

STATEMENT OF AUTHORITY AND PURPOSE

1. **Governing Principles**

Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). These principles are defined in the Belmont Report (Appendix A) as follows:

- **Beneficence** -- 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.
- **Autonomy** -- Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.
- **Justice** -- The selection of subjects is equitable and is representative of the group that will benefit from the research.

2. **Authority**

An Institution's IRB is established and empowered under the auspices of that Institution's executive authorities, and, if federal funding is used to support human subject research in whole or in part, by the Institution's Federal Wide Assurance (FWA - Appendix B) with the federal Office for Human Research Protections (OHRP). There may be more than one IRB, but all must subscribe to the same underlying principles and authorities. This Institution requires that all research projects involving humans as subjects or human material be reviewed and approved by the SHS IRB prior to initiation of any research related activities, including recruitment and screening activities.

IRB is established to review biomedical and behavioral research involving human subjects regardless of the source of funding and location of the study. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46 Section 101(b)(1-6) or 101(i), all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, are subject to these policies and procedures if one or more of the following apply:

- The research is sponsored by institutional authorities and/or;
- The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the Institution in connection with his or her institutional responsibilities; and/or
- The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the Institution using any property or facility of the Institution; and/or the research involves the use of the Institution's nonpublic information to identify or contact human research subjects.

IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically:

- IRB may disapprove, modify or approve studies based upon consideration of human subject protection aspects;
- IRB reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
- IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators and auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
- IRB may suspend or terminate approval of a study; and
- IRB may place restrictions on a study.

Regarding federally funded research, if the study is part of an application to a federal sponsoring agency, the human protocol must be reviewed by IRB before or when the application is processed and prior to expenditure of any grant funds.

IRB also has a relationship to other institutional research review committees. IRB functions independently of, but in coordination with those other committees. Research that has been reviewed and approved by IRB may be subject to review and disapproval by institutional officials or other committees. However, those officials or committees may not approve research if it has been disapproved by an IRB.

3. Responsibility

A. IRB Review of Research

All research involving human subjects (as defined below), and all other activities, which even in part involve such research, regardless of sponsorship, must be reviewed and approved by the Institution's IRB(s). No intervention or interaction with human subjects in research, including recruitment, may begin until IRB has reviewed and approved the research protocol. Specific determinations as to the definition of "research" or "human subjects," and their implications for the jurisdiction of IRB under Institutional policy are determined by IRB (Appendix C).

The IRB's purpose and responsibility is to protect the rights and welfare of human subjects. IRB reviews and oversees such research to ensure that it meets well established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonisation. If the research is exempt from IRB review per 45 CFR 46 Section 101(b)(1-6) or 101(i) but involves human subjects or materials, IRB strongly encourages that the research be reviewed in order to ensure that the subjects are appropriately protected.

According to federal regulations, the activities that require IRB review include any activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual must be reviewed by the IRB. Specific activities that require IRB review include, but are not necessarily limited to the following:

- Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (FDA) under relevant investigational drug or medical device provisions of the Food, Drug, and Cosmetic Act, or experiments that need not meet the requirements for prior submission to the FDA, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
- Collection of data about a series of standard procedures or treatments for dissemination or generalization.
- A patient's care or assignment to intervention is altered for research purposes in any way.
- A diagnostic procedure for research purposes that is added to a standard treatment.
- Systematic investigation involving innovative procedures of treatments, for example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment.
- Emergency use of an investigational drug or medical device. Note that when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject, and data generated from such care cannot be included in any report of a research activity.
- Human cell or tissue (genetic tissue) research that typically involves repositories that collect, store, and distribute human tissue materials for research purposes. However, human cell or tissue repositories activities do not require IRB review if material submitted to the repository satisfies both of the following conditions: (i) The material, in its entirety, was collected for purposes other than submission to the repository (e.g., the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no "extra" material collected for submission to the repository); and (ii) The material is submitted to the repository without any identifiable private data or information, i.e., no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained.
- Investigator-initiated research, where an Investigator both initiates and conducts, alone or with others, a clinical trial. In the case of Investigator-initiated studies, it is the Investigator's responsibility to keep IRB informed of unanticipated non-serious research related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the Institution's IRB is not the IRB of record. The IRB recommends an independent data safety monitoring board (DSMB) review all reportable adverse events and the DSMB reports are forwarded to the IRB in addition to individual reports.
- Student-conducted research, which includes all activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree, must be reviewed by the IRB. These activities include: (i) All master's theses and doctoral

dissertations that involve human subjects; and (ii) All projects that involve human subjects and for which findings may be published or otherwise disseminated.

- Case studies, such as when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases. Such activity constitutes research that must be reviewed by the IRB. Additionally, this type of activity must always be reviewed by the IRB when there is intent to publish or disseminate the data or findings.

B. Failure to Submit a Project for IRB Review

The implications of engaging in activities that qualify as research that is subject to IRB review without obtaining such review are significant. Results from such studies may not be published unless IRB approval had been obtained prior to collecting the data. To do so is in violation of Institutional policy. It is also against Institutional policy to use those data to satisfy thesis or dissertation requirements. If an Investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the Investigator should submit a proposal to the IRB for review as soon as possible. If the IRB does not approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be published. Furthermore, FDA may reject such data if it is submitted in support of a marketing application.

C. Assurance of Independence

IRB has the mandate to act as an independent entity within the corporate structure of Sparrow Health System. All decisions made by the Board are binding and cannot be overturned or overruled by the Sparrow Health System. The actions of the IRB, its chairperson, members and administrative staff in matters of human subject protection derive from the authority vested under federal regulations, separate and distinct from Sparrow Health System. It is the responsibility of the Institutional Official (IO) - Vice President of Medical Affairs - to maintain and enforce the independent nature of the relationship between the IRB and Sparrow Health System.

D. Sparrow Health System's IRB

Sparrow Health System has one IRB, the Institutional Research Review Committee (IRRC). The IRRC reviews applications for research involving human subjects in keeping with ethical principles and the U.S. Department of Health and Human Services regulations for the Protection of Human Subjects.

The IRRC is a multidisciplinary standing review committee comprised of:

- Members of the Sparrow Health System Medical Staff
- Representatives from Michigan State University Colleges of Human Medicine and Osteopathic Medicine
- Representatives from the Sparrow Health System Administration and Nursing Services
- At least one member not affiliated with the Sparrow Health System
- At least one member whose primary concerns are in nonscientific areas

- Community representatives including, but not limited to, an attorney, a clergyman, an ethicist and/or social scientist

E. Collaborative Research Agreements

SHS/MSU IRB Reliance Agreement – The IRB Reliance is an agreement between Sparrow Hospital’s IRRC and Michigan State University’s Committee on Research Involving Human Subjects (UCRIHS) which allows an MSU-paid faculty/staff member, intending to conduct research at a Sparrow facility, to have a research project undergo IRB review through UCRIHS, with the IRRC accepting the review of the lead institution.

SHS/MSU IRB Collaborative Authorization Agreement – The SHS/MSU IRB Collaborative Authorization Agreement, with Michigan State University’s Community Research Institutional Review Board (CRIRB), provides CRIRB review of collaborative, multi-community research projects, with IRRC appointed member representation on this committee.

Michigan Cancer Research Consortium’s OCIRB Agreement – The SHS contractual agreement with the Michigan Cancer Research Consortium’s Oncology Central IRB (OCIRB) provides for OCIRB review of MCRC research projects for the Sparrow Regional Cancer Center. SHS provides appointed representation on the OCIRB.