From: OC GCP Questions
To: [redacted]
Subject: ICH Guidance for Industry
Date: Monday, August 28, 2017 6:32:00 AM
Attachments: [redacted]

Good morning –

Please see the information below from the Center for Drugs (CDER) Office of Medical Policy (OMP)/

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, 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

From: [redacted]
Sent: Friday, August 25, 2017 10:15 AM
To: OC GCP Questions
Subject: ICH Guidance for Industry

I am trying to get a handle on the 3 ICH "available" guidelines:

1. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance
2. ICH Guideline for Good Clinical Practice E6R1
3. ICH Integrated Addendum to ICF E6R1: Guideline for Good Clinical Practice E6R2

Guidance from ICH: Which version should we be using as a guidance reference? and why?
Guidance from FDA: Which version should we be using as a guidance reference? and why?

thank you for your help!!!

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