

From: OC GCP Questions
To: [Redacted]
Subject: RE: Informed Consent and Screening
Date: Thursday, October 16, 2014 1:27:00 PM

Dear [Redacted]-

Thank you for your questions. Your questions appear to be related to a specific protocol, and without knowledge of the protocol, it is not possible for me to provide a definitive response. I recommend that you consult your sponsor with your specific protocol questions as the sponsor should be in a good position to assist you in accordance with the specific protocol.

I'm sorry I can't be more helpful, but I do hope this recommendation 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

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Tuesday, October 14, 2014 12:27 PM
To: OC GCP Questions
Subject: Informed Consent and Screening

Dear FDA: A subject consented on September 17, 2014. The study requires that a physical exam be performed as one of the screening activities. The site would like to use the PE that was performed on August 28, 2014. The PE on August 28, 2014 would be within the screening window and prior to Day 1. Can we use the PE given the subject had not signed the ICF at that point in time? Or can we use the PE as it is still within the window prior to Day 1?

If we cannot use the PE on August 28, would that be a protocol deviation? Thank you.

Kind regards,

[Redacted]