From: OC GCP Questions
To: [redacted]
Subject: Recruitment/Retention question
Date: Thursday, September 24, 2015 8:50:05 AM

Good morning—

FDA's official good clinical practice guidance, ICH E6 (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf), recommends that the clinical trial protocol address "Selection and Withdrawal of Subjects." Specifically, Section 6.5.3, states:

6.5.3 Subject withdrawal criteria (i.e., terminating investigational product treatment/trial treatment) and procedures specifying:...(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.

As recommended in ICH E6, the sponsor may provide direction in the protocol or the general investigational plan regarding how and how often/long to pursue a subject who fails to show up for follow-up visits. This would provide consistency across the study. If such guidance is not provided, it still might be worth consulting the sponsor as to their preference. Generally, a site would want to make several attempts to contact these subjects, including use of a certified letter. Log documentation of phone calls as well as copies of all correspondence should be maintained in the subject's study file. (FDA investigators conducting a bioresearch monitoring (BIMO) inspection of a study site would expect to find such documentation.) A large number of subjects lost to follow-up could indicate that potential study subjects were not adequately informed of study expectations and the need to commit to appropriate follow-up prior to their inclusion in the study. If a trend in this direction is obvious from early monitoring visits, proper training/retraining of study personnel involved with the informed consent process may therefore be appropriate. If this is observed study-wide, the sponsor may need to consult with the CIs to determine if protocol requirements become too onerous, even when subjects were well informed of expectations up front. A modification of the protocol may be necessary to alleviate some of the burden without sacrificing necessary data before the integrity of the entire study is compromised. Of course, it is also possible that adverse reactions are common and beyond what the average person is willing to tolerate, which might indicate a reduced usefulness for the product. If this is determined to be the case, the sponsor should consider whether continuing the study is justified.

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: Wednesday, September 23, 2015 4:27 PM
To: OC GCP Questions
Subject: Recruitment/Retention question

Hello – I am looking for some guidance on subject retention. Are there any GCP recommendations for how many attempts, what kind of attempts (text, email, call), and if certified letters are recommended by GCP guidelines for when we are unable to get in touch with a subject to conduct a follow-up study visit?

Thanks so much for your help

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