From: OC GCP Questions
To: [redacted]
Subject: Timely review of laboratory reports/results in clinical trials
Date: Friday, August 21, 2015 8:28:03 AM

Good morning –

Although not a true FDA requirement, generally all that you state below in question form sounds reasonable. Also you will not find the word "absolute" in FDA regulation or guidance. Additionally it could depend on the investigational product, sponsor requirements, and the protocol. FDA expects that all study activities, including reviewing lab results, should be performed to protect the rights, safety, and welfare of research subjects.

It might be helpful for you to review the guidance document below. Protecting the Rights, Safety, and Welfare of Study Subjects.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
Please see section b on page 6.

Lastly 21 CFR 312.23 describes what should be in the protocol. (6)(g) states "A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk."

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: Thursday, August 20, 2015 1:29 PM
To: OC GCP Questions
Subject: Timely review of laboratory reports/results in clinical trials

Hello

Recently I have received considerable pushback from sites as to what constitutes "timely review" of lab results at the investigative site and would appreciate your direction on the following:

- What constitutes timely review?
- Is it an expectation that lab results are to be reviewed prior to the next scheduled visit?

- Is it an expectation that even if the lab results are reported as being within normal limits, that a review by a Physician (listed on the 1572 and assigned this task on the Delegation of Responsibility Log) be documented?

- If the results are within normal limits is a review by a Registered Nurse acceptable (responsibility assigned on the Delegation of Responsibility) and the P.I. /S.I. review at a later date

My position is that absolutely prior to the next scheduled visit, absolutely by a Physician (on the 1572 and delegated the responsibility), abnormal results absolutely must be addressed asap and even immediately dependent upon the nature of the study/protocol, and that normal results does not negate the Investigators (P.I. or S.I.) overall responsibility to review prior to the next visit .

Thank you!

[redacted]