From: OC GCP Questions
To: [redacted]
Subject: Revised Informed Consent
Date: Monday, October 06, 2014 3:18:20 PM

Good afternoon –

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.

FDA has guidance titled, “Institutional Review Boards Frequently Asked Questions - Information Sheet” found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. FAQ #45 states:

45. When should study subjects be informed of changes to the study?

Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects (21 CFR 56.108(a)(4)). Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). FDA does not require reconsenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

That said, if your reviewing IRB requests all participants sign the new consent form before any study related procedures than you should follow their request.

FDA has a new draft guidance on informed consent. Please see the link below.

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

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

From: [redacted]
Sent: Friday, October 03, 2014 11:46 AM
To: OC GCP Questions
Subject: Revised Informed Consent

Good Afternoon,

My question pertains to the revised informed consent and when it should be discussed and signed by an active trial participant.

When a IRB approved revised consent is received at the site level and the IRB requires that alll new and active trial participants sign the revised consent is the site required to have the revised consent signed prior to any protocol procedures to be performed even if the changes were administrative changes only?

Thank you,
[redacted]