



MLH Human Research Protection Program (HRPP)

Fiscal Year 2018 Performance Dashboard

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Annual HRPP Update

MLH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

A systemwide integrated program for ethical oversight and administration of human subjects research

Andy Norton, MD serves as the HRPP Institutional Official (IO). The IO reports to the MLH Board of Governors through the Q&SC and the MLH President and CEO and is responsible for:

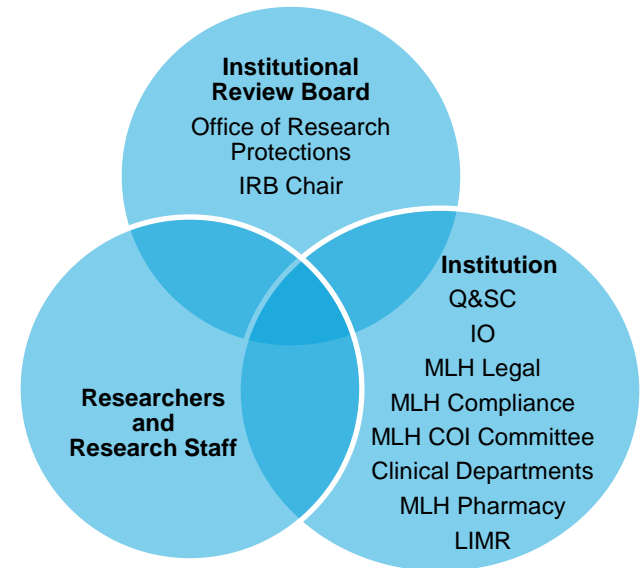
- The MLH Human Research Protection Program
- Ensuring the resources are provided to the HRPP, Office of Research Protections and Main Line Hospitals Institutional Review Board

Q&SC is responsible for:

- Appointing new IRB Members
- Reviewing and approving new HRPP initiatives
- Reviewing and approving MLH IRB policies
- Supporting the HRPP through the IO

ORP is responsible for:

- The ethical and regulatory oversight of research that involves human subjects
- The administration, supporting and guiding the work of the Institutional Review Board (IRB) and related activities
- Measuring the Effectiveness, Compliance Monitoring and Quality Improvement and operations and procedures of the HRPP



Accreditation of the MLH HRPP

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs.

- AAHRPP works to protect the rights and welfare of research participants by fostering and advancing the ethical and professional conduct of persons and organizations that engage in research with human participants.
- AAHRPP achieves its mission by using an accreditation process based on self-assessment, peer review, and education.
- AAHRPP accreditation signifies that an organization has built the necessary infrastructure for a quality human research protection program (HRPP).
- More than 60 percent of U.S. research-intensive universities and 65 percent of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process.

MLH Initial AAHRPP Accreditation obtained December 2015.

MLH reaccreditation site visit scheduled for August 20-21, 2018

- To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.
- Accredited Organizations renew their accreditations three years after the initial accreditation and every five years thereafter
- Accreditation decision anticipated by December 2018



Benefits of Accreditation

- Sponsors recognize AAHRPP-accredited organizations provide more comprehensive protections
- Increase knowledge and recognition of program internally and externally
- Gold standard of human subjects protection above the regulatory requirements



MLH HRPP Activity

Implementation of Revisions to the Common Rule*

(excludes FDA regulated research)

- The Common Rule was most recently revised in 2017, with an implementation date of January 2018. Early this year, the U.S. Department of Health and Human Services and 15 other federal agencies delayed implementation by six months to July 2018. In June, the implementation date was postponed again—to January 21, 2019.
- The most significant Common Rule changes that affect research institutions, Institutional Review Boards (IRBs), and investigators are outlined below.
- The complete rule is available at: [gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm](https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm)
- More information anticipated in fall of 2018!

Common Rule Changes

- Informed Consent:
- Establishes new requirements for information that must be given to prospective research subjects as part of the informed consent process/consent document to include a concise and focused presentation of key information to facilitate comprehension.
- Exempt Research Categories:
- Establishes new exempt categories of research based on risk profile (e.g. secondary research, benign behavioral interventions).
- Continuing IRB Reviews of Ongoing Research:
- Removes the requirement to conduct continuing review of ongoing research for studies that:
 - undergo expedited review;
 - that have completed study interventions and are merely analyzing study data; or
 - involve only observational follow up in conjunction with standard clinical care.

Electronic Submission System

- iMedRIS selected as the vendor to provide a web-based system, for IRB submissions, tracking and communication and COI management.
- iRIS Lite by iMedRIS Data Corporation is a comprehensive, user-friendly software solution
- Anticipated Implementation 3Q/4Q of Fiscal Year 19 (FY19)
- More information available soon!



Main Line Health
Well ahead.*

*Until an update is issued by FDA, compliance is required with the current FDA regulations (21 CFR 56) as well as the Common Rule (45 CFR 46).

IRB Activity

Policies/SOPs

- 34 IRB Policies
- 5 Administrative Policies
- 21 Standard Operating Procedures

Researchers

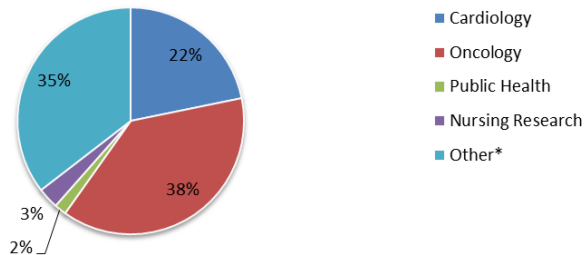
- 120 Principal Investigators
- 50 Study Coordinators

IRB Approved Studies

- FY16 297
- FY17 272
- FY18 295

FY 2018 Research by Specialty

(Percentages based on a total of 295 Studies)



*Other Pulmonology, Gastroenterology, Neurology, Orthopedic Surgery, LIMR



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IRB Metrics in Fiscal Year 2018

Full Board Reviews

- 81 in FY18
- 68% conducted by Lankenau Medical Center Subcommittee

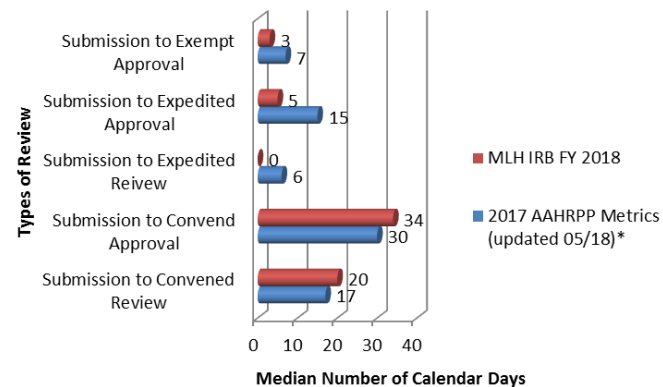
Reviews

- 471 Submissions reviewed in FY18|
- 74% studies reviewed by MLH IRB

Conflicts of Interest

- 891 Conflicts of Interests forms reviewed
- 5% require further evaluation and may require action

IRB Review Times by Type of Review



*Association for the Accreditation of Human Research Protection Programs. (2017). 2017 Metrics on Human Research Protection Program Performance for Hospitals (Updated May 2, 2018). Retrieved from AAHRPP Website: <http://www.aahrpp.org/grow/metrics-innovative-practices>

