



Maine Medical Center
MaineHealth
Human Research Protection Program

Human Research Protection Plan
April, 2014

Maine Medical Center (MMC)
Human Research Protection Program Policy (HRPP)

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MaineHealth

Maine Medical Center Human Research Protection Plan

Maine Medical Center (MMC) is committed to protect the rights, welfare and privacy of humans who participate in our human research programs. This plan describes MMC's commitment to comply with ethical and legal requirements for the conduct of human research.

Maine Medical Partners, Maine's largest multi-specialty medical group, with a dedicated high quality team of more than 300 physicians that provides a wide range of primary, specialty and sub-specialty care delivered through a network of more than 40 locations in and near Greater Portland.

MMC Human Research Protection Plan (MMC HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects. All individuals within Maine Medical Center and the physicians from Maine Medical Partners are responsible to:

- Be aware of the definition of human research.
- Consult with MMC IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or all human research to be conducted without review and approval by the MMC IRB.

Mission Statement

The MMC HRPP is committed to enhancing the responsible conduct of research for the protection of all of our human research participants. We serve to carry out this mission by:

- Promoting an environment of respect and understanding of the rights and welfare of human research participants;
- Ensuring that the risks and benefits of each research study are thoroughly considered;
- Ensuring that our human participants are well-informed of their research rights.

The MMC HRPP adheres to the Principles of the Belmont Report, the Common Rule (45 CFR 46), and Food and Drug Administration regulations relating to human participants (21 CFR Parts 50 and 56) as well as state and institutional policies that govern human participant research.

Maximizing Compliance by Meeting Our Goals

The MMC HRPP incorporates mechanisms to:

- Provide oversight of research participants;
- Continuously improve and enhance the Institutional Review Board's role in the review of research;
- Establish a process to monitor, evaluate and continually improve the protection of human research participants;
- Educate staff who conduct research about the federal regulations and ethical principles guiding research with humans; providing up-to-date information to keep staff current with any regulatory or Institutional policy changes;

- Implement quality improvements and quality assurance activities that will best serve the HRPP mission;
- Provide a process for responding to concerns of research participants or their families; research staff and the community.

Ethical Principals

The MMC commits to apply the *Ethical Principals and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, generally known as the “Belmont Report”.

The three main principals outlined in this report are:

Respect for Persons (e.g., applied by obtaining informed consent, giving consideration to privacy and confidentiality, and adding protections for vulnerable populations)

Beneficence (e.g., applied by weighing risks and benefits)

Justice (e.g., applied by the equitable selection of subjects)

Definitions

For the purpose of this policy, the terms used are defined as follows.

Agent: An Individual who is not an employee is considered an agent of the organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of the organization.

Human Research: Any activity that either:

Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS; or

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. 45 CFR 46.102(d)
- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information. 45 CFR 46.102(f)

Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA

- Research means 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 under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c), 21 CFR 56.102(c))
- Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Test Article: any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

Clinical Trial: Human research intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of a drug or biologic, to identify any adverse reactions to a drug or device, to evaluate the safety or effectiveness of a drug, biologic, or device, or to study absorption, distribution, metabolism, and secretion of a drug or biologic with the object of ascertaining its safety or efficacy.

Engagement in Research

MMC is engaged in human subject research whenever employees or agents of the institution intervene or interact with living individuals for research purposes or the institution receives a direct Health and Human Services award to support such human subject research. All MMC research must be reviewed by the MMC IRB before the research is conducted.

