From: OC GCP Questions
To: [redacted]
Subject: RE: Primary Care Physician - IRB approval required?
Date: Monday, March 10, 2014 2:40:00 PM

Dear ώwŜŘ͕ÖώŜŘϲ-

Thank you for your question. FDA's regulations do not mention a notification letter to a subject's primary care provider (PCP), so I am assuming that you are referring to the recommendation 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.

As to whether or not the IRB requires review and approval of a subject PCP notification, you will need to consult your IRB on their requirements and written procedures. However, since the PCP notification letter does reference the subject's participation in the research study, the IRB may likely wish to review the letter.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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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: Monday, March 10, 2014 11:22 AM
To: OC GCP Questions
Subject: Primary Care Physician - IRB approval required?

Does the notification letter to a subject PCP need IRB approval?