

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** 1572 NP/PA  
**Date:** Thursday, September 12, 2019 9:16:36 AM  
**Attachments:** [REDACTED]

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Good morning –

Thank you for your email. Please see the 1572 guidance - <https://www.fda.gov/media/78830/download> It 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(R2) section 4.3.1;*

[https://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_Step\\_4\\_2016\\_1109.pdf](https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf)

Kind regards,

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Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA



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 11, 2019 2:10 PM  
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>; CDER DRUG INFO <DRUGINFO@fda.hhs.gov>  
**Subject:** 1572 NP/PA

Hi,

Can a NP or PA with research experience as a sub-I be a Principal Investigator on a study?

Thanks,

[REDACTED]

[REDACTED]