Types of Research Conducted and Overseen by this HRPP

The single IRB at MMC oversees and reviews both **biomedical and social behavioral** research that could involve any of the following categories of human research:

- Food and Drug Administration (FDA) regulated research
- Department of Health and Human Services (DHHS) regulated research
- Research involving the need for an Investigational New Drug
- Research involving devices that require an Investigational Device Exemption issued by the FDA
- Emergency use of a test article in a life threatening situation
- Activities involving a Humanitarian Use Device
- Research involving drug/device for compassionate use
- Research involving pregnant women as subjects
- Research that plans to or is likely to involve prisoners
- Research involving children as subjects
- Research involving staff or students
- Investigator held IND or IDE
- Research involving a waiver of consent for planned emergency use

Participating Organizations under our Federal Wide Assurance - FWA 00003993

Maine Medical Center (MMC)

Maine Medical Partners (MMP) (see above reference to MMP)

Maine Medical Center's Federal Wide Assurance

Sponsored Research or Non-Sponsored Research

Maine Medical Center's Assurance with the Federal government defines its jurisdiction over the review of research activities involving human participants. Regardless of sponsorship, the IRB must review all research to determine if the research meets the regulatory definition of human participant research and one or more of the following apply:

- The research is sponsored by Maine Medical Center;
- The research is conducted by or under the direction of any employee, staff, student, or agent of Maine Medical Center, in connection with his/her institutional responsibilities;
- The research is conducted by or under the direction of any employee or agent of this institution using any of its property or facilities; agents include all individuals performing institutionally

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designated activities or exercising institutionally delegated authority or responsibility, including faculty, staff, employees, students and visiting scholars.

- The research involves the use of non-public information maintained by Maine Medical Center to identify or contact human participants or prospective participants;
- Maine Medical Center receives a direct Federal award to conduct human participant research, even where all activities involving human participants are carried out by a subcontractor or collaborator; and/or
- The research is conducted in accordance with federal, state and institutional requirements whereby the Maine Medical Center's IRB is designated as the IRB of record through an established Memorandum of Understanding.

Other activities that are not overseen by the IRB, include activities that have been determined to be:

- Quality improvement projects
- Case reports (3 or less cases)
- Program evaluation
- Surveillance activities

Authority

Institutional Official

The President of Maine Medical Center has delegated primary responsibility of the HRPP to Donald St. Germain, M.D, Associate Vice President of Research and Director of Maine Medical Center Research Institute (MMCRI). As MMC's Institutional Official for research, the AVP of Research signs the Federal-wide Assurance of Compliance (FWA) on behalf of the institution and is ultimately responsible for:

- Setting the tone for an institutional culture of respect for human subjects;
- Creating the Human Research Protection budget and assuring that there are sufficient resources to support the program;
- Ensuring effective institution-wide communication and guidance on human subjects issues;
- Appointing IRB Chairs and members;
- Ensuring that investigators and their associates fulfill their responsibilities;
- Submitting required reports to Office of Human Research Protection, FDA, Office of Research Integrity and other relevant federal and state agencies;
- Approving authorization agreements;
- Overseeing the implementation of a process to receive and act on complaints and allegations;
- Overseeing the education and monitoring program of the HRPP;
- Overseeing the maintenance of the policies and procedures for HRPP and related research policies and procedures on behalf of Maine Medical Center;
- Overseeing the protection of human research participants, regulatory compliance, and the implementation of the HRPP for Maine Medical Center;
- Ensuring that open channels of communication are maintained between the components of the MMC HRPP;
- Supporting the authority and decisions of the MMC IRB;
- Overseeing research investigators and staff, and research management;
- Ensuring the independence of the MMC IRB, including the authority to act without undue influence;
- Requiring periodic reviews of the MMC HRPP.

Legal Requirements

The single IRB at MMC oversees and reviews both **biomedical and social behavioral** research that could involve any of the following categories of human research.

