From: OC GCP Questions
To: [redacted]
Subject: IRB Question
Date: Monday, July 28, 2014 11:02:18 AM

Good morning –

Sorry I cannot specifically answer your question as the IC was approved by your IRB. You will need to consult your reviewing IRB to make sure they are okay with you changing the consent form. If they give you approval, you should document their response in the study records.

Additionally, this office cannot specifically address over-enrollment as all studies are different. Sometimes over-enrollment is not advisable. I recommend that you seek advice from the FDA Review Division that you are working with on your specific study (e.g. your assigned FDA Project Manager for the IND). You should also consult your reviewing IRB.

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: Monday, July 28, 2014 10:37 AM
To: OC GCP Questions
Subject: IRB Question

If my IRB has not put a cap on enrollment and I am not changing anything else that is contained in the ICF but it says “enrolling up to six” and our site wants to enroll seven, may we line through, initial and date on the ICF and enroll that additional subject as the protocol has not changed, subject safety hasn’t changed, etc? We are only changing one tiny thing but cannot wait for the 10-15 days for an IRB review?

Please advise. Thank you.

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