From: OC GCP Questions
To: [redacted]
Subject: IRB Question
Date: Monday, July 28, 2014 2:03:12 PM

Good afternoon –

Thank you for the clarification. However you will still need to consult your IRB to see if they are okay with changing the **approved ICD**.

Additionally, after you consult your IRB you will need to make sure that the suggested corrections are in line with your institution's policies and procedures, e.g., would your institution or IRB consider the correction that would need to be reported and would they ask you to re-consent the subject with a new document rather than correct the original consent?

We have said it is within good clinical practice to correct study documents, for example case report forms, however the ICD is different. This is what we have said is the past regarding corrections. The steps described in ICH E6 4.9.3 represent an acceptable method to make changes or corrections in study documents. The FDA recognized ICH E6: Good Clinical Practice: Consolidated Guidance, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf , does include the following recommendations:
Section 4.9.3: "Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections (see section 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections."

Generally, the change should be crossed out with a single line, initialed, dated in real time, and explained by writing "error" without obscuring the original document.

For more complicated corrections, a note to file might be appropriate. Document your corrections with a note to file, including how you followed up with the subject.

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 11:10 AM
To: OC GCP Questions
Subject: RE: IRB Question

Hello,

I apologize for not clarifying. The study is asking for 30 subjects. We are not enrolling more than the 30 subjects. There were 5 sites participating. Our site had written 6 in our ICF due to there being 5 sites participating but there was no cap in our contract, nor was there a cap in our enrollment with the IRB. As the study is competitive enrollment and the sponsor is very pleased with our site, they have asked us to enroll more than the 6 in our ICF as there have been issues at the other sites. Our IRB has no issue with the increased enrollment as there is no cap on the number we enroll. My question is if it is a violation of GCP to line through the current ICF of “up to six”, initial, date, and change that number if an entire ICF change is necessary causing expense for the sponsor and causing subjects to wait while the ICF change is completed which can take 2 weeks. Once again, no cap on enrollment with our IRB approval.

Thanks, I truly appreciate your response and feedback.

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