From: OC GCP Questions
To: [redacted]
Subject: 1572 Completion and Signature Requirements
Date: Friday, December 12, 2014 12:54:31 PM

Good afternoon ---

The clinical investigator (PI) that is overseeing the FDA-regulated study at a particular site should sign the 1572 form. No one else should sign for him. The signature on the form signifies a commitment by the clinical investigator that he/she will oversee the study. Please see the FDA 1572 guidance link below for additional information.

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

Please see questions 1-3.

I hope this information is helpful. Please contact us again at gcp.question@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.

-----Original Message-----
From: [redacted]
Sent: Wednesday, December 10, 2014 7:07 PM
To: OC GCP Questions
Subject: 1572 Completion and Signature Requirements

Please provide clarification regarding the requirements for 1572

completion and signature in an IND study for the following scenario

Can an individual who is part of a study steering committee sign a

1572 as the PI for the study center then delegate a different PI to be

responsible for the site and be listed on the ICF and IRB approval as

the PI? And if so, does that delegated PI also need to complete and

sign a 1572?

Thank you!