

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Regarding Incorrectly-Dated ICF or HIPAA Form
Date: Wednesday, May 09, 2018 8:41:00 AM
Attachments: [REDACTED]

Good morning –

I cannot comment on the HIPPA form but the IC document date should be changed when and before the subject comes back for study related procedures. You can also document the issue as a note-to-file (see below) indicating that you have found the issue and plan to correct it.

Generally speaking, 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 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.

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.

From: [REDACTED]
Sent: Monday, May 07, 2018 5:25 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Regarding Incorrectly-Dated ICF or HIPAA Form

Hello,

What does the FDA suggest to do in the case of an informed consent or HIPAA form that has been dated incorrectly by the subject who likely will not be coming in for a while?

Thanks,

Government	Percentage
Current government	65%
Previous government	35%

[REDACTED]