



Main Line Health[®]

Quality Assurance

November 11th, 2025

AGENDA

Purpose of QA

Services provided by QA

QA Audits

After the QA audit

Types of Non-compliance

How to correct Non-compliance

Purpose of QA

- To identify, limit and/or prevent regulatory and institutional non-compliance
- QA does this by:
 - Identifying processes within research that increase risk of non-compliance through For Cause/Not for Cause Audits
 - Identify gaps between expected and actual performance of research activities
 - Revise processes/policies to promote compliance
 - Provide educational tools to help researchers
- Liaison between the research team and the IRB
- Protect subject safety and privacy/confidentiality .

Services to be provided by QA

- **For Cause/Not for Cause Audits**

- For Cause – QA is alerted by a suspected noncompliance
- Not For Cause – routine evaluation

- **Requests for quality assurance evaluations**

- Teams reach out to QA to evaluate specific aspects of their study
 - Example: Are we following the policy for uploading the consent into EPIC?

- **Trainings**

- Provide guidance/education to regulatory compliance policy and standards
- Root Cause analysis
- Corrective and Preventative Action Plan development and execution

QA Audits

- Audits can be either For Cause or Not For Cause
- What to expect:
 - Audit announcement
 - Intro meeting
 - Study related documents and source files released
 - Closing meeting with PI and study team
 - Draft report sent to study team
 - Finalized audit report sent

After the QA Audit

- What happens after the audit?
 1. QA will provide the audit report and list any corrective actions needed to be taken to correct the non-compliance found
 2. The study team and PI will have the opportunity to correct the non-compliance themselves with CAPAs
 3. QA will provide the MLH IRB and Institutional Official (IO) with a detailed report of the study audit and any non-compliance found

Types of Non-compliance

- **Non-compliance**

- The failure to comply with federal, state or local laws or regulations or MLH IRB policies, procedures or requirements.
- This may include non-compliance with sponsor's protocol and written instructions, terms of Clinical Trial Agreement and/or HIPAA/Privacy

- **Serious non-compliance**

- Non-compliance that increases risks to subjects, adversely affects the rights and welfare of subjects, or adversely affects the scientific integrity of the study.

Types of Non-compliance

- **Continuing non-compliance**
 - An on-going pattern of non-compliance
 - Continuing non-compliance may be due to unwillingness to comply with, or lack of knowledge of, federal, state or local laws or regulations, or MLH IRB policies, procedures or requirements

How to fix Non-compliance

- **Identify the problem and the cause**

- Root cause analysis (RCA)

- 5 whys technique

- » Define the problem, then ask why it is happening until you reach the root cause

- **Develop and implement a CAPA**

- Corrective Action – correct the problem identified by the RCA

- Preventative Action – what is going to be done to ensure the problem does not occur again

- **CAPAs may be initiated on behalf of a certain study, but it is expected that the CAPA be executed across all studies that the team is apart of.**

- Examples: Consent practices, DOA log, EPIC documentation

- **Monitor and track progress**

- Regularly monitor the implementation and effectiveness of the CAPA



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Thank you

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