- MMC international (transnational) research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research at the MMC location while complying with local laws and taking into account cultural context.
- For international clinical Human Research, MMC commits to apply the “International Council on Harmonisation” – Good Clinical Practice E6, as applicable for drug and device studies regulated by the FDA.
- When human research is conducted or funded by the following agencies, we commit to comply with their regulations:
 - Department of Justice (DOJ), the organization commits to apply 28 CFR §22. Bureau of Prisons (DOJ), the organization relies on the Bureau Research Review Board to ensure compliance with 28 CFR §512.
 - Department of Defense (DOD), the organization commits to apply DOD Directive 3216.02. When Human Research is conducted or funded by the Department of the Navy, the organization commits to apply SECNAVINST 39000.39D.
 - Department of Education (ED), the organization commits to applying 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.
 - Department of Energy (DOE), the organization commits to applying DOE O 443.1A and to use “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements.”
- When Human Research is conducted or funded by, or when the results of research are intended to be submitted to the Environmental Protection Agency (EPA), the organization commits to applying 40 CFR §26.
- MMC prohibits payments to professional in exchange for referrals of potential subjects and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment.

The **Maine Medical Center IRB** at MMC has been formally designated by the Institutional Official to review and monitor research involving human subjects. All research projects involving human subjects, regardless of the source of funding, require review and approval by the MMC IRB prior to implementation. It is the role of the MMC IRB or its designees to determine if research activity requires review, including those activities that may meet exemption criteria.

In accordance with federal regulations, the IRB has the authority to approve, require modifications in, disapprove, terminate or suspend research at participating organizations. No Institutional official or other Institutional committee may override the decisions of the IRB to disapprove a study. However, the Institution may prevent the performance of a study approved by the IRB. No Institutional Official or other Institutional committee may approve research that has not been approved by the IRB, including research that was disapproved. The purpose of the IRB is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. The IRB Office is located in the Research Compliance Department of Maine Medical Center Research Institute.

IRB Chair and Members, and IRB Staff

The Chairperson, Vice Chairperson and members of the IRB are appointed by the Institutional Official. There is no designated term of service. Currently the Chair position is held by Laura Blaisdell, M.D. The Manager of the IRB, is a full time employee within the Research Compliance Office. Other support for the day-to-day business of the IRB Office includes one IRB compliance coordinator and part-time support from the Research Compliance Officer. The Manager of the IRB is evaluated yearly by the Director of Administration and the Chair, IRB. The appropriateness of these resources is evaluated annually by the Chair of the IRB, Research Compliance Officer and the Director of MMCRI (the Institutional Official).

The IRB is currently composed of **20 members and alternates**. The members of the IRB represent a wide range of disciplines and have medical, nursing, administrative and scientific experience. At least one member is not affiliated with MMC, and at least one is a non-scientist. We currently have two (2) community members. Prospective members of the IRB are recommended by the Chair, other IRB members or Department Chiefs. Members are nominated based on their area of professional expertise, experience and/or affiliation depending on the needs of the Board. Members are formally appointed by the Institutional Official and their selection is reported to the OHRP. Members are required to attend a majority of meetings. If an alternate member is designated, the IRB roster will be revised to identify the member for whom the alternate can substitute. There is no designated term of service, and members of the IRB are not compensated for their services. Annually, the IRB members' participation and attendance will be assessed by the IRB Chair and Manager, IRB for attendance and function. Any member deemed not able to perform their duties as a member will be asked to resign.

Shared Responsibilities for Protecting Human Subjects

Maine Medical Center participates in several shared review models, including:

- Central Institutional Review Board (cIRB) Initiative of the National Cancer Institute (NCI). A central review model for adult and pediatric national multi-center cooperative oncology group cancer treatment trials is employed for selected protocols previously reviewed by the NCI - cIRB.
- Chesapeake Central IRB to review all pharmaceutical company sponsored trials to be conducted at MMC or by MMP physicians and
- IRBShare.

It is the responsibility of each affiliate and partner of MMC to formally "assure" appropriate agencies in writing that they will comply with regulations governing the protection of human subjects. As part of its written Federalwide Assurance (FWA) to the government, each affiliate and partner must have written policies and procedures for conducting human subject research in a responsible and ethical fashion. These policies and procedures must reference and maintain compliance with MMC HRPP Policies and Procedures.

