From: OC GCP Questions
To: [redacted]
Subject: FDA Inquiry_[redacted]
Date: Friday, November 02, 2018 12:29:15 PM
Attachments: [redacted]

Good afternoon –

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. Please see ICH E6(2) section 4.3.1; https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.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(2)) for the conduct of clinical studies.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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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: Friday, November 02, 2018 11:51 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Inquiry_[redacted]

Good Morning,

Our institution has encountered a situation in which we have an individual that is a Ph.D. (in our radiology dept.) and would like to be listed as the Investigator for a study involving neurological scans. The issue is that

such scans are only a portion of the study procedures as the other portion involves actual treatment to participants. As such, we have a neurologist that is willing to be listed as the Investigator for the study (and it was suggested that our Ph.D. be a sub-investigator). However, our Ph.D. is adamant about being listed as the Investigator and our institution needs to ensure we are aligned with FDA regulations.

Can someone please offer some insight as to whether the Ph.D. can be listed as an Investigator? And if not, what would the proper "title" be for this individual (co, sub-investigator)?

Thank you,

[redacted]

[redacted]