

CLIA and Research Results

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CLIA

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TOPICS

- Briefly describe CLIA regulations
- Define “laboratories” subject to CLIA regulation
- Describe and discuss the exception for research laboratories and provide examples
- Dispel common misperceptions about research testing and CLIA
- Describe how CLIA applies to the return of individual research results

CLIA Regulations

- Registration and Inspection
- Facilities
- Personnel Qualifications and Responsibilities
- Quality Systems
 - Quality Control and Quality Assurance
 - Pre-analytic, Analytic, Post-analytic
- Proficiency Testing

CLIA

LABORATORY

CLIA definition (42 CFR part 493.2)

“A facility for the biological, microbiological, serological...or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings...”

Research Exception

42 CFR 493.3(b)(2)

Exception. These rules do not apply to components or functions of research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients.

KEY POINTS

Not all research testing is exempt from CLIA

Some research testing is subject to CLIA

CLIA APPLIES WHEN...

Patient specific results are reported from the laboratory to another entity

AND

The results are available to be used for health care for individual patients

Example #1

A laboratory is conducting research to evaluate a new test method.

Specimens are collected and tested in the laboratory. Only summary results are provided by the laboratory to the principal investigator.

DOES CLIA APPLY?

NO

Example #2

The laboratory reports patient-specific test results to the study coordinator, who uses the results to assign the patients to a treatment arm of the study.

DOES CLIA APPLY?

YES

COMMON MISCONCEPTION

#1

“If a clinical trial has IRB approval, and the patients are notified that their testing is investigational, it is not necessary for the testing to be performed in a CLIA-certified laboratory.”

TRUE or FALSE?

Answer: FALSE

COMMON MISCONCEPTION

#2

“As long as the testing is in the research phase and is not being billed, then CLIA does not apply. CLIA applies only when the testing moves from research to clinical practice and billing occurs.”

TRUE or FALSE?

Answer: FALSE

COMMON MISPERCEPTION

#3

“CLIA does not apply when test results are blinded to the principal investigator and the health care providers treating the patients in the course of the clinical trial.”

TRUE or FALSE?

Answer: IT DEPENDS

COMMON MISCONCEPTION

#4

“CLIA does not apply when patient specimens are coded and are not labeled with identifying information such as name or medical record number.”

TRUE or FALSE?

Answer: FALSE

RETURNING RESEARCH RESULTS TO INDIVIDUALS

- The test results are available to individuals or their health care providers for use in “providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of” the individual
- Test results returned to individuals are always considered subject to CLIA

Conclusion

When medical laboratory test results are returned to individuals, the laboratory conducting the testing is subject to CLIA regulations.