



Main Line Health[®]

Office of Research
Protections and IRB

Main Line Hospitals ORP/IRB:

External/Unaffiliated IRB Submission and Compliance

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Protections

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AGENDA

Defining Unaffiliated IRBs

Human Research Protection Program Oversight

Types of Unaffiliated IRBs

When to Use an Unaffiliated IRB

MLH Metrics for Use of Unaffiliated IRB

Process for Applying to use Unaffiliated IRB

Post Approval Principal Investigator Ongoing Responsibilities

Questions

What Are Central/External/Single (Unaffiliated) IRBs

Regardless of their “Surname”

Central

External

Single

Unaffiliated

A lawfully constituted and federally registered IRB responsible for the protection of human subjects who participate in or volunteer to be a part of human research, whether a clinical or non-clinical trial.

Regardless of ownership, affiliation, for profit, volunteer/not for profit status, all IRBs in the United States are beholden to the:

- Requirements of Federal Health and Human Service (HHS) , FDA, (and usually the Office of Civil Rights) regulations, statutes, guidance
- Operate in accordance with their IRB Organizational Roster
- Operate in congruence with their organization’s Federal Wide Assurance (FWA) when applicable.
- Operate in accordance with their SOPs and Guidelines

What Are External/Central/Single IRBs

Regardless of how an IRB is supported or affiliates with, or acts independently from an organization or researcher, the IRB is an IRB.

How the Unaffiliated IRB conducts business, operates its organization/business, or executes its mission will vary from IRB to IRB.

There will be similarities and differences in operations of an Affiliated vs. Unaffiliated IRB:

No Matter Who The IRB of Record Is:

MLH ORP is still the HUMAN RESEARCH PROTECTION PROGRAM OF RECORD

Human Research Protection Program of Record

MLH ORP is still the HUMAN RESEARCH PROTECTION PROGRAM (HRPP) OF RECORD

Oversight to affirm compliance with research protocol and protection of human subjects, and the subjects PHI/data, is a shared responsibility between IRB of record and MLH ORP/an organization's HRPP

Prior to final IRB approval written agreement/contract called an "IRB Authorization Agreement (IAA) or Reliance" will be finalized between research site/PI and IRB of record

The IAA/Reliance agreement details what the IRB is responsible for and not
AND details what the organization/research site is responsible for and not

- Whose policies/procedures will be followed and when

- Who reports incidents/events/noncompliance/deviations to who and when

- Who is responsible for direct oversight of researchers and when

- Reporting obligations

- Investigative obligations and next steps/final actions related to official reporting of event

Types of External and Unaffiliated IRBs

Commercial/Professional

Medical Facility

Academic/University

NIH Affiliated

Why Use an External/Unaffiliated IRB

PROS

Faster turn around time

More Support Staff

Sophisticated Software

Review special/unique protocols: Pediatric/Psychiatric/Genetic Research

Provide Radiation Safety/Biosafety approval services

CONS

Expensive/Fees for services

Limits on customization to ICF/Injury/HIPAA

IRB Staff not familiar with PI/Researchers or special institutional requirements

Unable to provide On-Site educational/compliance monitoring

When to Use a Single IRB (External/Unaffiliated IRB)

Single IRB Review required by H.S.S. regulation when human research trial is supported OR conducted by an NIH Agency

In effect since January 2019

Center for Disease Control

National Cancer Institute

Also: NIH Grants, Cooperative Agreements, Intramural Research

Required/Preferred by Industry Sponsor

Principal Investigator/Private Entity with sufficient funding

Researcher otherwise unaffiliated with an organization with its own IRB

MLH External IRBs of Record: As of March 17, 2026

Protocols Assigned to Single IRB Review/Approval

National Cancer Institute Central IRB (NCI/CIRB) (> 100 Studies to date)
Centers for Disease Control IRB (Now Closed)

Commercial IRBs (Industry Sponsored Research)

Western IRB/Western Copernicus Group (WCG) IRB

Advarra IRB

Sterling IRB

BRANY IRB

Pearl IRB

Salus IRB (Pending)

Other Institution's IRB

Drexel University

TJU

UPenn

Lehigh University (Expedited)

Wake Forest

NYU

Johns Hopkins

MLH IRB Approval and Review Metrics

IRB Review and Approval Actions: FY26 Quarters 1 & 2

	Q1	Q2	Q3	Q4	
• New Reviews =	26	14			Total New FY25 = 63
Exempt Reviews =	08	06			
Expedited Reviews =	01	00			
Full/GTMR Reviews					
MLH IRB =	03	03			
External IRB =	12	04			Commercial IRB Currently Approved = 47
• Protocol Renewal =	31	37			
• Final Reports =	08	05			University/Private IRB Currently Approved = 10
• Amendments =	113	61			
• General Reports =	10	21			
	Total Actions YTD = 353				

Process to Arrange Approval for use of External/Unaffiliated IRB

- Execution of IRB Authorization Agreement (IAA)
 - Also known as a Reliance Agreement
 - This process is completed/lead by the MLH ORP
- IAA describes the terms/roles/responsibilities for oversight of the research
 - Institutional/Investigator/Researcher/Local IRB/HRPP
 - IRB of record notification/reporting obligations
- IAA may be
 - Study Specific
 - Individual/specific study
 - Private Institution/Organizations (University/Health System)
 - OR
 - Standing Contractual Agreement on behalf of unlimited number of studies
 - Commercial IRBs
 - Consortium IRBs

Process to Arrange Approval for use of External/Unaffiliated IRB

- MLHs ORP/IRB conducts Review of External IRB Qualifications/Credentials
 - FWA with HHS is active/applicable?
 - IRB Organizational Roster Registration with HHS is active
 - External IRB is AAHRPP accredited?
 - IF NOT AAHRPP ACCREDITED,
 - What are risks associated with study design
 - Does unaffiliated IRB have equivalent protections in place?

