1.0 **Policy:**

The Sparrow IRB may rely on the review and documentation submitted by other IRBs. These other IRBs will become the IRB of record. They must provide the Sparrow IRB members with enough information about a study to assess if it adequately protects Sparrow patients, adheres to Sparrow policies and procedures, and meets the Sparrow IRB’s criteria for expedited approval.

**Both IRBs agree to:**

- Maintain an active FWA and IRB registration with OHRP in compliance with 45 CFR 46 Subpart E, and maintain an active IRB registration with the U.S. Food and Drug Administration in compliance with 21 CFR 56.106

- Execute a written agreement that establishes the reliance between an external IRB and the Sparrow IRB and signed by the FWA Signatory Officials of each IRB

- Maintain the signed agreement on file and provide to OHRP, FDA, other governmental agencies, and accrediting organizations as appropriate upon request.

- Have any Modifications to signed agreements written, reviewed, and approved by the FWA Signatory Officials of each IRB

- Follow written procedures for reporting findings and actions to appropriate officials at Sparrow and Sparrow for reporting findings and actions to appropriate officials at the collaborative IRB

Sparrow has contractual agreements in place with Michigan State University’s Biomedical & Health Institutional Review Board (BIRB), Community Research Institutional Review Board (CRIRB), and the Social Science/Behavioral/Education Institutional Review Board (SIRB). Sparrow also has a contractual agreement with the Michigan Cancer Research Consortium’s Oncology Central Institutional Review Board (OCIRB). Other Institutional Review Board Authorization Agreements (IAAs) may be entered into with Central IRBs, Sponsor required IRBs and other IRBs on a Protocol specific basis. These agreements must be reviewed by the Sparrow IRB and Agreements signed by the appropriate officials.

The IRB Administrator will review the submitted requested documents from the collaborative IRB/Investigator to determine whether adequate information and materials are available for review. If appropriate documentation is available, the IRB Chair or his/her designee may determine, under “expedited/facilitated review” procedures if the study is acceptable for conduct at Sparrow facilities.

Investigator and collaborative IRB will be notified in writing of the IRB determination. Investigators wishing to conduct research at Sparrow facilities with protocols, which meet the criteria under these contractual agreements, may not conduct research at Sparrow until Sparrow IRB approval has been given. Sparrow does not abdicate responsibility for studies conducted at Sparrow facilities that fall under these specific contractual agreements. The Sparrow IRB office will maintain records for each protocol approved under the collaborative
agreement(s). The contracted IRBs are expected to promptly report required activities to the Sparrow IRB office regarding these specific projects.

2.0 Scope:
This policy is applicable to all majority owned and controlled Sparrow Health System affiliates, Edward W. Sparrow Hospital Association and the Sparrow research community.

3.0 Definitions:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>IRB</td>
<td>Institutional Review Board: A group that is governed by federal regulations for the review of studies proposed by investigators. Each institution that conducts research uses an IRB made up of researchers and members of the public. The IRB must be sure that the study is managed in a way that protects those who participate in it.</td>
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<tr>
<td>Reliance Agreement</td>
<td>A reliance agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate Institutional Review Board (IRB) review to an independent IRB or an IRB of another institution. Institutions may use different descriptive terms, e.g., reliance agreement, cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU). Agreements may cover single studies, categories of studies, or all human subjects research under an organization’s Federal wide Assurance (FWA). The type of agreement may be based on the nature of established financial, legal, or collaborative relationships between the entities.</td>
</tr>
<tr>
<td>Federal Wide Assurance</td>
<td>Under the Department of Health and Human Services (DHHS) human subjects protection regulations (at 45 C.F.R. 46.103), every institution engaged in human subjects research that is funded or conducted by DHHS must obtain an Assurance of Compliance approved by the Office for Human Research Protections (OHRP). This Assurance Of Compliance, when granted, is called a Federal wide Assurance. All of the Institution’s human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.</td>
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<tr>
<td>Protocol</td>
<td>The written Investigational Plan or Study Design</td>
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4.0 Responsibilities & Procedures:

