

**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**  
**MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD**

**Part 5****Policy No. IV****Subject: Jurisdiction Over Clinical Research****I. Policy**

The Main Line Hospitals Institutional Review Board (MLH IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate as research subjects in research activities subject to review and approval by the MLH IRB. The purpose of this policy is to define activities which engage the institution in research and require review and approval by the MLH IRB. This policy also addresses the conditions under which non-affiliated individuals<sup>1</sup> and/or institutions may conduct research at the Main Line Health System.

**II. Procedure****Main Line Health System Engagement**

The research conducted throughout the Main Line Health (MLH) System is divided into two general categories. Activities defined in Category A below mandate review by the MLH IRB. These scenarios are not intended to be exclusive and there may be situations where specific facts and circumstances must be examined to determine the jurisdiction of the MLH IRB<sup>2</sup>.

**Category A – Review required by MLH IRB**

1. **Protocols that require hospital involvement.** This category includes research studies in which any part of the research is carried out within Main Line Hospitals with services provided by Main Line Hospitals or with the involvement of a Main Line Health affiliated entity (MLH Affiliate). A MLH Affiliate is defined to be an entity of which Main Line Health, Inc. (or a Main Line Health subsidiary) is the parent organization<sup>3</sup>.
2. **Research in which funding is received or administered by, or contracted with Lankenau Institute for Medical Research (LIMR) or other MLH Affiliate.** This category includes research which is sponsored, grant funded, MLH Affiliate supported or otherwise funded by a MLH Affiliate.

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<sup>1</sup> Refer to footnote 6 for additional information.

<sup>2</sup> In limited circumstances, the MLH IRB may consider entering into an IRB authorization agreement for review by an external IRB.

<sup>3</sup> Main Line Hospitals, Inc., if not referenced separately in this policy, is included among MLH Affiliates.

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3. **Employees of Main Line Health, Main Line Hospitals or other MLH Affiliate.** This category includes research studies conducted by employees of Main Line Health, Main Line Hospitals, or other MLH Affiliate.
4. **Research conducted to meet a Main Line Hospitals (or other MLH Affiliate) Educational Requirement or Institutional Responsibility.** This category includes research required to complete an approved Main Line Hospital's Residency, Fellowship Program or other MLH Affiliate approved educational requirement.
5. **Research involving the use of non-public information belonging to Main Line Health, Main Line Hospitals, or Other MLH Affiliate.** This category includes activities involved in contacting or identifying research subjects or prospective subjects including any activities which involve obtaining, from any MLH Affiliate, identifiable private information or identifiable specimens for research purposes. This category includes the use or disclosure of protected health information (PHI) for research purposes. May require review by the Chief Privacy Officer for MLH.

### **Category B –Review by MLH IRB at Investigator’s Option**

1. **Physicians who lease office space in a medical office building located on one of the Main Line Hospitals (or other MLH Affiliate) campuses.** This category includes research studies that are conducted exclusively in a physician’s office<sup>4</sup>, the physician is not an employee of Main Line Health, Main Line Hospitals, or other MLH Affiliate; and the research does not fall within any of the activities described in Category A. In this category, the only relationship the physician has with Main Line Health or a MLH Affiliate, aside from medical staff membership, is that the physician leases space in a building located on a Main Line Hospitals or MLH Affiliate campus. Main Line Health or a MLH Affiliate is not engaged<sup>5</sup> in the research and review by the MLH IRB is optional and voluntary and an external IRB may review the research.

## **III. Process**

The Office of Research Affairs, Lankenau Institute for Medical Research is responsible for, among other activities related to medical research, providing direction and assistance to the research community at Main Line Health regarding MLH IRB jurisdiction over research engaged in by, or with the participation of, any MLH Affiliate. When questions arise regarding the jurisdiction of the MLH IRB and research, the Office of Research Affairs shall make the final determination.

### **A. MLH IRB Fees**

Research reviewed by the MLH IRB which is sponsored by industry or grant, excluding federally sponsored research, is subject to a fee.

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<sup>4</sup>Research that is conducted by non-employees at non-MLH locations (not owned by Main Line Health, Main Line Hospitals or other MLH Affiliate) are not covered under the Main Line Hospitals Federalwide Assurance.

<sup>5</sup>Refer to OHRP Guidance on Engagement of Institutions in Human Subjects Research for a complete discussion on engagement of institutions and individuals in research.

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**B. Institutional Department Review**

When a research project is reviewed by the MLH IRB, the review by the Institutional Department(s) outlined in the table below is required. **Institutional Department review is required for each type of research that applies to the investigator’s project.** *Research in Category II. B.1., Review by MLH IRB at Investigator’s Option, when reviewed by the MLH IRB does not require any MLH institutional department review other than those of supporting hospital departments or supporting MLH Affiliate providing services.*

*Type of Research	Department Chair(s)/ Clinical Division Chief(s)	Supporting Hospital Department(s) (e.g. pharmacy or lab)	Nursing Research Council Chair	LIMR Administration	Medical Education
Resident/Fellow or other Educational Research	X	X		X	X
**Sponsored Research	X	X		X	
Nursing Research	X***	X	X	X	
Non-Funded Research	X	X		X	
<p>*More than one type of research may apply to your project. Institutional Department review is required for each type of research involved in your project (i.e. a project may be a sponsored, nursing research project and would require the signatures listed for each type).</p> <p>**Refer to Section II, Category A.2, above for more information.</p> <p>*** Nursing Research requires the signature of appropriate Nurse Manager and/or supervisor.</p>					

**IV. Other**

**Research conducted by non-affiliated<sup>6</sup> individuals and/or institutions at Main Line Health System**

Research is not permitted to be conducted at the Main Line Health System by non-affiliated individuals and/or institutions. The MLH IRB recognizes that collaborative research programs may originate at non-affiliated institutions. Collaborative research protocols may only be submitted to MLH IRB by affiliated individuals who are sufficiently active collaborators in the research to assume full responsibility for the ethical and scientific conduct of the research at the MLH System, entity or MLH Affiliate.

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<sup>6</sup>The following categories are considered to be affiliated with Main Line Health 1.) employees of Main Line Health, Main Line Hospitals or other MLH Affiliate; 2.) participant in a Main Line Hospital’s Residency, Fellowship Program or other MLH Affiliate approved educational requirement; 3.) have Medical staff appointment at Main Line Hospitals or other MLH Affiliate; 4.) are part of the covered work-force at Main Line Health, Main Line Hospitals or other MLH Affiliate. When non-affiliated individuals are engaged in a collaborative research project on any campus or have access to Protected Health Information (PHI) of Main Line Health System, Main Line Hospitals or MLH affiliate, individuals must have appropriate permissions (e.g. vendor clear and/or other necessary or required credentialing).