

SOP: RR 402 Version No: Effective Date: 01/01/07	INITIAL REVIEW - CRITERIA FOR IRB APPROVAL	Supersedes Document Dated: 02/01/03
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1. POLICY

All research proposals that intend to enroll human subjects must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and respect for persons (autonomy) as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Sparrow Health System may apply and must be met as well.

Specific Policies

1.1 Minimal Criteria for Approval of Research

In order for a research project to be approved, the IRB must find, by using the Informed Consent form Checklist (IC 701-A), that:

- A. Risks to subjects are minimized:
 - By using procedures, as outlined in the IRB Protocol Review Worksheet (RR 402-A) that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
 - In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- C. Selection of subjects is equitable.
 - In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as (but not limited to) children, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.
- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations. Under certain conditions a Waiver of Informed Consent may be approved by the IRB.
- E. Informed consent will be appropriately documented as required by local, state and federal regulations.

- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Data stored electronically must be kept in accordance with the Security Guidelines for Clinical Research at Sparrow Health System procedures (FO 301-D).
- H. When some or all of the subjects, such as children, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
- I. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.

1.2 Other Criteria

The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification is required may include:

- Investigators that conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators that conduct studies that involve large numbers of subjects, and
- Investigators selected at the discretion of the IRB.

Outside reviewers may perform reviews as requested by the IRB Chairperson which may include ethical, research design, or statistical analysis among other types of reviews.

1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at Sparrow Health System facilities.

Under authority granted by the Institutional (Signatory) Official of Sparrow Health System, the Sparrow Health System's IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreement (FWA).

The Sparrow IRB has entered into contractual reliance agreements with, but not limited to, the following institutions for specified studies conducted at Sparrow facilities (also See SOP FO 306):

- 1.3.1. SHS/MSU IRB Reliance Agreement. The IRB Reliance is an agreement between Michigan State University's Biomedical & Health Institutional Review

Board (BIRB) and Sparrow Hospital which, if accepted under facilitated review by the Sparrow IRB, allows an MSU-paid faculty/staff member, intending to conduct research at a Sparrow facility, to have a research project undergo IRB review through BIRB, with the IRRC accepting the subsequent review by BIRB.

1.3.2. SHS/MSU IRB Collaborative Authorization Agreement. The IRB Collaborative Authorization Agreement, with MSU's Community Research Institutional Review Board (CRIRB), provides CRIRB review of collaborative, multi-community research projects, with IRRC-appointed member representation on this committee. The Sparrow IRB retains the right to facilitated review and acceptance for conduct at Sparrow facilities of CRIRB-approved studies.

1.3.2. Michigan Cancer Research Consortium's OCIRB Agreement. The SHS contractual agreement with Michigan Cancer Research Consortium's Oncology Central Institutional Review Board (OCIRB) provides for OCIRB review of MCRC research projects for the Sparrow Regional Cancer Center. The IRRC provides appointed member representation on the OCIRB. The Sparrow IRB retains the right to facilitated review and acceptance for conduct at Sparrow facilities of OCIRB-approved studies.

1.4 Qualifications of Principal Investigators.

The IRB shall review the Investigator's qualifications in relation to the research proposal. Where the Investigator conducts research involving human subjects, the IRB shall consider the following:

1.4.1. The IRB shall consider whether the investigator is qualified in the area of the proposed research by reviewing information submitted by the Investigator including the Investigator's references, resume, and/or curriculum vitae.

1.4.2. The IRB shall consider whether the Investigator has the appropriate professional experience in the field to be researched.

1.4.3. The IRB shall consider whether the Investigator has access to appropriate facilities to conduct the research, including the Investigator's medical staff privileges at Sparrow Health System. An Investigator shall not conduct clinical research without the appropriate medical staff privileges.

1.4.4. The IRB shall consider the Investigator's previous research activities.

1.4.5. The IRB shall consider the nature of the research protocol. If the protocol requires skills or qualifications beyond those of the proposed Investigator: (i) the protocol should be modified to match the Investigator's skills; (ii) qualified Investigators should be added; (iii) the protocol should be tabled; or (iv) the protocol should be denied.

1.4.6. The IRB may ask Investigators to address the topic in supplemental application materials.

All Resident, Fellow, and Student research projects must be sponsored by a responsible principal Investigator qualified in the area of the research to be conducted (also see SOP RI 801, 1.7).

2. SCOPE

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

3. RESPONSIBILITY

IRB Coordinator is responsible for ensuring that IRB reviewers have all the tools and resources they need to complete their research reviews.

IRB Chairperson (or IRB Administrator) is responsible for providing IRB members adequate submission review training and ongoing guidance, and for selecting the primary reviewers with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB.

IRB Reviewer is responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

21 CFR 56.108, 56.111

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

RR 402-A	Protocol Review Worksheet: Primary Reviewer
RR 402-B	Risk Assessment Checklist for Research Studies
RR 402-C	Significant and Non-Significant Risk Checklist (Medical Devices)

7. PROCESS OVERVIEW

Reviewers (primary review team, entire committee, and outside reviewers, if applicable) will look at research design, the risk level of the study, and the consent form as outlined in the Protocol Review Worksheet (RR 402-A) and the Informed Consent Form Checklist (IC 701-A). The primary reviewers are expected to complete the forms prior to the IRB meeting. At the convened IRB meeting, the primary reviewers are asked to present the results of their review to the entire committee. Then the committee discusses the project and makes further comments before a decision is made as to approval/non-approval.

For new studies requiring full IRB review, the principal investigator, or their designee, is required to come before the committee to briefly present their proposed project and answer any questions the IRB members may have. Once discussion is completed, the principal investigator, or their designee, is excused and does not remain present for formal discussion or action(s) taken by the IRB.

At the discretion of the IRB Chairperson or upon request by committee members, the principal investigators, or their designee, may be asked to come before the committee to discuss other IRB review issues.

Under the terms of the collaborative/reliance agreements, studies submitted to the IRB receive expedited-like review by the IRB Chairperson, or designee. The IRB is notified of these decisions in an upcoming agenda.

The OROC office will notify the principal investigator, in writing, of the IRB's decision.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Coordinator</i>	Provide primary reviewers with appropriate protocol review worksheets.	Protocol Review Worksheet: Primary Reviewer (RR 402-A) Informed Consent Checklist (IC 701-A)
<i>IRB Chairperson or IRB Administrator</i>	Select reviewers with appropriate expertise for the research to be reviewed.	
<i>IRB Chairperson</i>	Ascertain whether the evidence exists that third party verification (outside reviewer) of submitted information is needed.	Refer to SOP RR 403
<i>IRB Member (Reviewer)</i>	Review research proposal and summarize findings on appropriate protocol review worksheet (RR 402-A) and Informed Consent Checklist (IC 701-A).	Refer to Section SC 500
	Ascertain whether any special considerations exist that may influence the review of a proposal.	
<i>IRB Member (Reviewer)</i>	Prepare summary of findings and recommendations for presentation at the next convened IRB meeting.	