From: OC GCP Questions
To: [redacted]
Subject: GCP and reconsenting subjects with updated ICFs
Date: Monday, November 03, 2014 10:52:27 AM

Good morning –

FDA regulations do not dictate the time limit on the consenting process. Whether or not a "reconsent" is needed depends upon the nature of the change in the study protocol or information about the study that warranted the change. For example, if the informed consent was updated because new adverse effects (AEs) were detected at some study sites, it is extremely important to convey that information to all study subjects. Depending upon the nature and/or severity of the AEs, some existing subjects may choose to discontinue their participation in the study. Therefore, capturing the renewed consent of those who choose to remain in the study is also significant.

However, if the change is due to a new test, procedure, or treatment that was added to the study protocol and only new study subjects will be subject to the addition(s), then it would not be necessary to inform existing study subjects.

When considering reconsenting -- reconsenting the subject shows respect for the subject and, because the subject may not remember all of the information previously provided about the study, repeating the informed consent process and reviewing the information in the consent form with the subject will allow the subject the opportunity to refresh his/her memory about what participation in the trial will entail, the risks that may be involved, who to contact in case he/she has any adverse experiences, etc., and to ask any questions that he/she may have.

Additionally you are correct the informed consent process is ongoing. Please the guidance document below for reference.

Guidances > A Guide to Informed Consent - Information Sheet

We also have a new *draft* guidance document on informed consent. Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

FDA considers informed consent a process and the written consent form is a part of that process. Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation, facilitating the potential subject's comprehension of the information, providing adequate opportunity for the potential subject to consider whether or not to participate, obtaining the potential subject's voluntary agreement to participate, and continuing to provide information as the clinical investigation progresses or as the subject or situation requires. To be effective, the process must provide sufficient opportunity for the subject to consider whether or not to participate. The person obtaining consent and the subject should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence.

Based on the limited information in your email, it appears the scenario you describe does not pose a violation of FDA regulations. Additionally, if you are concerned, you can always write a note-to-file to make sure that if an FDA inspection occurred at your site, the situation would be documented and explained.

I hope this information is helpful. Please contact us again at gcp.question@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.

-----Original Message-----
From: [redacted]
Sent: Monday, November 03, 2014 10:06 AM
To: OC GCP Questions
Subject: GCP and reconsenting subjects with updated ICFs

> Good Morning,

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> I am not sure if you are able to help on this or not but I am having difficulty finding a thorough answer to an issue regarding re-consenting subjects. I am on a trial where an amendment was released that resulted in an updated informed consent. The amendment resulted in clarifications that were updated in the ICF. The ICF was approved by IRB and approval noted all subjects are to be reconsented. Subject came for next visit and it was split up into 3 dates over a 12 day period (16Jan2014, 21Jan2014 and 28Jan2014.)The subject did not sign the until the last date they came in for the visit on 28Jan2014. The first 2 dates of the visit were not affected by the updated ICF (but the procedures done on last date of visit were updated in the ICF and subject signed at beginning of that day prior to the updated procedures being performed.) Would it be GCP violation if subject did not sign on the 1st day of the next visit or as long as subject signed at some point during next visit prior to the updated procedures it is not a violation?

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> It was my understanding ICF should be signed at beginning of next visit prior to any procedures being performed.

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> Your help is greatly appreciated!

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> Kind Regards,

[redacted]