From: OC GCP Questions
To: [redacted]
Subject: Worksheets
Date: Friday, December 18, 2015 9:36:21 AM

Good morning ---

I can speak only to what is expected by FDA for study related documents. Worksheets are not specifically mentioned in FDA regulations.

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs 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: Friday, December 18, 2015 9:19 AM
To: OC GCP Questions
Subject: Worksheets

Good Morning,

Is it acceptable that the worksheets have strike offs/cancelations and readings changed but not dated and initialized…..
These are worksheets , which would serve as source documents.
The calculations change and so are the strike offs.

Thanks,
[redacted]