From: OC GCP Questions
To: [redacted]
Subject: RE: Reporting positive results in Clinical Trials
Date: Tuesday, September 09, 2014 10:03:57 AM

Hi [redacted],

From the details you provided (e.g., the protocol includes language related to not providing the results to subjects), I do not see any prohibition against providing the results of these tests to the Principal Investigator. The greater question may be is it appropriate to not give the results to the subjects. This is a very difficult question that is best answered by having a complete understanding of the specifics of the protocol(s) and the nature of the test(s) being performed. Additionally, certain clinical tests, such as for HIV infection, may have State requirements regarding (1) the information that must be provided to the participant, (2) which organizations have access to the test results and (3) whether a positive result has to be reported to the health department. If necessary, the PI may want to discuss this issue with the Institutional Review Board (IRB) that has oversight responsibilities for the affected studies.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov

Kevin

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From: [redacted]
Sent: Friday, September 05, 2014 11:53 AM
To: OC GCP Questions
Subject: Reporting positive results in Clinical Trials

As an organization conducting clinical trials, we periodically receive questions pertaining to reporting of positive test results, for example, if we are performing a technical study for a new [redacted], we may have a testing algorithum that screens for HIV positives and then performs confirmatory testing (which may or may not be the standard of care). We do this under the preview of our testing protocol.

What are our obligations to notify the Principal Investigator in cases such as this (or other infectious diseases), where a test result is positive on an approved, marketed test? As part of the clinical study, we state in our protocols that the study is for research and the subjects will not receive results from any testing performed as part of the study. However, if they enrolled in the study as someone who is considered healthy, and they receive a positive HIV test, syphillis test, hepatitis C test, etc. - are we obligated to notify the PI?

We are struggling with this for many reasons.

Any guidance you can provide us is greatly appreciated.

[redacted]