From: OC GCP Questions
To: [redacted]
Subject: Form 1572 and lab procedures done at the clinical site
Date: Wednesday, June 18, 2014 11:49:03 AM

Good morning –

We sent your 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 should cover the point of care testing. 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

From: Jackson, Steven
Sent: Wednesday, June 11, 2014 1:47 PM
To: Kim, Sonia (FDA)
Subject: RE: Form 1572 and lab procedures done at the clinical site

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

Steve Jackson, PharmD
Food and Drug Administration

Center for Drug Evaluation and Research
Division of Drug Information
Phone: 301.796.0353 **Cell**: 703.606.6438
Fax: 301.431.6353

From: [redacted]
Sent: Friday, June 06, 2014 1:27 PM
To: OC GCP Questions
Subject: Form 1572 and lab procedures done at the clinical site

FDA,

When filling out the Form 1572 does the clinical site need to list their own address under the laboratory section as well if they are doing point-of-care testing that is CLIA-waived such as urine dipstick, blood glucose, etc., as part of the study procedures.

Also if the clinical site has ECG's performed and read by an investigator on site does the clinic site need to add it's own address to the laboratory section also.

Thank you,
[Redacted]