From: OC GCP Questions
To: [redacted]
Subject: Informed Consents - Expiration
Date: Monday, July 21, 2014 12:45:37 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.

Your reviewing IRB might have some requirements timeframe for reconsenting, however FDA does not.

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.

There is also a new guidance document (in draft) on informed consent that was just issued last week. 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.question@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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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.

From: [Redacted]
Sent: Saturday, July 19, 2014 11:18 AM
To: OC GCP Questions
Subject: Informed Consents - Expiration

Hello,

I've had several discussions with peers of mine over a subject signing ICF prior to assessments.

If a subject signs an Informed Consent Form and have no procedures/assessments completed, at the end of 30 days does a subject need to sign a new ICF?

I am not able to find anything in the CFR or in ICH GCP regarding recommendations. I suggest that a site document that a discussion took place continuing the Informed Consent Process.

Other co-workers say that a new ICF must be signed.

They further go on to say: I have also seen FDA cite sites for a finding when the period has gone past 30 days and questioned the site's practice of ensuring subject welfare and consent.

Are you able to provide any guidance on this question?

Thank you.

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