From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Selecting the same site to participate in 2 Phase 3 studies conducted in parallel by same sponsor
Date: Monday, August 06, 2018 9:30:00 AM
Attachments: [redacted]

Good morning:

The regulations only address that the sponsor select qualified investigators. They do not specifically address the scenario that you describe in your email.

Under 21 CFR 312.53, sponsors "shall select only investigators qualified by training and experience as appropriate experts to investigate the [investigational] drug." Similar language is found in 21 CFR 812.43 for studies involving medical devices.

As you can see, FDA regulations broadly require that investigators (and site staff) be qualified by education, training, and experience to perform their assigned clinical trial duties. The regulations do not specify what must be included to be considered qualified, however, so sponsors have discretion in determining what qualifications will be needed, based on the general recognition that this would include familiarity with human subject protection (HSP) requirements and practices, as well as good clinical practice (GCP) standards for the conduct of clinical studies. Sponsors would also take into consideration any specific education, training, and experience pertinent to the particular clinical study and its design and execution.

FDA encourages sponsors who have questions about a study and its design, to contact the agency for assistance. It might be best to contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov They most likely will have to confer with one of their review divisions to see if there are issues with the situation you describe.

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Friday, August 03, 2018 12:20 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Selecting the same site to participate in 2 Phase 3 studies conducted in parallel by same sponsor

Is there any regulation applicable guidance regarding selecting the same site to participate in 2 Phase 3 studies conducted in parallel by same sponsor? The sites that would be selected for both

studies would ensure that they have a documented process in place for how subject enrollment is done when there are competing studies being run at the same time to ensure there is no bias. Thanks!

[redacted]