

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Optional Informed Consent Signature  
**Date:** Friday, August 14, 2015 9:59:48 AM

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Good morning –

Given that the subject has exited the study, I don't see how you can have the subject make the change to the optional consent. A note to file might be the best approach as I understand that all the information is there but not in the designated area. I don't think that the scenario you describe would be cited during an FDA inspection as all the requested/necessary information is present on the form. Below is some general information regarding making changes/corrections to study documents.

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.

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.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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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.

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**From:** [REDACTED]  
**Sent:** Thursday, August 13, 2015 3:11 PM  
**To:** OC GCP Questions  
**Subject:** Optional Informed Consent Signature

Hello

During a recent sponsor audit it was found that a subject correctly signed and dated the Optional Consent for Genetic Research, however, the subject's printed name and address were also required. While the subject supplied the printed name on the correct line, the street address and the city, state and zip code were all written on the same line instead of the line specifically indicated for the street address, then on the line specifically indicated for the city, state, and zip code.

While all the correct information is there, supplied by the subject, we have been asked to have the subject correct this minor error. Unfortunately, by now, this subject has exited the study. The sponsor recommended following the IRB guidelines about this, however, there are none since all of the information is present and correct, just all on one line instead of two.

Since this was technically an audit finding, the sponsor has insisted this be corrected. Please advise as to why this would be an audit finding. Would this be something considered an audit finding during an FDA audit? Additionally, how should this be corrected now? Any guidance would be helpful. Thank you.

[REDACTED]