From: OC GCP Questions
To: [redacted]
Subject: Informed consent-Timeliness of reconsenting
Date: Tuesday, June 24, 2014 10:38:55 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

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.

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

and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Monday, June 23, 2014 5:38 PM
To: OC GCP Questions
Subject: Informed consent-Timeliness of reconsenting

Hello,

We would like to have the FDA's guidance on the timing of re-consenting.

We have noticed there are various viewpoints on when during a study visit the subject must be re-consented if a consent has been revised and re-consenting is required. As you know, consents are often revised as a result of protocol amendments during the course of a study. Depending on the protocol amendment changes the IRB or the Sponsor may feel that the changes are significant enough to require existing subjects to be re-consented.

While 21CFR50 addresses the fact that a subject must be consented prior to any study procedures occurring it doesn't address re consenting. For this reason we recommend that when a revised consent is required that it be obtained at the first study visit after it is approved and prior to any study procedures being obtained at that visit. We have recently received push back from a site that conducted the re-consent at the end of the visit after all study procedures had been done for that visit.

Can the FDA give us any guidance on what an FDA inspector would expect to see as documentation of a re-consent regarding the timing?

ICH GCP E6 section 4.8.2 states:
The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favorable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

21CFR50.20 states:Except as provided in §§50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Thanks for your assistance with this matter. We look forward to your reply!

Take care,

[Redacted]