From: OC GCP Questions
To: [redacted]
Subject: RE: Transfer of a subject to a different site location
Date: Thursday, May 28, 2015 10:24 00 AM

Dear [redacted] -

Thank you for your question. The FDA regulations do not specifically address the transfer of study subjects from one study site to another. When the regulations are silent, sponsors, investigators, IRBs, and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

Based on responses to similar questions our office has received in the past on this topic, I included a few points-to-consider that you may wish to discuss as you think through the process you will use to adequately transfer a subject from one site to another. **This is not an all-inclusive list**, and I suggest you discuss the transfer process you intend to use with the appropriate representatives at your company, the sponsor company, both investigators/sites, and the associated IRB(s). You may wish to consider preparing a written plan or SOP about how you will go about transferring the subject, ensuring that all involved parties are clear about their respective responsibilities.

- The sponsor, investigator #1 and investigator #2 must all be in agreement to transferring the subject from site #1 to site #2.
- The subject must agree to the transfer.
- The transferring site IRB should be told that the subject is moving to the receiving site and responsibility for the subject is being transferred to the receiving investigator/site. The receiving site IRB should be informed that a subject under the protocol is being transferred to the site and the investigator will be responsible for that subject beginning with date/study visit.
- You should discuss expectations for documenting the subject's agreement to the transfer with the sponsor, the investigators and the IRB(s) involved, as the subject must be provided with information such as the name of whom to contact at site #2 for answers to pertinent questions about the research and their rights as a research subject, and whom to contact in the event of a research-related injury.
- Site #1 should maintain records of the subject up to the time of transfer and should note in their site's records that the subject transferred to site #2 and when this occurred. Site #2 should receive copies of the patient's records from site #1 and document in their records that the subject transferred from site #1 and when the transfer occurred.
- For data analysis purposes, you should ensure that a subject is consistently identified in a way that allows all data regarding a single subject to be attributable to that subject. The data used in the analyses must be traceable back to the records maintained at the clinical sites and complete transparency is important.
- Good communication is going to be very important.

In general, your process should clearly reflect the subject's participation in the study so that someone uninvolved with the study understands what actually happened during the study. The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) provides some general information on documentation for clinical trials and assuring data quality and integrity. Beyond that, there may be other criteria that you need to address. For this reason, you should discuss your question with the appropriate management, including resources such as legal and clinical data management staff at your company, to develop and document an acceptable plan for transferring a subject from one site to another.

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
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

---

From: [redacted]
Sent: Tuesday, May 26, 2015 7:37 PM
To: OC GCP Questions
Subject: Transfer of a subject to a different site location

In cases where a subject is enrolled in a study and moves to a different geographic location and the study has a research site in the vicinity of the new location, does FDA have any recommendations, dos/don'ts in the transfer of that subject from the original research

site location to a new one?

Thank you.

[redacted]