From: OC GCP Questions
To: [redacted]
Subject: Please comment: CRA previously as Study Coordinator
Date: Tuesday, August 05, 2014 11:54:22 AM

Good afternoon –

I believe FDA would expect the monitor of a study to be as independent as possible. Therefore it probably would not be best to have the study monitor and previous study coordinator (same person) monitor the site where he/she previously worked as the SC. As he/her new role as the CRA, he/she might be monitoring study documents and subjects that he/she was involved with as the SC. Additionally to avoid a conflict of interest, the sponsor or the CRO responsible would ensure that the monitor does not report to the same department/division that chooses the sites. There will usually be company standard operating procedures (SOPs) in place that spell this out for the specific reason of avoiding even the appearance of a conflict of interest.

Please also see FDA's guidances on a Risk-Based approach to monitoring and protecting the rights, safety, and welfare of research subjects.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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: Monday, August 04, 2014 8:08 AM
To: OC GCP Questions
Subject: Please comment: CRA previously as Study Coordinator

Dear HHS,

Could you please help to address my below query.

If a CRA who had worked in a site as a study coordinator in the past for a study (e.gg: duration as SC = 4 months). Now the CRA joined the CRO/ Sponsor Company and would like to monitor the same site for the same study conducted by the same Principal Investigator.
Please advise if this is acceptable or do you foresee any issue in this?

Best Regards