From: OC GCP Questions
Sent: Tuesday, July 01, 2014 11:01 AM
To: [redacted]
Subject: Consent form completed with incorrect information in a response

Good morning –

It does appear that the information was to be filled in was for someone other than the person participating in the clinical trial and signing the consent. Since the consent is an IRB approved consent, I would discuss this situation with the reviewing IRB that approved the consent. Clearly if 14 out of 15 consents were not completed as intended, the consent language might need to be changed.

Additionally you should check with the reviewing IRB to see if they have procedures in place to correct an error on the informed consent document if the IRB chooses not to change the language in the existing informed consent
.
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.

You also may want to develop a standard operating procedure (SOP) for all study staff to follow with regard to corrections. This will minimize inconsistencies. Make sure that the corrections you describe are in line with your institution’s policies and procedures, e.g., would your institution or IRB consider these deviations that would need to be reported and would they ask you to re-consent the subject rather than correct the original consent?

Any corrective actions to address this issue should be well documented including additional training of study staff to made sure the consent is completed correctly if the IRB chooses not to change the consent language.

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, June 30, 2014 2:34 PM
To: OC GCP Questions
Subject: Consent form completed with incorrect information in a response

Hello,

I am writing for clarification of what is expected in a situation of a subject completing a response on the ICF that is not expected. This is what is on the consent form.

Follow Up After the Study

After the study is over, the investigator will contact you about once a month by telephone and ask you some brief questions about your general health. If you are not feeling well enough to speak, we would like you to name a person responsible for your care who may be able to answer some of these questions. You should list that person in the line below.

Name_____ Telephone number

At two different sites in 14 of 15 executed consents that have been reviewed, the subjects listed their own name and number. Apparently, this paragraph wasn't reviewed during the consent process. Is this considered a deviation or an optional entry that has no specific requirements and can be completed in any manner the subject chooses, i.e., left blank, their own name and number entered, or anything else that might be recorded? Thank you.
[Redacted]