From: OC GCP Questions
To: [redacted]
Subject: 1572 Section 4 Study Site Locations that perform only CLIA waived tests
Date: Monday, September 08, 2014 3:32:31 PM

Good afternoon [redacted] –

We recently had a similar email request. We sent that email to the Center for Drugs (CDER) forms team. Please see their answer below. Based on our understanding of the response, it seems that listing your information in Field 3. It appears as if you do not need to relist their address, etc in Field 4.

Kind regards,

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

Here is some CLEAR language from a related email.
Feel free to respond with this.
Provide the address(s) of the location(s) where the investigation will be conducted and clinical data will be generated or collected and to where the test articles will be shipped, if different form the investigator's address of record.

Field 3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures performed, e.g., locations such as health care facilities where the test articles will be administered, or where physical exam will be performed. Facilities where other important clinical investigation functions are performed may also be identified. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are collected should be in this section.

If an investigator sees study subjects at more than one site, the names and addresses of each of the study sites should be identified in Field 3. However, if the protocol specifies that the investigative product can be administered at a subject's home (for example, the protocol allows for daily injections to be administered by a registered nurse in the subject's home), the subjects' home addresses do not have to be listed on the Form 1572. Study records should reflect that the test article was administered at subjects' homes

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From: [redacted]
Sent: Friday, September 05, 2014 3:55 PM
To: OC GCP Questions
Subject: 1572 Section 4 Study Site Locations that perform only CLIA waived tests

I have a question on whether or not a location should be listed in Section 4 of the 1572.

If a study site, listed in Section 3, performs only CLIA-waived tests like urine pregnancy tests, would they be listed in both sections?

If we were to list them in Section 4, there is no documentation to collect as the tests are CLIA waived. Usually for clinical labs we would collect reference ranges (there would be none) and CLIA certifications (there would be none), there is no lab director and no formal laboratory as all of the tests are simple CLIA-waived tests.

Would the location being listed in Section 3 suffice?

Thanks for your guidance,