From: OC GCP Questions
To: [redacted]
Subject: FDA Form 1572 Box 3
Date: Tuesday, October 11, 2016 1:25:00 PM
Attachments: [redacted]

Good afternoon –

I agree with your interpretation that the PI (CI) information should only be listed in Section #3. You mentioned our guidance. Please see section IV. Additionally the 1572 form is a Statement of the Investigator that provides information to the sponsor. The CI assures that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Kind regards,

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

From: [redacted]
Sent: Monday, October 10, 2016 3:23 PM
To: OC GCP Questions
Subject: FDA Form 1572 Box 3

Hello,

We are a participating site in a multicenter trial sponsored and coordinated by another academic institution. The Sponsor and coordinating center is requesting that their institution also be listed in Box 3 of the 1572 signed by our local Principal Investigator. I reviewed the current 1572 guidance and it is unclear if the Sponsor location should also be included on the participating site's 1572 Box 3. I have routinely only included information on the 1572 Box 3 that is relevant to locations where the local PI would conduct study activities and not include the sponsor/coordinating institution. If the sponsor is performing laboratory assays, then they would be listed in Box 4 but not Box 3.

Please advise.

Thank you,
[redacted]