From: OC GCP Questions
To: [redacted]
Subject: Expectations of PI On-Site Presence and Oversight
Date: Friday, December 12, 2014 1:00:27 PM

Good afternoon --

I believe FDA would not agree with a clinical investigator (PI) that is overseeing an FDA-regulated clinical study (IND study) not being on site to oversee the study. 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)). Ultimately it is the CI who is responsible for overseeing the clinical trial at his/her site and if he/she is off site for a period of time he/she may not be able to adequately oversee the study 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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Wednesday, December 10, 2014 7:11 PM
To: OC GCP Questions
Subject: Expectations of PI On-Site Presence and Oversight

Please provide clarification regarding the expectations for on-site presence of a PI in overseeing study conduct for an IND study. For example, is it acceptable for a PI to spend part of the year out of state and still fulfill the requirements to supervise a study as the PI?

Thank you!