From: OC GCP Questions
To: [redacted].
Subject: ICF Question
Date: Thursday, December 08, 2016 12:35:00 PM
Attachments: [redacted]

Good afternoon –

Back dating is considered a serious violation that could be considered falsifying the document. I would recommend that study staff who obtain informed consent be trained and reminded, as needed, of the need to check all aspects of the informed consent form for accuracy when they are signing the forms to reduce the occurrence of this error.

The answer to your first question is yes. (Please see previous email to you regarding corrections and documentation.)

For the second question, again you should have SOPs in place to address the scenario you describe. Re-consenting the subject is a possibility. However I would consult your reviewing IRB.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, December 07, 2016 8:59 AM
To: OC GCP Questions
Subject: ICF Question

Subject signed the wrong ICF on their screening visit. The study coordinator (SC) realized that the original (wet ink) signed ICF was not in the subjects source and requested the subject fax him a copy of the signature page of the ICF. A fax copy of the ICF signature page is filed in the subjects source; however, the fax copy was signed (original ink) by the SC with a date of 15Nov2016.

On the header of the fax page, the following dates were noted 16Nov2016 and 17Nov2016. When the CRA asked the SC about the wet signature date (15Nov2016) on the fax copy and the transmission dates of 16Nov2016 and 17Nov2016 in the header of the page, the SC noted that he did not sign the ICF on 15Nov2016 (while the subject was in the office in error) and thought he should back date the fax copy the same date that the subject signed and he would update the original signed ICF with the same date when he received the original ICF. When the subject returned to the clinic, the SC did have the subject sign the correct ICF.

Should the SC have not signed off on the fax copy and just documented this issue in the source and reported this discrepancy to the IRB?

What would be the best practice to have put in place when the subject returned to the clinic?

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Best Regards,

[redacted]