From: OC GCP Questions
To: [redacted]
Subject: Inspections against E6 R2
Date: Wednesday, November 22, 2017 10:14:00 AM

Good morning --

When an FDA inspection occurs at a site, FDA investigators inspect against the regulations. Please see the link below to the regulations.

Clinical Trials and Human Subject Protection > Regulations

We considered ICH E-6 a guidance document. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA's guidances means that something is suggested or recommended, but not required.

Please see the information below from the Center for Drugs (CDER) Office of Medical Policy (OMP) that was recently sent to our office.

Sponsors and other FDA-regulated entities (such as clinical investigators) are responsible for complying with applicable statutes and regulations (for example, requirements described in 21 CFR parts 50, 56, and 312). At the time FDA publishes the ICH E6(R2) addendum, it will represent the Agency's current thinking and recommendations on the topic. Sponsors and other FDA-regulated entities can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. FDA announces the publication of guidance in the Federal Register.

FDA plans to recognize/adopt ICH E-6 (R2) but the date at this time is unknown. When FDA adopts ICD E-6 (R2), it will be announced in the Federal Register. Currently FDA recognizes ICH E-6 as a guidance document.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Tuesday, November 21, 2017 7:24 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Inspections against E6 R2

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> Hello,

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> I wanted to get some insight into holding a clinic central reader vendor to the R2 standard of a risk based approach.

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> ICH E6 R2 was 'released' June. I wanted to know when the FDA would inspect against the new guidelines and do you hold a vendor such as this type (central CT-scan / MRI reader to the standards of a CRO or sponsor?

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> Thank you kindly,

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> [redacted]

[redacted]

[redacted]