From: OC GCP Questions
To: [redacted]
Subject: 1572 Form and ePRO -eCOA providers
Date: Tuesday, April 28, 2015 10:59:41 AM

Good morning –

Based on the limited information in your email, it appears that the ePRO or eCOA providers do not need to be listed on the 1572 form. Please see the link below that provides additional guidance on the 1572 form.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, April 28, 2015 8:18 AM
To: OC GCP Questions
Subject: 1572 Form and ePRO -eCOA providers

Hello,

Should an ePRO or eCOA provider (firm that supplies eDiaries and software to sites and patients on a clinical trial) be listed on the 1572 form?

If the scope of ePRO or eCOA service is to collect and report data but not provide analysis of the data is that scope relevant to this question?

Thank you.

[redacted]