From: OC GCP Questions
To: [redacted]
Subject: Question on Lost to Follow-up Guidance
Date: Friday, January 19, 2018 1:33:00 PM
Attachments: [redacted]

Good afternoon –

You have the latest guidance documents (attached above). Please also see ICH-E-6 Good Clinical Practice Guidance (See link)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Section 4.3.4 of the guidance states, "Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights."

The July 2014 draft guidance on informed consent is currently being worked on. I am unclear as to when a final guidance will become available.

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

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: Friday, January 19, 2018 9:42 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question on Lost to Follow-up Guidance

Dear HHS Staff,

My name is [redacted] and I am writing to ask for your assistance, in confirming that I am in possession of the most current guidance by FDA on lost to follow-up Subjects in clinical trials.

The latest guidance document I could find are attached:

1. October 2008: Guidance for Sponsors, Clinical Investigators, and IRBS_ Data Retention When Subjects Withdraw From FDA-Regulated Clinical Trials

2. ***Draft document***_July 2014: Informed Consent Information Sheet_Guidance for IRBs, Clinical Investigators, and Sponsors
    - Please confirm if there is a final version of this document available ☺

Lastly, are there any other available FDA guidance documents on the topic of "lost to follow-up Subjects in clinical trials" that are available?

Many, many thanks!

[redacted]

[redacted]