Principal Investigator

The Principal Investigator (PI) is primarily responsible for protecting the rights and welfare of human subjects participating in research. PIs may not commence human-subjects research prior to obtaining IRB, and, as appropriate, other institutional approvals of their protocols. For each protocol submitted to the MMC IRB for approval, the PI must certify that s/he accepts responsibility for assuring adherence to applicable federal and state research regulations and hospital policies relative to the protection of the rights and welfare of subjects enrolled in the research.

PIs must be qualified by training and experience to conduct the research outlined in their protocol and must be in compliance with the MMC Conflicts of Interest Policy. The PI's department chair or chief or his/her designee must review and sign new protocol applications for any research that involves human subjects prior to submission to the MMC IRB. When the research involves the administration of a drug or use of a device, the PI must be a licensed physician. Exceptions to this requirement are made by the MMC IRB on a case by case basis; exceptions require a licensed physicians co-investigator and approval of the department chair/chief.

PIs may delegate certain roles or authority to appropriately qualified co-investigators and research staff. However, co-investigators and research staff must be qualified by training and experience to perform these responsibilities. Additionally, co-investigators and research staff must be in compliance with the MMC Conflict of Interest Policy when applicable. The PI remains responsible for the conduct of all persons to whom s/he delegates tasks.

All investigators and research staff must complete the Collaborative IRB Training Initiative (CITI) program(s) in order to participate in the conduct of human research and must sign a Statement of Commitment to Human Subject Protection. The Human Subjects Refresher Course must be completed every three years.

Other Members of the Research Team

Every member of the research team is responsible for protecting human participants. Co-investigators, study coordinators, nurses, research assistants, faculty sponsors, student/staff investigators, and all other research staff have the following strict obligations to:

- Comply with all IRB determinations and procedures;
- Adhere rigorously to all protocol requirements;
- Inform the PI, and thus the IRB, of unanticipated problems;
- Ensure the adequacy of the informed consent process;
- Take necessary measures to ensure adequate protection for study participants.

Legal Counsel

Legal Counsel at Maine Health provides advice upon request to the Institutional Official, the IRB and other individuals involved in the Human Research Protection Program. Legal Counsel will determine if someone is acting as an agent of the organization. Legal Counsel will assist in conflict resolution between federal law and other applicable laws and will determine the laws to be followed when the research is conducted outside of our jurisdiction.

Research Education and Compliance Officer (RECO)

The Research Education and Compliance Officer is responsible for developing, implementing and maintaining the **Supporting Education and Quality in Research (SEQUR)** Program. SEQUR is independent of the IRB and accomplishes these responsibilities utilizing two distinct strategies: authority and providing services.

Strategy one: SEQUR has the authority to:

- Develop and implement HRPP Quality Improvement/Assurance Plan.
- Perform routine onsite reviews of any study that has been approved by the MMC IRB.
- Conduct directed (for-cause) audits at the request of the IRB or Institutional Official.
- Provide Investigators with quality improvement recommendations to ensure that research is conducted in accordance with good clinical practice guidelines.

- Provide investigator training and education to the research community.
- Recommend action to the IRB, based on onsite observations during directed (for-cause) audits.
- Investigate allegations and findings of non-compliance.
- Report potential serious or continuing non-compliance with applicable regulations or institutional policies to the IRB and/or Institutional Official.

Strategy two: SEQR offers the following services:

- Navigating new investigators through the research process.
- Providing investigator/study staff with study documentation and management tools.
- Providing orientation to new research coordinators.
- Providing or supporting ongoing professional development opportunities for research staff.

Department Chiefs

Department chiefs are responsible for ensuring that investigators conducting human subject research are qualified by training and experience to conduct the proposed research. In addition, department chairs/chiefs are responsible for ensuring that investigators have sufficient resources (time, research personnel, and access to appropriate populations) facilities to conduct the proposed research and availability of medical and psychosocial resources that participants might need as a consequence of the research. For each protocol submitted to the IRB for approval, the department chair/chief must certify that s/he accepts responsibility for assuring adherence to federal and state research regulations and institutional policies governing the protection of human subjects and conflict of interest, including applicable institutional credentialing requirements.

