

INSTITUTIONAL REVIEW BOARD (IRB)

Saint Joseph Mercy Health System (SJMHS) recognizes the need for investigations (clinical research) in which human beings may serve as research subjects. SJMHS is also cognizant of its responsibility for insuring the privacy, safety, health and welfare of such subjects are adequately protected. SJMHS has established two Institutional Review Boards (IRBs) to provide independent review and continuing compliance of research involving the use of human subjects and to approve the adequacy of human subject protection. The two IRBs are IRB#1 and IRB#2 (Oncology Central IRB (OCIRB)). The OCIRB reviews and approves all oncology trials and is the exclusive IRB approving Michigan Cancer Research Consortium trials. The member institutions of the Michigan Cancer Research Consortium have agreed that no MCRC trial shall be conducted unless and until the OCIRB has reviewed and approved the applicable protocols.

Purpose

The Institutional Review Board (IRB) is an independent committee designated by SJMHS to safeguard the rights and welfare of all human subjects who volunteer to participate in clinical research studies. It oversees institutional compliance with institutional and Federal regulations, the requirements of applicable law, SJMHS's Assurance, and SJMHS's policies and procedures.

Responsibilities

The IRB is responsible for reviewing all research involving human subjects and that: there is equitable selection of research subjects, potential research-related risks are minimized, and full disclosure is provided of methods and procedures so that volunteers can make an informed decision to voluntarily participate.

Members

The committee consists of at least five members who are sufficiently qualified, through experienced expertise, to review the research presented to them. The committee also has at least one member whose primary concerns are in nonscientific areas and one member who is not affiliated with SJMHS. All IRB members are volunteers

FREQUENTLY ASKED QUESTIONS

Who needs IRB approval?

Any member of the SJMHS medical staff, an allied health professional, or a member of the employed professional staff, who are responsible for the overall conduct of the research project. This includes the following locations: Saline, Livingston, St. Mary's Livonia, Chelsea and Mercy Hospital in Port Huron.

What types of research must be submitted to the IRB?

All research involving the treatment of, interactions or interventions, and collection of data from or about human subjects, must be submitted to the IRB for review. Some research activities may be exempt from full IRB review but the IRB must approve that an exemption is appropriate.

What are the SJMHS requirements for conducting research?

All research team members must complete a web-based course on the rights and welfare of human participants in research prior to conducting research. <http://www.citiprogram.org/>

Where are the forms for IRB submission?

A complete list of forms to be submitted is listed on the intranet and Internet. <http://infonet.trinity-health.org/clinical/research/forms/>

How do I submit to the IRB?

A signed copy of the required documents must be submitted to the IRB office located in the Riechert Health Building Rm 2018, and an electronic version may also be sent to the appropriate IRB coordinator.

What are the submission deadlines?

Submission deadlines vary between the IRBs. Please check the appropriate meeting

deadlines on: <http://infonet.trinity-health.org/clinical/research/staff/>

How long does the review process take?

For Full board reviews: the approval notifications take about 3 to 7 business days from the date of the IRB meeting. Expedited reviews generally take about 1-15 days for review and receipt of letter approval.

What is an Expedited review?

A member of the IRB is designated as an expedited reviewer, meaning that the review and approval can occur without full-board review.

Does the IRB need to be notified if there are any changes to the project?

Yes, all changes to an approved study must be submitted for review and receive IRB approval before the changes can be implemented. Examples of changes include protocol and consent revisions, & adding investigators, etc.

What is a continuing (annual) review?

A continuing review is a reevaluation of an approved project conducted at least once a year mandated by federal regulations. This allows the IRB to monitor the progress of the research. A continuing review form must be submitted 45 days prior to the expiration date of the last year's approval.

What is informed consent?

Informed consent is the process by which a research candidate is fully informed and determines whether to enroll in a research study. It is based on the legal and ethical rights that the decision is voluntary and autonomous about whether they wish to participate in a research study. The Principal investigator or study team member conducts this salient task.