From: OC GCP Questions
Sent: Thursday, July 30, 2015 11:38 AM
To: [redacted]
Subject: study participation

Good morning –

An investigator 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 prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. An investigator could not provide prospective subjects with any information specific to a study prior to approval/go-ahead from both the reviewing IRB and FDA but an investigator could provide general information about research at the institution to prospective subjects provided that no information specific to studies that have not received approval/go-ahead is provided.

Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility without first obtaining consent. On the other hand, informed consent must be obtained (the patient becomes a subject) prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research.

So, if for the prospective subject, the tests are being performed as part of patient care, than the tests could be conducted prior to informed consent even though those tests could also be used to determine study eligibility. If the sole purpose for performing the tests is to determine eligibility for the study (that is, the tests are not being performed as part of the care of the prospective subject) then informed consent should be obtained prior to the tests being performed.

You may wish to review FDA's guidance document on recruitment of study subjects and screening tests prior to enrollments. Please see the links below.

http:///www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

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, July 29, 2015 11:08 AM
To: OC GCP Questions
Subject: study participation

Hello,

Is a subject considered to be participating in the study before the subject is determined to qualify for the study and meet entry criteria and is randomized to a treatment group?

Thank you,
[redacted]