From: OC GCP Questions
To: [redacted]
Subject: Regarding documentation on PI"s notification to subject"s primary doctor on thier participationin the trial
Date: Monday, June 29, 2020 9:45:13 AM
Attachments: [redacted]

Good morning –

Thank you for your inquiry. This is not required under FDA regulations, nor is it specifically addressed in FDA guidance documents that the subjects' primary physician be informed about the subject participating in a clinical trial. As you state, this is mentioned in ICH E6(R2) and this is only a recommendation.

How you document that you informed the subject's primary care physician would be addressed in your internal standard operating procedures. FDA has no preference.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]
Sent: Sunday, June 28, 2020 7:50 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Regarding documentation on PI's notification to subject's primary doctor on thier participationin the trial

Dear GCP helpdesk

In ICH E6 (R2) 4.3.3, there is a statement like below;

"*It is recommended that the investigator inform the subject's primary physician about the subject's*

participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed"

So, some of sponsors insert a specific section of it in an ICF, but others do not consider or check if PI informs subject'sprimary doctor on thier participation in the trial.

My questions are;

1) What is your opnion on this practice ? Do you think this practice (=PI informs subject's primary doctor on their participation in the trial) need to be implemented ?

I usually strongly recommend this practice to be implemented as Safety is the first thing to be considered.

2) If PI informs subject's primary doctor about subject's participation in the trial, then should PI record it on EMR (or worksheet) like ICF obatining process ?

Thank you in advance.

Kind regards,