From: OC GCP Questions
To: [redacted]
Subject: Form 1572 investigator
Date: Monday, February 25, 2019 8:38:24 AM
Attachments: [redacted]

Good morning –

If the commercially available drug is not the investigational product under the IND and is being given under the practice of medicine, then the local physician and the other location would not need to be listed on the 1572.

If this is still not clear, the S/I should contact the regulatory project manager (RPM) of the IND for guidance.

I hope this information is helpful.

Kind regards,

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

From: [redacted]
Sent: Friday, February 22, 2019 3:32 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Form 1572 investigator

Hello,
For a clinical research study being conducted under an IND by a sponsor-investigator, if the subject were to receive a commercially available drug that is covered by the protocol at another location administered by a local physician, would that other location need to be listed on the 1572? If so, could the treating physician administering the drug be added to the existing 1572 as a sub investigator, or would they need to complete their own 1572 as an investigator?
Thank you,
[redacted]

[redacted]