

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: NP as PI
Date: Wednesday, May 29, 2019 10:57:21 AM

Good morning -

Please see FDA's 1572 guidance. <https://www.fda.gov/media/78830/download>

Please see questions 1-4. Specifically question 4 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.fda.gov/media/93884/download>).

Based on the information above, it would seem that the NP should sign the 1572 and the MD should be listed as the subinvestigator.

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN

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.

-----Original Message-----

From: [REDACTED]
Sent: Tuesday, May 28, 2019 9:48 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: NP as PI

Hello GCP Team,

I am considering doing an outpatient women's health infectious disease study in Rhode Island and the Nurse Practitioner is the PI. Per RI law, NP has full independent practice authority and they are licensed by state board of nursing. They have independent prescriptive authority. They are also recognized as primary care providers. The study site has an MD who has limited availability but is listed on 1572 as the

MD on trial. The trial is for low risk population. Can NP be a PI when the MD may have very limited role in medical care of patients since that role is already full filled by NPs at the site.

Thanks

[REDACTED]

[REDACTED]