From: OC GCP Questions
To: [redacted]
Subject: question
Date: Thursday, April 06, 2017 9:28:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations do not specifically discuss "prescreening" and I'm not sure what activities you are considering for prescreening. A physician may review his/her patients' charts to determine if there are any patients who may be eligible to participate in a study and may discuss the availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent. Informed consent must be obtained, however, prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out).

While FDA does state that no procedure that is study-specific can occur prior to receiving informed consent even specific study screening can be accomplished with the use of a screening informed consent rather than a consent that describes the entire study. The site should be able to write a screening informed consent document in such a way as to notify potential study subjects that the questions asked and procedures done will be relevant to a specific study they may then be asked to participate in. It is possible, however, that a generic informed consent document may not be appropriate for all studies, with some studies requiring more study-specific information to be included. The completed inclusion/exclusion document - which will obviously be study-specific - along with the informed consent document the individual signed in agreeing to be screened would then become part of the files of all screened individuals, whether or not they qualify for the study and even become study subjects. That is, the signed screening informed consent document will always be associated with the completed inclusion/exclusion document to provide evidence that the subject consented to be screened

You may find it helpful to review FDA's information sheet guidance "Screening Tests Prior to Study Enrollment" to determine what activities would require prior consent. The guidance is available at www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm.

I've consulted a few of my colleagues here is OGCP. Based on the limited information in your email, it appears the screening "visits" should be included in the protocol. We strongly suggest you consult your reviewing IRB for guidance.

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, April 05, 2017 1:27 PM
To: OC GCP Questions
Cc: [redacted]
Subject: question

We are currently doing a trial where the CRO is asking us to do a prescreening visit which includes an additional ICF and blood draw to determine eligibility. This visit is not in the protocol.
We believe that if we did this we would be working outside of the protocol.
Please advise.

[redacted]