From: OC GCP Questions
To: [redacted]
Subject: Protocol Non-Investigational Meds
Date: Wednesday, November 04, 2015 6:12:21 AM

Good morning –

There is no FDA requirement that the maintenance medication be supplied by the sponsor or the research site. If the medication is being supplied to the study subjects, the subjects should be notified in the informed consent document as well as the protocol.

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: Tuesday, November 03, 2015 12:13 PM
To: OC GCP Questions
Subject: Protocol Non-Investigational Meds

Good day.

I have a question. If a clinical trial protocol states that a subject will be required to stay on a particular maintenance medication (background medication) while participating in the study, which will impact results for the efficacy of the investigational study drug; should the non-investigational medication (subjects background med) be supplied to the subjects by the either the sponsor or research site?

I hope this makes sense.

Regards,

[redacted]