From: OC GCP Questions
To: [redacted]
Subject: Informed Consent
Date: Thursday, July 31, 2014 11:53:15 AM

Good morning–

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.

The FDA regulations do not specifically address how and when to capture information regarding the informed consent process. We do recommend that some statement regarding the process and when the informed consent document is signed be captured in the subject's study file. That is, we do not only want to see a signed and date consent form. However, if a study sponsor requires specific information be captured regarding the informed consent process during a specific time span as part of the investigational plan, then FDA would expect to see that information in the study files. Whether or not it is specified in the actual study protocol or in other study documents, it is still considered part of the investigational plan for the study, with which FDA expects compliance for FDA-regulated studies. Please remember that when FDA regulations are silent, sponsors, sites, and institutions may develop their own standard operating procedures for specific situations or issues.

You might wish to review FDA's information sheet on a -- Guide to Informed Consent. Please see the link below.
Guidances > A Guide to Informed Consent - Information Sheet

Please also see our new *draft* guidance on Informed consent.
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: Wednesday, July 30, 2014 3:44 PM

To: OC GCP Questions
Subject: Informed Consent

Good afternoon,

During a recent monitoring visit we were informed by the monitor that the FDA now requires a "hand written" statement be made in the subject's source binder describing our Informed Consent process. We currently have as part of every subject's chart a paragraph that describes our standard operating procedure of obtaining an Informed Consent. This form is signed, dated by the coordinator and filed in each subject's chart as a form of confirmation that this process was followed.

Would you confirm if the FDA is now requiring the process of obtaining an Informed Consent be hand written every time a subject is consented, or is our process as described above sufficient enough to confirm we are following our own SOP.

Thank you,

[redacted]