From: OC GCP Questions
To: [redacted]
Subject: question on clinical trials
Date: Monday, August 31, 2015 5:59:03 AM

Good morning –

Please see the guidance document below for screening of study subjects --
"Screening Tests Prior to Study Enrollment - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators", at
http:///www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

FDA's regulations do not specifically discuss "re-screening". Since this is a human subject protection issue, I would consult with the reviewing IRB for re-screening process recommendations. Depending partly on the actual time between screenings, an IRB might request that the site obtain some type of documentation from the prospective subject - that he/she understands the need for rescreening - if not an actual signature on a second informed consent document. However, just to be sure, I would recommend that you contact the IRB to determine the preferred method of re-screening or whether re-screening is or should be allowed for a particular clinical investigation.

The IRB contact information should be located on the informed consent document that your mother first reviewed and received.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

-----Original Message-----
From: [redacted]
Sent: Friday, August 28, 2015 11:41 AM
To: OC GCP Questions
Subject: re: question on clinical trials

Hello,
My mother is considering joining a clinical trial for a new diabetes medication. I went with her for the first visit, and she got a call saying that one of her blood tests was out of range. They asked her to come in and have a discussion with the study doctor. They stated that the test could be re-tested and that she was to be re-screened.

Is that allowed? When they discussed it with us initially, they said the labs were done to make sure that my mom would be a suitable candidate for the study. I am assuming that there was no error in the lab, but I guess there could be. But I am concerned about this re-testing of the lab.

Any information would be appreciated. Thanks.

[redacted]