From: OC GCP Questions
To: [redacted]
Subject: Question regarding US subject data
Date: Wednesday, June 13, 2018 10:56:00 AM
Attachments: [redacted]

Good morning –

If the physician is part of the research team (co-investigator) and the visit included all the elements needed for the study per protocol, then yes I think you may include that has a research visit. Otherwise if it was was a routine visit for practice of medicine, I don't think you can use that information. I would strongly discuss this issue with the sponsor of the study.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Wednesday, June 13, 2018 8:42 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question regarding US subject data

Hello

Would you be able to tell me whether in cases where a scheduled research visit was not conducted however the site can see in the medical record that the subject has followed up with another physician, Is it acceptable to use this information for the purpose of the clinical trial based on US regulations?

Many Thanks

[redacted]