From: OC GCP Questions
To: [redacted]
Subject: Radiologist Listed on 1572 and Required Reg Doc Needed
Date: Wednesday, December 13, 2017 1:34:00 PM
Attachments: [redacted]

Good afternoon –

I reached out to the Center for Drugs (CDER). The 1572 is their form. See their answer below. You will have to determine if the radiologists meet the requirements as outlined in red. Again, if you are still unclear, please contact the RPM of the IND at FDA.

Kind regards,

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

From: CDER DRUG INFO
Sent: Wednesday, December 13, 2017 1:26 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: RE: Radiologist Listed on 1572 and Required Reg Doc Needed

Dear Doreen,

Please see the below information that's provided at Instructions For Filling Out Form FDA 1572 –Statement Of Investigator. Hope this is helpful. Thank you!

NAMES OF SUBINVESTIGATORS
21 CFR 312.3(b) states: "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." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Field 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 Field 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 Form FDA 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 Field 6.

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually.

Best regards,

Kimberly DeFronzo
Pharmacist/Consumer Safety Officer
Division of Drug Information
CDER | OCOMM
U.S. Food and Drug Administration
Tel: 301-796-2959
kimberly.defronzo@fda.hhs.gov

From: [redacted]
Sent: Wednesday, December 13, 2017 12:14 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Cc: [redacted]
Subject: RE: Radiologist Listed on 1572 and Required Reg Doc Needed

Hello Doreen
Thank you for your response.
Is there any way I can talk with you directly.
I did not see a phone number.
I understand to list the MRI Facility on the 1572 however do I need to list the Radiologist in Box 6 who will be reading the images?
I really need clarity on what is required.

Thank you

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Wednesday, December 13, 2017 11:40 AM
To: [redacted]

Subject: Radiologist Listed on 1572 and Required Reg Doc Needed
Importance: High

[redacted]

Good morning –

Please see FDA's 1572 guidance. It states --

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

28. What qualifies as a clinical laboratory facility for Section #4?

Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4?

It is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

From the limited information in your email, it appears that the MRI facilities should be listed on the 1572, not necessarily the rotating radiologists. If the MRI facilities are satellites, only the main one needs to be listed. If you are still unsure, you can always contact the FDA regulatory project manager of the IND to obtain their advice on the situation.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, December 12, 2017 3:32 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Cc: [redacted]
Subject: Radiologist Listed on 1572 and Required Reg Doc Needed
Importance: High

Hello
I have a question regarding listing a Radiologist on the 1572 and what are the required documents (CV, GCP, ML and FDF) that will need to be collected for that Radiologist to be in compliance and audit ready.
I have a study that subjects will be sent to an MRI/CT facility for scans that will be read by a Radiologist at that MRI/CT Facility and used as data in the subjects folder. The MRI/CT Facility will be chosen by each individual sites; hence the MRI/CT Facility is NOT a Central Facility for all sites to use.
Questions:

1. Will the Radiologist that reads the scans and sign off on the report need to be listed on that site's 1572?
2. What if that imaging center have more then 1 Radiologist, therefore there is no way of knowing who will be the Radiologist who will be reading the scans and signing off on any given day…How can the site capture the Radiologist on the 1572?
3. What regulatory documents will need to be collected for the Radiologist (GCP Certificate, CV, Financial Disclosure Form, Medical License)?

Overall I want to know how to I ensure each site is in compliance and is audit ready for using an offsite MRI/CT Facility.

Any help guidance would be greatly appreciated.

Thank you

[redacted]

[redacted]