
In addition to the duties described in SOP OR 203, section 1.3.2, each regular member or alternate member will be expected to act as a primary reviewer for assigned studies at convened meetings. The primary reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommendations specific actions to the IRB. He or she leads the IRB discussion of the study. The primary reviewers may be required to review additional material requested by the IRB for the purpose of study approval.
Training Checklist and documentation – IRB Members

**Purpose:**
- [ ] New Member
- [ ] Annual Requirements
- [ ] Other

**Name:**

<table>
<thead>
<tr>
<th>Training/Education Source</th>
<th>Completed</th>
<th>Verified by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundations of Human Subject Protection (as an example)</td>
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<tr>
<td>IRB Policies</td>
<td></td>
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<td>The Belmont Report</td>
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<td>Investigator Guidelines</td>
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<tr>
<td>OHRP Web-based training</td>
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