From: OC GCP Questions
To: [redacted]
Subject: Clinical Trial Principle Investigator question:
Date: Wednesday, January 03, 2018 10:49:00 AM
Attachments: [redacted]

Good morning –

Please see FDA's 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).

5. What are the minimum qualifications of an investigator?

As stated in #4, the regulations require that sponsors select investigators who are qualified by training and experience as appropriate experts to investigate the drug. The regulations do not specify the minimum requirements nor do the regulations specify what qualifications an investigator must have in order to be considered qualified by training and experience to conduct a clinical investigation. Sponsors have discretion in determining what qualifications, training, and experience will be needed, based on the general recognition that this would include familiarity with human subject protection (HSP) regulations (i.e., 21 CFR Parts 50 and 56) and practices as well as good clinical practice (GCP) regulations (see 21 CFR Part 312) and standards (e.g., ICH E6) for the conduct of clinical studies.

Also FDA defers to state and local laws regarding licensing.

Kind regards,

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

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: Tuesday, January 02, 2018 2:10 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Clinical Trial Principle Investigator question:

Good afternoon;

My question is in regard to MD degree holder from WHO approved schools, who has no active state license to practice outside of research.

Suppose an MD doesn't hold a state license to practice but once did, for example, a revocation occurs. The MD is an expert in the area of a clinical trial. Can the MD be a PI or Sub I If no medical decision is made or if there is another on the study that can make medical decisions or conduct a medical procedure?
From what I understand, PhDs and Dentists and Doctors of Pharmacology can be a PI.
My question is really about whether an MD has to also have a state license to be on a clinical trial or if it's up to the sponser.

Thank you!!