**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Question about clinical data
**Date:** Friday, August 14, 2015 9:51:50 AM

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Good morning –

The guidance on Electronic Source Data in Clinical Trials
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf
states

4. Modifications and Corrections
Only a clinical investigator(s) or delegated clinical study staff should perform modifications or corrections to eCRF data. Modified and/or corrected data elements must have data element identifiers that reflect the date, time, originator and reason for the change, and must not obscure previous entries. [CFR 11.10] A field should be provided allowing originators to describe the reason for the change (e.g., transcription error). Automatic transmissions should have traceability and controls via the audit trail to reflect the reason for the change.

Additionally 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.

Other guidances listed below might be helpful to you.

Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Given that I don’t know the details of the trial you describe, you can always check with the sponsor or the FDA regulatory project manager of the IND/IDE to make sure what your are doing is acceptable to them.

I hope this information is useful. 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:** Thursday, August 13, 2015 2:33 PM
**To:** OC GCP Questions
**Subject:** Question about clinical data

Hello,

I have a question about clinical data. We have a study where the instrument generated data is automatically uploaded into the eCRF. Therefore, we consider the instrument print-outs and a supplementary run worksheet as source documents. There are rare instances where the user enters information incorrectly as they are testing, but does document it correctly on run worksheets. A specific example is where a user ran a negative control sample as documented by the run worksheet, but accidentally selected on the instrument interface that it was a specimen. What is the most appropriate way to reconcile this in the eCRF? As we have source documentation in the form of the run worksheet showing that what was actually tested was a negative control (and not a specimen), should we query in the eCRF and have the site correct the specimen type and corresponding information? If so, should the site cross out the incorrect information on the instrument print-out and write the correct information so that the instrument print-out aligns with the run worksheet? Or is it better to leave the data as specimen and note with an asterisk that it should be considered a negative control per source documentation?

Thank you,

[redacted]