From: OC GCP Questions
To: [redacted]
Subject: 1572 and Coordinators who only consent subjects
Date: Tuesday, May 06, 2014 11:30:42 AM

Good morning –

FDA's guidance on informed consent states --
Guidances > A Guide to Informed Consent - Information Sheet
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.

Since FDA considers the informed consent process critical to the research process and based on the limited information in your email, the study coordinators should be listed on the 1572 form

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: Monday, May 05, 2014 3:23 PM
To: OC GCP Questions
Subject: 1572 and Coordinators who only consent subjects

I'm having a hard time discerning whether or not a study coordinator who's only role on a clinical trial is consenting study subjects. They don't collect any study data or perform any procedures.

If that was an individual's only role, obtaining informed consent, would the FDA expect to see them on the 1572?

I wouldn’t think so, but thought I’d confirm it.

Thanks in advance for your help,

[Redacted]