From: OC GCP Questions
To: [redacted] OC GCP Questions
Subject: RE: Consent Form Question
Date: Friday, July 15, 2016 9:24:00 AM

FDA's regulations and guidance documents do not directly address the situation you describe. When the regulations are silent, sites, sponsors, IRBs, and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. You may wish to check with the Sponsor whose study is affected and the IRB/IEC who is overseeing this particular study regarding which method you note below, or other method not mentioned, they would prefer in order to address the missing information.

Documentation of the Sponsor/IRB decision(s) should be kept with the study records. You may also wish to document the subject's decision to notify/not notify their PCP in a note to the study record, in addition to whichever method the Sponsor and IRB prefer regarding the consent form.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Thursday, July 07, 2016 3:15 PM
To: OC GCP Questions
Subject: Consent Form Question

Hello,

Our site has received conflicting instructions from different sponsors about what to do in the following scenario:

An ICF for a study is 15 pages long. Page 15 is the signature page, but [redacted] the consent form asks that the subject mark whether they would like their PCP notified regarding their participation in the study. A subject signs the informed consent form for the study and is given a copy. Though the signature page is correctly completed, the subject did not mark a preference regarding PCP notification. Which is the correct way to resolve this issue?

A) Allow the subject to mark their preference at their next visit and have them initial and date the new addition to the ICF? (Making a change to the original document.)
B) Re-consent the subject, even though the version has not changed, so the subject can answer the

question?

Kind regards,

[redacted]