From: OC GCP Questions
To: [redacted]
Subject: Question on Subject Self Administration of study drug log
Date: Monday, April 24, 2017 11:21:00 AM
Attachments: [redacted]

Good morning –

It would be difficult to answer your question as I have limited knowledge of the study. You should consult the study sponsor. How and who completes the forms should be outlined in the protocol. If not, standard operating procedures should be developed. If the study is under IND, FDA's regulatory project manager can be consulted.

Kind regards,

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

From: [redacted]
Sent: Monday, April 24, 2017 9:59 AM
To: OC GCP Questions
Subject: Question on Subject Self Administration of study drug log

Good Morning,

We have an ongoing investigation at our site that involves the subject recording the self-administration (SQ Injection) of study drug. The sponsor has provided a log for the subject to complete at home. Is there any issue with us completing the study kit numbering on the forms for the patient? Or, because this log is intended to be completed by study subject, are we not allowed to record anything on it?

Any guidance would be greatly appreciated.

[redacted]