**From:** OC GCP Questions
**To:** [redacted]
**Subject:** 1572
**Date:** Wednesday, August 07, 2019 1:25:56 PM
**Attachments:** [redacted]

---

Good afternoon –

I asked the Center for Drugs (CDER) for their thoughts. Please see their response below.

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, August 07, 2019 1:21 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** RE: 1572

Hello GCP!

We have received this inquiry previously. Here is our answer:

The local labs are not required to be listed on the 1572 form as long as the clinical investigator verifies the CLIA certification. Note however, that if the sponsor of the IND requires the investigator to include them, then the investigator needs to comply with the sponsor's requirements so that all the sites are consistent.

**Holli E. Tierno, PharmD**
Pharmacist

Center for Drug Evaluation and Research
Division of Drug Information
U.S. Food and Drug Administration
Tel: 240-402-4526
Holli.Tierno@fda.hhs.gov


**From:** OC GCP Questions
**Sent:** Tuesday, August 6, 2019 1:30 PM
**To:** CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
**Subject:** 1572

Hi DDI –

Can you comment on her f/u 1572 question? I don't think the local labs or the PCP performing the limited PEs should be listed on the 1572. I know what our guidance says, but it would require too many names for the 1572 form and might complicate things. Your thoughts? Thanks Doreen

---

**From:** [redacted]
**Sent:** Monday, August 05, 2019 3:02 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** 1572

Good afternoon

And thank you for the speedy response – it makes total sense. This then goes to my next question I assume a local lab would have to be listed on the 1572 and the PCP performing the local limited PE also?
This could result in a site with several patients having many labs PCPs listed on the 1572 in addition to the site local lab and site staff.

Thank you for confirming. I truly appreciate it.

[redacted]

---

**From:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Sent:** Monday, August 5, 2019 2:05 PM
**To:** [redacted]
**Subject:** Delegation Of Duties Log and an independent LabCorp or Quest and PCP Physical Exams, used at the patient's home
**Importance:** High

Good afternoon –

As you are probably aware, delegation logs are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). Such a log is also not specified in the list of essential documents in the ICH good clinical practice (GCP) guidance document (ICH E6(R2)), though signature sheets are included there. Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf).

The guidance document states:

It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.

Though a delegation log is not required, it is commonly used at clinical sites to document who is assigned essential study tasks. While an FDA investigator would not routinely request to see such a log during a bioresearch monitoring (BIMO) inspection of a site, since it is not a regulatory requirement, he/she may request documentation of who performed which task during a study, particularly when regulatory noncompliance is observed. The clinical investigator

is ultimately responsible for the conduct of the study. However, determining if an observed noncompliance resulted from improper delegation of a task is essential to correction of the problem, in the present study or in future studies if the study inspected is already complete. However a site chooses to document those assigned to essential study tasks, it should be updated whenever there is a change in personnel performing any of those tasks. The date on which the designation of the individual was made should be captured, but an ending date would not be necessary. Later addition of a different person for the same task would suffice. If the same study site personnel are assigned essential tasks throughout the life of the study, then no update would be required.

I don't think the workers at the local labs or the individuals who perform the PEs would be required to be listed on the delegation log.

All the other information you state in your email should be okay as long as it is spelled out (outlined) specifically in the protocol that has been approved by the sponsor and your reviewing IRB. I cannot answer the alternative use of telemedicine. Please consult the sponsor and the IRB.

Kind regards,

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




---

**From:** [redacted]
**Sent:** Monday, August 05, 2019 7:36 AM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** Delegation Of Duties Log and an independent LabCorp or Quest and PCP Physical Exams, used at the patient's home
**Importance:** High

Hello,

Labs:

1. As the labs for our study is the local lab at the sites, who will process and issue the results of the samples. Does the lab director have to sign the delegation of duties log?
2. Also, there are only blood draws and a limited Physical Exam occurring for several visits where no other study assessments are done. To improve compliance as it is a rare disease where some patients live far away, we want to be able to allow patients to have blood draws done close to their homes ([redacted] and use those results for the study. Sites are worried if we insist patients come to the clinic we will risk patients missing visits.
3. So if the PI sends them with a script to use a lab close to their homes would they

need to document training of those individual lab collection sites and have someone from that lab on the Delegation Log and sign it? It seems highly impractical and unnecessary but I want to confirm it would be acceptable to not have to do this?

**Limited Physical Exams:**

1. We are asking for a limited Physical Exam at 3 visits and again we are concerned patients may not come in as it is a rare disease and some subjects live far away. We think we would get better compliance if we allow patients to go to their local PCP instead? And if so would be need a train a qualified physician to perform a physical? It seems not and also getting them to sign the delegation log will again be impractical. Please advise
2. An alternative is we could use telemedicine, or have patients send photos of their arms and legs (for signs of bleeding) to a secure hospital site server so the PI can determine if there are signs of bleeding. Again we would appreciate your feedback.

Thank you kindly.