From: OC GCP Questions
To: [redacted]
Subject: study procedures question
Date: Thursday, July 31, 2014 2:55:30 PM

Good afternoon—

FDA regulations do not address the need for doctor's orders for study related procedures. Doctors/physicians will need to follow state and local laws for practicing medicine.

Below is what we say about study related procedures and informed consent.

FDA has a guidance titled, "Screening Tests Prior to Study Enrollment," available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm, that addresses whether informed consent should be obtained prior to screening tests for study enrollment. The guidance states, "informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purposes of determining eligibility for research," and more specifically says:

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 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.

Another information sheet -- Recruiting Study Subjects -- should also be helpful to you.

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

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, July 31, 2014 9:28 AM
To: OC GCP Questions
Subject: study procedures question

To Whom it May Concern:

Does the FDA has regulations regarding the ordering of blood tests for study protocols?

My understanding is that it is a study procedure and not a diagnostic test and therefore does not need a doctor's order.

Your insight and direction would be greatly appreciated.

Kind Regards,
[redacted]