From: OC GCP Questions
To: [redacted]
Subject: Filing Contracts/Clinical Trial Agreements with regulatory documents
Date: Wednesday, August 27, 2014 10:49:07 AM

Good morning –

FDA would generally not review clinical trial agreements or contracts during an inspection. Therefore sponsors may choose to file these documents wherever they choose.

Kind regards,

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

From: [redacted]
Sent: Tuesday, August 26, 2014 12:32 PM
To: OC GCP Questions
Subject: Filing Contracts/Clinical Trial Agreements with regulatory documents

I had a question come and I cannot seem to find supporting guidance on it.

Would the FDA expect to see site-level contracts or signed clinical trial agreements filed with the rest of the study's regulatory documents either in the study binder at a study site or in the sponsor's regulatory document files? Or would the expectation be that contracts with study sites would be filed elsewhere away from the regulatory documents?

If you steer to the appropriate guidance, I would greatly appreciate it.

Thanks for your help,

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