Process to Arrange Approval for use of External/Unaffiliated IRB

- Costs related to use of External IRB
 - Who is responsible to pay for External IRB oversight
 - Will the MLH ORP be reimbursed for oversight of External IRB Approved Studies
- Review of Protocol/Researchers/Internal Support
- Scientific Review by
 - MLH PI, LIMR
 - PI's Department / Department Head
 - Supporting Departments (Radiology/Lab/Surgery/ED, Nursing, Pharmacy, Biosafety, Radiation Safety)
 - LIMR Research Administrative Review (Contract/DUA/Budget/Publicity)

Process to Arrange Approval for use of External/Unaffiliated IRB

- MLH ORP/IRB Review of Protocol Design and Associated Risks
 - Transmittal Form Fully Executed/ORP Funding
 - Consent Language and Process
 - Inclusion of MLH IRB and Privacy statements
 - HIPAA, Injury, GINA, Vulnerable Populations, LAR, HIV, Psychiatric Care/Notes
 - Considerations for state/local Laws
 - Researcher Qualifications/CITI Training/Expertise
 - Financial Conflict Disclosure
 - Conflict of Interest Management Plan

PI ongoing responsibilities for use of External/Unaffiliated IRB

- MLH ORP/IRB Maintains Cooperative Oversight of Research Along with External IRB
- PI is Responsible to Report to MLH ORP/IRB
 - Initial Submission Through Final Report
 - All Intermittent/Periodic Reporting
 - Amendments/Continuing Reviews/Annual Updates
 - Unanticipated Problems/Adverse Events
 - Complaints
 - As instructed by the sponsor/monitor/CRA
 - HIPAA Violations/Breeches
 - Audits by External IRB/FDA/HHS/Other Entity
 - Changes in Study Status
 - Closed/Data Analysis Only

PI ongoing responsibilities for use of External/Unaffiliated IRB

- PI will monitor and oversee all actions on behalf of an unaffiliated IRB approved study in usual manner
- PI and study team will manage study, retain official/relevant official documentation and instruction in usual manner
- PI responsibilities for oversight of staff are unchanged regardless of IRB of record
- IRB of record will very likely always require a PI/site to follow their own policies and procedures regarding the conduct/oversight of human research activities
- Study will be monitored by the MLH ORP QA/IRB in a usual manner

Thank you

Questions???



QA and External IRBs

Maintaining Compliance Post Approval

Emily Cento M.R.A.

Quality Assurance Reviewer

March 18, 2026

AGENDA

Purpose

Why is QA present

Internal vs. External IRBs

QA and External IRBs

Issues that QA can prevent when using external IRBs

Compliance with MLH IRB

How to be Proactive

Purpose

- The MLH ORP and QA want to ensure that researchers have all the necessary tools available to them so they are maintaining compliance with not only Main Line Health but any external parties.
- There have been some questions on the utilization of external IRBs and the processes that need to be followed, so this training is here to help researchers better understand their role as well as the IRB/QAs role in these processes.

Why is QA present

- Conduct regular audits of BOTH research studies and MLH IRB to ensure compliance
 - For cause/not for cause audits
 - Study requested audits
 - Monthly and annual IRB audits
- Ensure reporting requirements with MLH IRB and external IRB are met

Internal vs. External IRBs

- QA will audit and review studies using both internal and external IRBs
 - Ensure overall compliance with the protocol
 - Maintain that the study team is following the plan that the IRB, internal or external, has approved
 - Ensure safety of subjects and their health information

QA and External IRBs

What QA will expect to see from studies using external IRBs.

- Record of the following to the MLH IRB:
 - Initial Submission through Final Report
 - All Intermittent/Periodic Reporting
 - Amendments
 - Unanticipated Problems/Adverse Events
 - HIPAA Violations/Breeches
 - Audits by External IRB/FDA/Other Entity
 - Changes in Study Status

QA and External IRBs

- IRB authorization/Reliance Agreement
- Alignment between MLH IRB and external IRB
 - What documents have been retained by study team vs what is in iMedris
 - What does the MLH IRB have on record, and does it match with what the external IRB has
 - What documents does the MLH IRB have on record vs. What has a study monitor required to be reported to both IRB of record and the MLH IRB?

Issues QA can prevent when using external IRBs

- Studies operating without IRB authority
- Missing institutional approvals
- Straying from the protocol
- Unreported deviations
- Missing reporting deadlines
- PHI breaches
- IRB Misalignment

Compliance with MLH IRB

Compliance with both the MLH IRB and external IRBs is essential for ethical research.

While the MLH IRB may not always be the IRB of record, they still will maintain oversight of research along with the external IRB.

MLH IRB has the responsibility to ensure all institutional requirements are communicated and completed, maintaining oversight throughout the study's life, and ensuring staff are qualified and trained.

How to be Proactive

- Similar to when MLH is the IRB of record
- Be familiar with policies and procedures
 - Understand both MLH policies and external IRB policies
- Regularly assess compliance
 - Self-audits
 - Request QA audits
- Maintain organized records
 - Approved protocol and amendments
 - Current consent form version
 - Adverse event reporting
 - IRB communications

Summary

- If a study is using an external IRB, QA is ensuring that:
 - The external IRB was authorized
 - The study follows the approved protocol
 - Subjects are consented correctly
 - Safety obligations are met
 - MLH responsibilities are still fulfilled
 - Documentation is complete, current, and accurate.



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Thank you