From: OC GCP Questions
To: [redacted]
Subject: Primary investigator inquiry
Date: Friday, December 21, 2018 1:44:37 PM
Attachments: [redacted]

Good afternoon –

Please see the 1572 guidance.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf 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 section 4.3.1; http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf).

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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U.S. FOOD & DRUG ADMINISTRATION

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.

From: [redacted]
Sent: Thursday, December 20, 2018 3:27 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Primary investigator inquiry

Hello,

I am a clinical research coordinator in Denver, Colorado. I have a medical doctorate, however I am not licensed and I do not wish you complete the United States Medical Licensing exams. Is there any way I can still apply for Primary Investigator jobs? What are the requirements? Is there another exam I can do? Thanks.

[redacted]