From: OC GCP Questions
To: [redacted]
Subject: BIMO Sponsor, CRO, and Monitors Guidance for FDA Staff
Date: Thursday, June 29, 2017 7:57:00 AM
Attachments: [redacted]

Good morning –

The updates to CP 7348.810, Sponsors, Contract Research Organizations, and Monitors, of April 19, 2017, includes revisions to Part III, Section D, that provide additional instructions to FDA investigators related to the ClinicalTrials.gov reporting and registration requirements that are specified at 42 CFR Part 11, which became effective on January 18, 2017, and required a responsible party to have come into compliance by April 18, 2017. There were also minor edits as you mentioned (fixes and formatting).

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, June 28, 2017 9:00 AM
To: OC GCP Questions
Subject: BIMO Sponsor, CRO, and Monitors Guidance for FDA Staff

Hi –

I wanted to reach out to see if there were any updates in the BIMO: Sponsor, CRO, and Monitor Guidance for FDA staff released 19 April 2017. When I compared this to the version released on 11 March 2011, I did not see any significant changes, only administrative (fixing formatting, etc). Can you please let me know the reason for the update so I can make sure all of our tools we have accurately reflect the BIMO guidance material?

Thanks in advance,

[redacted]

[redacted]