Regulations which apply to clinical laboratory testing.From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, September 11, 2006 9:05 AM
To: [purged]
Subject: RE: Regulations which apply to clinical laboratory testing.

Dear [purged]:

This is in response to both your e-mail (below) and the voice mail message that you left for me.

As you have discovered, FDA does not have any specific guidances or regulations 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 principal government standard, enforced now by the Centers for Medicare and Medicaid Services (CMS), is certification under the Clinical Laboratory Improvement Act (CLIA). It 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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Rockville, MD 20857
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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: Friday, September 08, 2006 4:52 PM
To: OC GCP Questions
Subject: Regulations which apply to clinical laboratory testing.

To Whom It May Concern:
I am uncertain as to which regulations apply to clinical laboratories and tests conducted by biopharmaceutical companies performing research under an IND. It appears that the GLP regulations apply only to nonclinical studies, GMP applies to drug products for human use, and CLIA, 42 CFR Part 493 applies to laboratories intended to diagnose a disease, etc.
If we are planning to perform serology tests on samples from subjects in a clinical trial, which portion of the CFRs are we required to follow?
Thank you for your assistance.

[purged]