

Maine Medical Center (MMC) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted under the auspices of MMC. In the review and conduct of research, actions by MMC will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (often referred to as the [Belmont Report](#)). The actions of MMC will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, MMC has established a human research protections program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- Provide timely and high quality education, review, and monitoring of human research projects; and
- Facilitate excellence in human subjects research.

MMC will designate an Institutional Official who has overall responsibility for MMC's HRPP. The duties of the Institutional Official are as follows:

- Fostering, supporting, and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects;
- Ensuring adherence to regulations and organizational policies;
- Ensuring that the IRB functions independently by, among other mechanisms, being directly accessible to the IRB Chair and members if they experience undue influence or if they have concerns about the function of the IRB;
- Oversight of the Institutional Review Board (IRB);
- Oversight of research conducted by all MMC investigators;
- Ensuring the IRB members are qualified to review research in accordance with ethical standards and applicable regulations;
- Ensuring that all investigators are qualified to conduct research in accordance with ethical standards and applicable regulations;
- Oversight of the development and implementation of an educational plan for IRB members, staff, and investigators;
- Ensuring compliance with institutional policies and all applicable regulations for the protection of human subjects;
- Serving as the signatory authority and ensuring compliance with the terms of the Federal-wide Assurance to the Office of Human Research Protections; and
- Providing support to the HRPP by ensuring it has sufficient staff and resources to fulfill its mission and obligations.

In carrying out these responsibilities, the Institutional Official has the authority to delegate such activities as may be necessary to fulfill these duties.

To conduct its responsibility effectively, MMC maintains an Institutional Review Board (IRB) to review research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted at MMC. The IRB has the following authority:

- To approve, require modifications to secure approval, or disapprove any human subjects research activities overseen by MMC, regardless of the location of the research activities;
- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects;
- To conduct continuing review of research at intervals appropriate to the degree of risk presented by the research, but not less than once per year;
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects;
- To observe, or have a third party observe, the consent process;
- To observe, or have a third party observe, the conduct of the research; and
- To determine whether data or information gathered without IRB approval, or in association with serious noncompliance, may be published or used for research purposes.

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless it is determined to be in the best interest of already enrolled subjects to continue participating in the research. The investigator can petition the IRB to continue an individual subject's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interest of the individual participant to do so.

The IRB has jurisdiction over all human subjects research overseen by MMC, regardless of the funding source or location of the research activities. Research by the institution includes research:

- Conducted at this organization;
- Conducted by or under the direction of any employee or agent of this organization in connection with his or her organization responsibilities;
- Conducted by or under the direction of any employee or agent of this organization using any property or facility of this organization; or
- Involving the use of this organization's non-public information to identify, contact, or study human subjects.

No research involving human subjects may be conducted without IRB approval and no research may commence until all required Institutional approvals (including IRB) are obtained. Exempt research is subject to review for determination of exemption status. At MMC, exemptions are reviewed and granted by the IRB Manager or designee.

MMC may review any human subjects research protocol and has the right to disapprove or terminate approval of a research protocol that has been approved by the IRB. However, no one at MMC shall approve the implementation of human subjects research that has not been approved by the IRB nor may anyone override a decision of the IRB. See 45CFR46.112

All institutional and non-institutional performance sites for MMC, domestic or foreign, will be obligated by this policy to conform to ethical principles, which are at least equivalent to those of this institution, or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

The Institutional Official, in consultation with the Director and staff of the ORC, shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of MMC.