From: OC GCP Questions
To: [redacted]
Subject: Question regarding PI involvement in a study
Date: Wednesday, August 06, 2014 9:12:25 AM

Good morning –

Your email was forwarded to my office for a response. 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, since the clinical investigator (PI) will be on family leave, FDA recommends that a new clinical investigator be assigned to the site and therefore will also need to sign a new 1572 with the sponsor. Although you mention that the (PI) will still be available even on family leave, it ultimately the CI who is responsible for overseeing the clinical trial at his/her site and may not be able to adequately do this remotely.

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: Monday, August 04, 2014 2:14 PM
To: Walters, Dana L
Cc:[redacted]
Subject: Question regarding PI involvement in a study

Dana,
In a situation where a PI goes on FMLA on an FDA-regulated interventional study, is it the FDA's expectation that he/she would designate a PI in his/her absence? Would the FDA ever consider the PI's contention that he/she can be available by phone or email and attend regular study meetings as sufficient involvement in the study? In such a case, the PI would continue to act as PI without naming an interim with the IRB.

As always, thank you. ώŶŚŘŀŎűŜŘϐ