From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Investigator Data
Date: Thursday, August 30, 2018 8:16:00 AM
Attachments: [redacted]

Good morning –

Sponsors is not required to submit the 1572 forms in an IND application to FDA however most do. In the situation you describe, the sponsor should retain both 1572 forms from the first and second clinical investigator and if the sponsor does submit the 1572 form(s) with the IND application, the sponsor should probably submit both forms.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Wednesday, August 29, 2018 2:00 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Investigator Data

Dear FDA-

If a site is activated under an investigator who is replaced by another investigator prior to any subject activities (e.g. informed consent/screening), does the sponsor have to submit both 1572 Forms to the IND or only the current investigators information?

Thank you for your advice.

Kind Regards,
[redacted]

[redacted]