

**From:** OC GCP Questions  
**Sent:** Friday, October 23, 2015 4:05 PM  
**To:** [REDACTED]  
**Subject:** RE: Question

Dear [REDACTED]:

FDA's regulations do not identify specific educational requirements for investigators. Instead, the regulations require sponsors of clinical investigations to select only investigators qualified by training and experience to investigate the test article (see 21 CFR §§ 312.53 and 812.43). FDA considers this to include the investigator meeting any licensing requirements of the jurisdiction where the trial takes place. The regulations further require investigators to supervise the testing (for investigations of drugs, including biological products, under 21 CFR Part 312, investigators commit themselves to personally conduct or supervise the investigation; for investigations of medical devices, under 21 CFR Part 812, investigators commit themselves to supervise all testing of the device involving human subjects). Investigators may delegate a task to individuals who are qualified to perform the task, including being appropriately licensed.

FDA's "Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)), includes the following information:

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Licensing requirements may vary by jurisdiction (e.g., states, countries). Investigators should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care.

While technically a non-physician can be a clinical investigator, this requires that the non-physician be qualified to personally conduct or personally supervise all aspects of the study. In practice, we have found it very rare that a non-physician can comply with this requirement. In general where we have seen non-physicians assuming responsibility for a study, we usually would also find an MD, as a subinvestigator, who performs those study functions requiring the appropriate level of medical expertise. For example, a PhD pharmacologist may be listed as a principal investigator on a pharmacokinetic study with an MD as a subinvestigator. Another example might be a clinical psychologist principal investigator with an MD subinvestigator.

I hope that this information is helpful. Please contact us at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)  
Policy Analyst, Office of Good Clinical Practice  
Office of the Commissioner, Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** [REDACTED]  
**Sent:** Friday, October 23, 2015 3:31 PM  
**To:** OC GCP Questions  
**Subject:** Question

Dear Mr. or Ms.,

Could you help me with this question?

A non-physician or non-medical doctor can be principal investigator in a clinical trial?

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Best regards,

[REDACTED]