From: OC GCP Questions
To: [redacted]
Subject: GCP section 4.9.1
Date: Wednesday, August 29, 2018 1:46:00 PM

Good afternoon ---

From the limited information in your email, it appears a note-to-file would be appropriate and would coincide with GCP 4.9.1. However, you state this situation happens multiple times so keep in mind that a note-to-file might have to address each fax/subject. Not very practicable I would think. Please see the information below about corrections and notes-to-file. We have stated this information in past queries.

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 (2): Good Clinical Practice: Consolidated Guidance, available at https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.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 should follow your SOP as it relates 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 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

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.

From: [redacted]
Sent: Wednesday, August 29, 2018 11:06 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP section 4.9.1

Hello,

I would like to know if you may help me with a GCP question. Per GCP section 4.9.1 the investigator is required to keep complete files. If a site receives a fax containing test results and the fax pages are numbered as follow.

Pages 4 through 6 are missing. The testing organization only faxes pages 1-3 because pages 4-6 are blank. Would a Note to File be enough to cover the sites file completeness requirement? This has occurred on multiple subjects.

Thank you,
[redacted]