From: OC GCP Questions
Sent: Friday, March 21, 2014 12:42 PM
To: [redacted]
Subject: 1 Continuing Review question

Good afternoon –

The guidance document that you refer to says that the IRB should review the IB at continuing review but it appears that the IRB would not need to review the IB if there have not been any changes. I would expect that the CI has indicated that there have not been changes. Your IRB should have a version of the IB from prior reviews and can review that if you think it is necessary. Additionally, If the IB is not reviewed, it best to document in your meeting minutes why it was not reviewed.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [Redacted]
Sent: Wednesday, March 19, 2014 5:30 PM
To: OC GCP Questions
Subject: 1 Continuing Review question

> The study involves an investigational drug, the study is closed to accrual and will remain open until all remaining participants are deceased or the cooperative decides otherwise. At the time of Continuing Review we ask for all the FDA recommended documents (if not already available as part of the existing IRB records for the research). The last modification to the Investigational Brochure was years prior and reviewed by an IRB member qualified to review Investigational Brochures. **At this year's Continuing Review ~ Does the FDA require the IRB to review and approve the Investigational Brochure in full again if no modifications were done to the Investigational Brochure?**

I have reviewed the Guidance for IRBs, Clinical Investigators, and Sponsors ~ IRB Continuing Review after Clinical Investigation Approval. However there are no references to studies that are closed to accrual.

Your guidance to my question above would be appreciated. If you need further information or have additional questions I would be happy to provide answers.

Thank you for your time. [Redacted]