From: OC GCP Questions
To: [redacted]
Subject: question
Date: Wednesday, June 04, 2014 11:44:31 AM

Good morning –

Based on the limited information in your email, I would say the lab result out of window is the deviation because the lab was completed and would show as resulted in the study records.

Kind regards,

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

From: [Redacted]
Sent: Tuesday, June 03, 2014 2:57 PM
To: OC GCP Questions
Subject: RE: question

Sorry that did not answer my question. The protocol is written wit a window of +/- 1 hour. Outside of this is a protocol deviation. The CRN is questioning me on the deviation being- lab out of window. Or is the deviation - lab not done. And if there is a point where the lab even though done – out of window – is too far out of window – cannot be included in that time and must be a deviation of – not done. Hope this will clarify what I'm trying to get an answer for.
Thank you

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Tuesday, June 03, 2014 2:36 PM
To: [Redacted]
Subject: question

Good afternoon –

The protocol should be followed as written. Not knowing the details of the study, it appears that the blood draws at those specific times are important. Generally the situation you describe may be considered a protocol deviation however you should check with the study sponsor. If the sponsor wants to change or amend the protocol, they would need to get approval from FDA and the IRB. Sponsors are often confused on what needs to be recorded versus what needs to be reported within a given timeframe. Any and all deviations from normal that occur for a study subject after treatment with an investigational product must be recorded on a case report form (CRF) and provided to the sponsor, whether or not it seems far-fetched that there is any relationship to the use of the investigational product

Kind regards,

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

From: [Redacted]
Sent: Monday, June 02, 2014 2:06 PM
To: OC GCP Questions
Subject: question

Hi,
I'm monitoring a study that has windows of plus or minus 1 hour for lab draws at 7, 24 and 48 hours post op. At what point are the protocol deviations not done and not just out of window?
Thank you,
[Redacted]