**To:** [redacted]
**Subject:** Query re Principal Investigator on Clinical Trials

Good afternoon –

For FDA-regulated studies, 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 the study from a different country and this might call into question his/her ability to properly oversee that specific study. Ultimately the CI who is responsible for overseeing the clinical trial at his/her site and may not be able to adequately if the clinical investigator (PI) does not reside in the same country.

However, I might also add that some INDs for the Center for Drugs (CDER) and IDE for the Center for Devices (CDRH) do have foreign sites so it might be okay for the clinical investigator to live outside the US. These sites should be documented in the IND/IDE applications to FDA and have the approval of the sponsor.

Please see the FDA guidance on Determining Whether Human Research can be conducted without an IND --

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

Also Protecting the Rights, Safety, and Welfare of Study Subjects –

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

Lastly, FDA's Compliance Manuel on inspections of Clinical Investigators –

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.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



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**From:** [redacted]
**Sent:** Tuesday, January 27, 2015 12:39 PM
**To:** OC GCP Questions
**Subject:** Query re Principal Investigator on Clinical Trials

Hi

Can I check if it is necessary for the Principal Investigator on a Clinical Trial, being run in the United States, to be living in the United States?

Thank you for your help.

Best wishes.
[redacted]