From: OC GCP Questions
To: [redacted]
Subject: RE: Transfer of PI responsibilities
Date: Monday, July 13, 2015 4:35:00 PM

Dear [redacted] -

Thank you for your question. As you know, the regulations do not specifically address the scenario you describe. When the regulations are silent, IRBs, institutions, sponsors, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

Based on the limited information in your email, it is difficult to determine who is currently responsible for the study, whether the new PI was already a subinvestigator on the study and is knowledgeable about the study, how long it has been since the old IRB-approved PI left, how many subjects are on study, etc. I suggest you contact your IRB to find out what their requirements are and discuss your question with them. You should also talk to the sponsor about your specific question.

Generally speaking, if the sponsor changes the principal investigator for a study, the new PI's responsibilities are effective when he/she signs the 1572. The sponsor, of course, is also required to submit a protocol amendment to the IND, notifying FDA about the new investigator [see 21 CFR 312.30(c)]. However, there may be other important information contained in that letter relinquishing and transferring responsibility of PI oversight that I am not aware of that may be driving the exact date of the transfer, so it is difficult to give you a more definitive answer.

Your IRB is required to follow written procedures for ensuring prompt reporting to the IRB of changes in research activity, and for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. Your institution and IRB may also have other requirements that must be met regarding a change in PI, so it is important to discuss your question with the appropriate institutional and IRB representatives.

It will be important that your records show who is responsible for the study at your site at all times and what transpired regarding the change in PI.

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

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Wednesday, July 08, 2015 5:13 PM
To: OC GCP Questions
Subject: Transfer of PI responsibilities

PI is leaving the institution and signs a letter relinquishing and transferring responsibility of PI oversight to another subinvestigator (who accepts this responsibility). The sponsor is contacted for FDA regulated research and takes a few weeks approving the new PI. In the meantime, the new PI signs the 1572 form and the form is forwarded to the sponsor. The old PI leaves the institution and the sponsor approves the new PI, but the new PI has not been approved by the IRB yet. Is this sufficient oversight to permit study patients to continue on the study, or does the study activities need to end until the PI is approved by the IRB? What would be the date that the PI became the PI of the study from a regulatory perspective? When he signed the 1572 or when IRB approved?

[redacted]