

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** Can a Nurse Practitioner be a PI?  
**Date:** Friday, April 14, 2017 11:33:00 AM  
**Attachments:** [REDACTED]

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Good morning –

FDA's 1572 guidance <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> states --

#### 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>).

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:** Thursday, April 13, 2017 5:23 PM  
**To:** OC GCP Questions  
**Subject:** Can a Nurse Practitioner be a PI?

Dear GCP Questions,

We have recently had a site request that one of their nurse practitioners serve as PI and this has never been raised.

What are the FDA views on this scenario?

[REDACTED]

[REDACTED]