From: OC GCP Questions
To: [redacted]
Subject: FORM 1572
Date: Thursday, June 04, 2015 11:42:46 AM

Good morning –

The purpose of the Form FDA 1572 (the 1572) is to provide the study sponsor full information about each of the study sites participating in their study. If the sponsor-investigator in question were the **only investigator for this study**, he/she would **not** need to complete a 1572. However, if there are other sites participating in the studies, the investigators at those sites should each sign a 1572 as the clinical investigator for the site. The information about each of those sites is something the sponsor-investigator must supply as IND information to the FDA review division and most commercial sponsors simply submit copies of their 1572s rather than duplicate the information elsewhere in their application or required progress reports. Your sponsor-investigator can therefore do the same.

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

From: [redacted]
Sent: Thursday, June 04, 2015 10:09 AM
To: OC GCP Questions
Subject: FORM 1572

Hello,

Is FDA Form 1572 necessary for investigator-initiated trials; where there is no industrial or government sponsor (where the investigator or his/her institution is the sponsor)?

Thank you.
[redacted]