From: OC GCP Questions
To: [redacted]
Subject: Imaging facilities inclusion on FDA form 1572
Date: Wednesday, February 06, 2019 11:54:54 AM
Attachments: [redacted]

Good morning –

I believe that the "new insurance driven" imagining center would need to be listed on the 1572. The 1572 guidance states in the second paragraph that new information can be submitted in an information amendment or a protocol amendment.

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

The local labs should be listed on the 1572 form if they are the primary laboratory. Please see below from the guidance.

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.

If you still have questions regarding the 1572 form, you as the sponsor, can consult the regulatory project manager of your IND for advice.

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
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, February 04, 2019 2:28 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Imaging facilities inclusion on FDA form 1572

Dear GCP questions,

Attached is a (sample) response from "GCP.questions" regarding a similar question I have, however there may be a mitigating issue that is not addressed.

I would agree that if a sponsor has contacted with a central imaging facility, to scan or to read all scans from patients in a trial, it shall indeed be listed in box 4, on the 1572. However, am I to understand that when patients need scans, which would be covered by their insurance, and are limited to preauthorized facilities, any and all of each subjects imaging center be listed on the sites' 1572? If so, this would have to be retroactive, as the sponsor would not know in advance which imaging facilities are going to be used?

I would also be curious as to whether local labs be listed (e.g. Labcorp, Quest) too?

Please provide your best interpretation of this guidance.

Kind regards.

[redacted]