<table>
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<tr>
<th>Responsible Party</th>
<th>Actions</th>
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</table>
| Collaborative IRB (A) | • Satisfy the requirements for human subject protections as applicable at 45 CFR 46 / 21 CFR 50 / 21 CFR 56, and as codified by other federal agencies or departments, and the requirements of (A) and Sparrow’s U.S. Office for Human Research Protections (OHRP) approved Federal Wide Assurance (FWA).  
• Maintain IRB membership as required by federal agencies or departments. |
| **Make available to Sparrow, rosters, policies, and procedures of (A) upon request** |
| For projects that come under the (IAA) or Reliance Agreement, IRB (A) will need to agree to the terms and conditions set forth in the IAA (study specific) Agreement, and appropriately execute the Agreement. |
| **Sparrow IRB** |
| • Remain responsible for ensuring compliance with (A) IRB’s determinations and with the Terms of (A) OHRP-approved FWA.  
• Review and manage any unanticipated problems involving risks to subjects or others occurring at the institution.  
• Notify (A) IRB of audits by federal departments or agencies that may affect specified projects, or any of the terms the “Reliance” agreement.  
• Ensure qualifications of Investigators and research staff conducting the research  
• Maintain records for each IRB approved study at the local institution in accordance with federal, state, local laws and Institutional policies  
• Expedited/facilitated review is conducted by designated IRB member reviewers and approval determination made  
• Agree to the terms and conditions set forth in the IAA (study specific) and appropriately execute the Agreement.  
• Perform periodic audits to monitor protocol compliance, track Investigator compliance with IRB requirements stipulated during the IRB’s review of the Investigator’s research, and engage appropriate Investigator sanctions when Investigators are not in compliance with IRB requirements. |
| **IRB Staff/Administrator** |
| • Log Project into the IRB tracking database. Assign a protocol tracking ID number specific to the individual IRB, for example:  
  - Michigan State University BIRB studies - ####M  
  - Michigan State University CRIRB studies - ####C  
  - Michigan State University SIRB studies - ####S  
  - Michigan Cancer Research Consortium OCIRB studies - ####R  
  - Other External IRB – Name ####  
• Create a file with appropriate labeling for the project  
• For studies that fall under the MSU/Sparrow Reliance Agreement, the IRB administrator will access the study documents on the MSU IRB online submission platform, and upload necessary documentation onto IRBNet for Sparrow IRB review.  
• IRB Administrator will conduct an initial overview of submitted documents to ensure adequate documentation is available for review.  
• Organize the submitted material in the following order:  
  – The appropriately signed IAA  
  – Collaborative IRB Application  
  – Collaborative IRB Approval Letter  
  – Application for Sparrow IRB Reliance Review  
  – Protocol  
  – Informed Consent Document  
  – Grant Proposal (if applicable)  
  – Proposed Advertising  
  – Data Collection Tools  
  – Human Subjects Training Verification*  
  – Other supporting documentation as appropriate  
• Project is given to the IRB Chair or his/her designee for “expedited/facilitated” review and determination. |
• Determination letter is sent to Investigator with a copy to the individual collaborative IRB.
• All determinations are recorded in the Agenda/Minutes under the appropriate category.
• Proceed in accordance with any specific steps outlined in individual collaborative IRB agreements.
• Ensure reporting of all formal actions taken by collaborative IRB are recorded in the Agenda/Minutes and the IRB protocol tracking database.
• Maintain study documents as defined in FO-305.

| IRB Chair/Designee | • Review and make determination for study proposal, or designate Reviewer
• Follow Policy for Expedited Review if appropriate. |
|---------------------|--------------------------------------------------|
| Investigator        | • See Research guidance and contact information on the website, [www.sparrow.org](http://www.sparrow.org) before conducting research at SHS
• Complete and provide documentation of completion to the Sparrow IRB Administrator of the required and necessary Human Subject Research Training*
• Follow all regulations, polices and guidelines when submitting your Project to the “IRB of Record” (Collaborative IRB).
• Submit the Sparrow IRB Reliance Review application in IRBNet*
• Attach the appropriate documents. (You will need the approval verification from the IRB of Record)
• Consult with the Research Analyst for Billing and Protocol Impact issues
• Do not start any human research activities until you have the final Sparrow IRB approval letter
• Ensure that the Principal Investigator (PI) personally conducts or supervises the human research in accordance with the relevant current protocol as approved by the IRB
• Conduct your research in an ethical manner, according to ICH, GCP, written contracts and agreements, SHS policies and procedures, Federal, State, and Local guidelines and regulations
• Always protect the rights, safety, and welfare of the research subject

* MSU affiliated investigators conducting research under the MSU/Sparrow Reliance Agreement need only to submit this documentation to the MSU IRB. The Sparrow IRB administrator will access this information through the MSU submission system.


6.0 Other Documentation: [hhs.gov/ohrp](http://hhs.gov/ohrp)