From: OC GCP Questions
To: [redacted]
Subject: RE: Informed Consent Question
Date: Wednesday, August 12, 2015 4:59:00 PM

Dear [redacted] -

Thank you for your question. The FDA IND regulations found at 21 CFR part 312 subpart D address general responsibilities of sponsors and investigators for drug and biologic studies (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4). Similarly, the FDA device regulations found at 21 CFR part 812 subparts C and E address sponsor responsibilities, as well as investigator responsibilities for device studies (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.3 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.5).

You will note that the regulations do not specifically address site initiation visits. When the regulations are silent, sponsors/CROs, investigators/sites, IRBs, and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

Site initiation visits are typically organized and conducted by the sponsor/CRO. The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) addresses the essential documents for the conduct of a clinical trial in section 8. Specifically, section 8.2.20 addresses a trial initiation monitoring report as a document that should be generated and be on file before the trial formally starts to document that trial procedures were reviewed with the investigator and investigator's trial staff.

A site initiation visit may also be considered part of the sponsor's monitoring plan to ensure that investigator's understand their responsibilities regarding study processes and regulatory requirements. This topic is discussed in FDA's guidance "Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring" which can be found at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf.

For these reasons, I suggest you discuss your question directly with the sponsor. Since the sponsor conducts the initiation visit, it is important for you to consult them so that you are aware of any expectations they may have for beginning any study activities prior to completing an initiation visit at your site. Also, there may be other important details the sponsor is aware of that your site may not be aware of. For example, the regulations at 21 CFR 312.20(b) state that "*A sponsor shall not begin a clinical investigation subject to 312.2(a) until the investigation is subject to an IND which is in effect in accordance with 312.40.*" FDA's interpretation is that obtaining informed consent and screening subjects for a specific study that is subject to an IND before the IND is in effect is considered "*beginning the clinical investigation*" and such activities cannot be performed until an IND is in effect (30 days after FDA receives the IND, or earlier if the sponsor is so notified by FDA).

In addition, since it sounds like your proposed plan will facilitate recruitment for the proposed study, I suggest that you consult your IRB who should review the methods and materials that an investigator proposes to use to recruit study subjects. You may also want to consult the appropriate individuals at your institution about any institutional policies and procedures that must also be followed.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Monday, August 10, 2015 9:26 PM
To: OC GCP Questions
Cc: OC GCP Questions
Subject: Informed Consent Question

Hello,

Have a query regarding handing over the informed consent to the subject.

If a study at site is not yet initiated by the sponsor, however the site has obtained IRB approved informed consent for the study, can the copy of the consent be given or emailed to the subject to read the consent and decide whether he/she would consider

participating?

The actual process of informed consent including the signing of the consent would however be undertaken only once the site is initiated.

Thanking you,

Regards,

[redacted]