From: OC GCP Questions
To: [redacted]
Subject: Question -PCP
Date: Thursday, April 09, 2015 11:31:44 AM

Good morning --

FDA's regulations do not mention a notification letter to a subject's primary care provider (PCP) or specifically how the PCP should be notified. Notification to the PCP is mentioned in the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) section 4.3.3 which states:

> 4.3.3 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.

I'm also assuming that for a particular study, there is a requirement to notify a subject's PCP about the subject's participation in that particular study. You should make sure that you understand who is requiring the notification of a subject's PCP (e.g., the IRB, the sponsor, the clinical investigator site, other). You should also be aware of any and all Standard Operating Procedures (SOPs) written procedures that govern the process of notifying the PCP, especially the process to be followed when a subject does not agree to have their PCP notified.

As stated in the FDA Information Sheet Guidance, "Recruiting Study Subjects" (available at www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm, "FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research."

IRBs typically outline in written procedures which documents they require to be submitted in order for the IRB to fulfill its regulatory obligations. Such written procedures may address the IRB's policies and procedures on submission and review of materials/documents. Because each IRB may have differing requirements, it is best that each site discuss and understand what each IRB requires and adhere to the reviewing IRB's requirements.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, April 07, 2015 12:35 PM
To: OC GCP Questions
Subject: Question -PCP

If the informed consent has noted that the subject indicated notification of primary care physician of study, would the agency accept documentation of study participation of clinic notes that was sent to the primary care physician? Or should a formal letter of notification be sent to primary care physician?

[redacted]