From: OC GCP Questions
To: [redacted]
Subject: Draft Informed Consent Guidance
Date: Thursday, October 23, 2014 11:41:40 AM

Good morning –

I am answering your follow-up question as Marsha in unavailable. Regarding implementing process changes based on the draft guidance, in the front of the guidance is a note that it is a draft guidance document and is not for implementation.

However, the guidance notes that alternative approaches to informed consent may be used if the applicable statutory and regulatory requirements are satisfied and alternative approaches may be discussed with FDA staff (presumably the review division or the project manager of the IND).

Please also see another guidance on informed consent.

Guidances > A Guide to Informed Consent - Information Sheet

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, October 22, 2014 12:18 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Draft Informed Consent Guidance

Ms. Melvin,
Thank you for your timely response. My reason for asking about these guidances stems from preparation to begin a phase one safety study investigating a topical hemostat under an IND that would be used for bleeding during operative procedures.

Language in the draft guidance states:

"Note that coercion and undue influence may be situational. For example, in a clinical investigation involving the surgical insertion of an investigational device, waiting to obtain informed consent until the potential subject is in the preoperative area may fail to minimize the possibility of undue influence."

In some circumstances it would not be possible to consent the participant prior to the day of the procedure and the investigator feels as though the participant would have adequate time to consider participation in the study.

We are wondering how an FDA auditor would perceive the investigator obtaining consent on the day of surgery for this phase 1 study and are also wondering if we would be responsible for implementing process changes with a draft guidance or not until the guidance is final.

Thank you in advance for your time and attention.

[redacted]