From: OC GCP Questions
To: [redacted]
Subject: Guidance on Sponsor Request
Date: Monday, April 14, 2014 1:12:19 PM

Good afternoon –

The guidance documents on Informed Consent below

Guidances > A Guide to Informed Consent - Information Sheet – states –

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.

Although not addressed specifically in FDA regulations, the situation that you describe might pose a problem as the subject might not completely understand both protocols and the risk involved in each protocol (investigational study(ies)) in additional to fully understanding what is explained in the informed consent and what they are consenting to. It is probably best to screen the subjects separately for each protocol. However, your reviewing IRB(s) should be aware that this situation is occurring and they should give you guidance as to how to proceed.

Additionally, please see the guidance document below that address subject screening.

Guidances > Screening Tests Prior to Study Enrollment - 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: Thursday, April 10, 2014 12:12 PM
To: OC GCP Questions

Subject: Guidance on Sponsor Request

We have a sponsor requesting us to consent a single subject on two separate protocols at the same time . The subject would complete screening at the same time for both and at visit two would be screen failed from one of the studies.

Is this proper practice? Can you please provide some guidance?

Thanks,

[Redacted]