From: OC GCP Questions
Sent: Friday, October 30, 2015 12:20 PM
To: [redacted]
Subject: RE: background therapy and SOC

Dear [redacted],

I am not aware of any regulation mandating that the sponsor financially provide the background therapy or Standard of Care specified in a clinical trial; however as with the requirements of the investigational product, any costs that are passed on to the subject must be disclosed in the informed consent document [21 CFR 50.25(b)(3)]. Additional information regarding charging for investigational products can be found in the following guidance documents:

Draft Guidance on Charging for Investigational Drugs Under an IND – Qs & As :
http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm351264.pdf
Information Sheet on Charging for Investigational Products :
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126427.htm

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Friday, October 23, 2015 4:23 PM
To: OC GCP Questions
Subject: background therapy and SOC

Hi – is there a regulatory requirement for a Sponsor to provide (without charge or by reimbursing investigative sites) and background therapy or Standard of Care specified in a clinical trial? This assumes that the background med and SOC are approved products marketed in the US.

I am aware that this is typically done but am not aware of any regulation mandating this financial study consideration.

Thanks for your help –

[redacted]