From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, November 15, 2006 11:52 AM
To: [purged]
Subject: RE: CLIA vs. CAP

Dear [purged]:

FDA does not have any specific regulations or guidances applicable to clinical laboratories supporting clinical trials.

There are on the other hand, a number of organizations, accreditation bodies, and other government agencies that do have various standards for clinical laboratories. As you may know, the principle government standard, enforced now by the Centers for Medicare and Medicaid Services (CMS), is CLIA certification. This is carried out under the Clinical Laboratory Improvement Act and applies to just about any clinical laboratory which carries out clinical testing (except for research) in interstate commerce.

Although CLIA certification is not required for a clinical lab to participate in an IND study, it does represent a standard that is acceptable to FDA for the purposes of clinical diagnostic testing. To learn more about CLIA, you can visit their website at http://www.cms.hhs.gov/clia/

I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [purged]
Sent: Wednesday, November 15, 2006 8:58 AM
To: OC GCP Questions
Subject: CLIA vs. CAP

Hello,

I have a question regarding the particular regulation(s) for filing CLIA and CAP lab certifications in clinical research study files. I know both of these certifications are important for a clinical research site lab, but, is one cert more important to have in site files than the other?

Thank you,
[purged]