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

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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]