From: OC GCP Questions
To: [redacted]
Subject: RE: holding payments to research subjects
Date: Tuesday, February 02, 2016 1:46:30 PM

Your comments raise two issues I will deal with separately; first the issue of payment, then the issue of withdrawing from the research. FDA regulations do not specifically address the payment situation you describe; however, FDA guidance on the payment of research subjects states that when payment is part of the research plan, "*the amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present under influence*." (See "Payment to Research Subjects – Information Sheet" available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm.). You do not state whether the IRB reviewed and approved the payment plan being followed by the investigator. As a general rule, FDA would expect IRBs to review the proposed amount and schedule of payments to subjects to ensure payments are appropriate to the time commitment and study procedures, and that subjects will not be unduly influenced by these incentives. The IRB may decide that withholding some amount of payment to the end of a study is not unreasonable so long as the amount does not constitute undue influence.

The issue of withdrawing from the research is a bit more complicated. The regulations state that the "subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled" (see 21 CFR 50.25(a)(8)). Plainly speaking, this means subjects can withdraw from research at any time they want. However, there are times when withdrawing from research could pose significant risk to the individual and precautions may be prudent to take in order to protect the subject. If abrupt withdrawal from research involves risks, then any special procedures related to withdrawing from the research should be outlined in the informed consent document and discussed with the subject or their legally authorized representative. When withdrawal from a clinical investigation may adversely affect the subject, the informed consent process must explain the withdrawal procedures that are recommended in order to ensure the subject's safety, and should specifically state why they are important to the subject's welfare. The scenario you describe suggests the subject may have been in an acute psychotic state and it may not have been in the subject's best interest to abruptly discharge the subject. I would suggest speaking to the responsible IRB for the study to determine whether this is a reportable event. You may also want to work with your IRB and institutional officials about what to include in your planned standard operating procedure.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Kevin

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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: Sunday, January 31, 2016 8:51 AM
To: OC GCP Questions
Subject: holding payments to research subjects

The following was the topic of conversation between several principal investigators conducting clinical studies. One PI uses with holding of payments as an incentive to keep subjects in his trial. One PI mentioned one of his subjects expressed wanting out of the study after a weeks participation and he refused payment at that time. To further complicate things the subjects are considered vulnerable population as they are schizophrenic. The PI stated he believed the subject at this time was psychotic and it was his judgement to keep the subject for a few more days to determine if she was stable enough to be discharged. He stated he thought he could be responsible if anything happened upon her early discharge such as harm to self or someone else.

I have read the guidance "payment to research subjects-information sheet and think this is an IRB reportable problem. I also think this practice of withholding payments may also be considered "coercive" in nature by the FDA .I am concerned that this practice of both with holding payments and keeping subjects in study when they state they want out, is coercive and want to write a policy or SOP stating how to discharge such vulnerable populations ethically. I would like your opinion on this complicated manner.