From: OC GCP Questions
To: [redacted]
Subject: Several questions
Date: Wednesday, April 01, 2015 12:22:09 PM

Good afternoon –

The guidance document that I sent you previously on informed consent Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet states the following

The Consent Process

Informed consent is more than just a signature on a form, it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

In addition to signing the consent, the subject/representative should enter the date of signature on the consent document, to permit verification that consent was actually obtained before the subject began participation in the study. If consent is obtained the same day that the subject's involvement in the study begins, the subject's medical records/case report form should document that consent was obtained prior to participation in the research. A copy of the consent document must be provided to the subject and the original signed consent document should be retained in the study records. Note that the FDA regulations do not require the subject's copy to be a signed copy, although a photocopy with signature(s) is preferred.

The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the subject and obtaining the consent) that will be observed.

The consent process begins when a potential research subject is initially contacted. Although an investigator may not recruit subjects to participate in a research study before the IRB reviews and approves the study, an investigator may query potential subjects to determine if an adequate number of potentially eligible subjects is available.

Based on the limited information in your email, it appears that perhaps the consent process at your site may conflict with FDA regulations. Please see my earlier email to report potential non-compliance to FDA.

Kind regards

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From: [redacted]
Sent: Wednesday, April 01, 2015 7:05 AM
To: OC GCP Questions
Subject: RE: Several questions

This is helpful, but my main question was not answered. Is it acceptable to the FDA to withhold the informed consent form until the patient comes in to screen for a study? Meaning, the subject and their study partner do not see the consent form until they arrive to be screened for the trial? Does the FDA approve of me reviewing *only* the serious adverse events listed in the ICF and not reviewing all the adverse events with them? Is it also acceptable to skip the HIPPA language portion of the ICF with the potential subjects during ICF review?

These policies do not appear to follow the FDA regulations regarding giving subjects adequate time to review the materials and have their questions answered. My employer feels that giving the subjects a one page, ten point bullet paper listing how many visits, what tests and what the serious side effects is sufficient. When I questioned this policy the explanation I was given was that the consent forms are too long and complicated to give to the potential subjects ahead of time, as they are demented and wouldn't understand them anyway. Yet, the PI and my manager assured the IRB that all the subjects understand what they are signing.

It seems to me that this is a paradox. If the subjects understand what they are signing, why do they not get to take the ICF home and review it ahead of time? If the ICF is "too long and complicated" implying that they cannot understand it, then why am I asking them to sign it in the first place?

This appears to me a convenient way to bypass the federal regulations for expediency sake and make it make it look as if this is "informed" consent when it is clearly not.