From: OC GCP Questions
To: [redacted]
Subject: Definition of Investigator
Date: Thursday, December 13, 2018 8:40:27 AM
Attachments: [redacted]

Good morning –

This is not an easy question to answer based on the information given.

The best resource for this seems to be the 1572 FAQ guidance https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf, section VII, #'s 31-33. This office agrees that the PAUs don't appear to qualify as investigator.

It might be best to review the protocol and the discussions under #31-33 and make a judgement about whether they should be listed as subinvestigators.

From #31: The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6.

Based on your description, the PAU may be directly involved in procedures required by the protocol, however, you say they're not involved in collecting data. So, they don't seem to meet both conditions listed above in green. The example in yellow doesn't support listing the PAUs because it's not one specified PAU but several as you state.

It might be best to contact the FDA regulatory project manager of the IND to get their advice as to whether the PAUs need to be listed on the 1572.

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Tuesday, December 11, 2018 3:25 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Cc: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: Definition of Investigator

Hello. I would like some further clarification on the definition for investigator from 21CFR312.3. This is in regards to FDA Form 1572.

Investigator means an individual who actually conducts a clinical investigation (*i.e.* , under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

Our situation is this:

Our IND drug is radioactive, and as such needs a Physician Authorized User to be responsible for administering the drug. We have several Physician AUs at our facility who may be dispensing the drug during the course of the IND study.

While our Physician Authorized Users are well informed as to the design, safety aspects and protocols of the study, they are not responsible or involved in investigative aspects such as data collection, interpretation, evaluation, etc. Their role is limited to clinical administration of the drug.

My interpretation is that there is one primary Investigator who the sponsor needs to collect information on per 21CFR312.53, and the form 1572 needs only to be submitted to the sponsor for that one individual. The rest of the Physician AUs would not need to collect the information or sign a 1572.

Furthermore, as the AUs typically have limited or no actual investigative duties, they are not truly team members and do not need to be listed as Sub investigators- we may add or lose an AU during the course of a study.

Thank you for your help with this matter.

[redacted]