From: OC GCP Questions
To: [redacted]
Subject: E6 R2 ICH GCP applicability in US
Date: Tuesday, August 22, 2017 8:39:00 AM

Good morning –

Sorry it took so long to respond to your second question. Below is the response from FDA's Office of Medical Policy (OMP).

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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.

The information provided in response to this inquiry does not address any specific product or trial. Follow up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, August 07, 2017 9:27 AM
To: OC GCP Questions
Subject: RE: E6 R2 ICH GCP applicability in US

Thank you for the clarification. I have one follow-up question:

Do we need to comply with ICH E6 (R2) for US trials although the guideline has not been adopted by FDA yet?