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is established specifically for the review and oversight of recombinant DNA research at the local level. The charge of the IBC is to assure the safe use of recombinant DNA in research for conformity with and compliance to the NIH Guidelines. All human subject research involving the use of recombinant DNA technology must have IBC approval before research activities may commence.

Human Embryonic Stem Cell Research Oversight Committee

The Human Embryonic Stem Cell Research Oversight (heSCRO) Committee is specifically established to ensure that all federal and state regulations governing the conduct of human embryonic stem cell research are met and that all human stem cell research is conducted in accordance with the general principles expression in the NAS Guidelines for Human Embryonic Stem Cell research. All human subject research involving stem cells must have been reviewed by the Committee or registered before activities may commence.

HIPAA Privacy Officer

The Privacy Officer is responsible for the implementation and enforcement of the Privacy and Security Rules under HIPAA for the Maine Medical Center Affiliated Covered Entity.

Radiation Safety Committee

The MMC Radiation Safety Committee (RSC) is responsible for reviewing all exposures to ionizing radiation from x-ray procedures or nuclear medicine procedures performed for research purposes. This includes exposing normal volunteers to obtain data for new equipment. All human subject research involving ionizing radiation must have RSC approval before research activities may commence.

Research Contracts and Agreements

With respect to sponsored research, MMC addresses the protection of research participants by including in their standard contract templates a provision that the sponsor acknowledges and understands that the MMC HRPP is applicable to all human participant research at MMC. The Research Contract Administrator is responsible for reviewing sponsor contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Policies, Procedures and Required Training

The IRB/HRPP understands that the protection of participants is the responsibility of many individuals and has written policies and procedures for training requirements that apply to the IRB staff, IRB members, researchers, research staff and the institutional official.

Researchers and Research Staff

[Educational Requirements](#): Collaborative IRB Training Initiative (CITI) Program:

Human Subjects Protection Course (Biomedical or Social/Behavioral Research)
Health Information Privacy and Security Training

Every three years: *CITI Refresher Course for Human Subjects Protection*

The IRB will not review any proposal until the PI and each member of his/her staff involved in the research has completed the training.

Research coordinators receive a competency-based orientation through our Research Education and Research Compliance Office when they are first hired. In addition, we hold a monthly Clinical Research Coordinator meeting where new information and training is provided.

An Investigator Manual is available to all researchers and their staff on our website
http://www.mmcri.org/investigator_manual

IRB Members, IRB Staff and Institutional Official

Newly appointed members meet with the IRB Chair and IRB Manager to review policies, their duties, and information from OHRP and the FDA. They are also provided with an IRB Members handbook and requested to take the CITI Basic Ethics training. Ongoing education of IRB members is incorporated into our monthly meetings via the use of presentations and discussions.

IRB Staff

Staff in the Research Compliance Office must complete CITI training. Continuing education is encouraged and resources provided for national conferences, webinars and journals.

Institutional Official

It is the role of the Director of Research Compliance to keep the IO up to date with current requirements and policies of the IRB.

Research Participants

MMC ensures research participants have reliable channels of communication to the investigators or to the Research Compliance Office, for voicing concerns or complaints about research. Participants are encouraged to call the IRB if they feel they are being pressured to enroll in the research or, once enrolled, to continue with the research.

All informed consent forms provided to participants will include contact information for the investigator conducting the research and the IRB.

Participants are encouraged to ask questions about the research process or the regulatory process for research review. Participants can reach the IRB at:

Maine Medical Center Research Institute

Research Compliance Manager

81 Research Drive

Scarborough, ME 04074

Ph: 207-396-8184

Fax: 207-396-8141

Or submit a concern on our website at: <http://www.mmcri.org/hrpp>

Human Research Protection Program Policies and Procedures

Policies and Procedures for the Human Research Protection Program are available on the following website: <http://www.mmcri.org/SOP>

Human Research Protection Program Organizational Chart





