

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** MD vs. APN Investigators  
**Date:** Thursday, September 03, 2015 6:41:01 AM

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Good morning –

The regulations are very broad. 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)).

Please see the guidance document (link) here.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

*4. Must the investigator be a physician?*

*The regulations do not require that the investigator be a physician. Sponsors are required to select only investigators qualified by training and experience as appropriate experts to investigate the drug (21 CFR 312.53(a)). In the event the clinical investigator is a non-physician, a qualified physician (or dentist, when appropriate) should be listed as a subinvestigator for the trial and should be responsible for all trial-related medical (or dental) decisions. (ICH E6 section 4.3.1;*

*<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>*  
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Training, education, and experience required for sponsor personnel may necessarily, and appropriately, vary depending on the type of product, the indication, the study being conducted, and its associated risk. FDA's regulations are not explicit as to what constitutes adequate training, education and experience, nor do they outline specific qualifications, including whether such personnel must hold an active medical license. Moreover, sponsors have discretion in determining what qualifications are needed in certain positions based on the general recognition that this would include education, training and experience pertinent to the particular clinical study and its design and execution, as well as familiarity with human subject protection (HSP) regulations, recordkeeping, data integrity, and good clinical practice (GCP) standards and requirements. Whether or not certain sponsor personnel should hold an active medical license depends on the considerations outlined above.

FDA would expect physicians and study staff to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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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.

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**From:** [REDACTED]  
**Sent:** Wednesday, September 02, 2015 5:36 PM  
**To:** OC GCP Questions

**Subject:** MD vs. APN Investigators

Hello,

This question is in regard to the delegation of duties to advanced practice nurses (APN) for a clinical trial.

Per GCP 4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

This statement is also referenced in the FDA Guidance for Industry – Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects, page 3.

If the state license does not prohibit it, can an APN perform all the same duties a physician sub-investigator would perform for a clinical trial?

Specifically, can they determine eligibility, assess adverse events for causality/relationship to study drug, sign study drug orders, evaluate status of disease?

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