**From:** OC GCP Questions
**To:** [redacted]
**Subject:** ICF Question
**Date:** Wednesday, December 07, 2016 8:16:00 AM

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Good morning -

The FDA regulations do not specifically address how to make corrections or changes to an IRB-approved document such as the ICF. When the regulations are silent, IRBs, institutions, sponsors, CROs, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

This is what we have said in the past regarding corrections.

Please see ICH E6, Good Clinical Practice, Consolidated Guidance, section 4.9.3:

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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.

During an inspection, FDA's inspector would expect to see original entries and corrections, and (as indicated above) the date(s) the corrections were made, who made them, and the explanation why the correction was necessary.

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.

If you are not the IRB or sponsor, I suggest you consult your reviewing IRB and the sponsor for guidance.

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Tuesday, December 06, 2016 6:59 PM
To: OC GCP Questions
Subject: ICF Question

Good day. If an ICF requires the subject to initial and date in the footer of each page and the subject does not initial/date the footer of the pages on the day of consent, should the subject initial and date the ICF at the next study visit date or should this omission be documented in the source leaving the footer (where the initials/date were suppose to be done) blank?

Thank you for your time.

[redacted]