From: OC GCP Questions
To: [redacted]
Subject: PI duties
Date: Friday, November 21, 2014 8:40:31 AM

Good morning –

The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). In the scenario that you describe, while not against FDA regulations, the clinical investigator (PI) will be overseeing two studies at different sites and this might call into question his/her ability to properly oversee both studies especially the one that the CI is at the site part-time. Ultimately the CI who is responsible for overseeing the clinical trial at his/her site and may not be able to adequately do this part-time.

Please see FDA's guidance to Protecting the Rights, Safety, and Welfare of Study Subjects

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: Wednesday, November 19, 2014 1:10 PM
To: OC GCP Questions
Subject: PI duties

Good afternoon,
I have looked in the ICH and GCP guidelines and can not find the information that I am looking for. Can you provide clarification on whether a M.D. can be a P.I at 2 different sites (but not on the same study). One site where they work full time and the other site, where they do some part time contract work on certain studies?

Thanks,
[redacted]