From: OC GCP Questions
To: [redacted]
Subject: Question about transferring subjects from one site to another site
Date: Tuesday, October 28, 2014 1:26:21 PM

Good afternoon –

We have had a similar email in the past. The answers to someone else's questions are below. This should help you as well.

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The situation that you described in your e-mail is not addressed in FDA's regulations guidance, although FDA's Information Sheet Guidance, "Use of Investigational Products When Subjects Enter a Second Institution," addresses some corollary situations. I've included a link to that guidance below.
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126432.htm

1- With a study, Is transfer of one subject from one center to other is allowed?

Assuming that investigators/centers are indeed participating in the same protocol, and neither the subject, sponsor nor the IRB objects, I do not see a problem with allowing the subject to transfer. With the subject's consent, the investigator at the "transferring" center should provide a complete copy of the subject's medical and study files to the "receiving" center. The sponsor should be informed of the move/transfer to assure that the subject (and any AEs) are not counted twice.

2-What are all procedure need to taken in place if it is allowed(eg EC notification, source records need to be shared between two PI etc)?

Again assuming that investigators/centers are indeed participating in the same protocol, the transferring center IRB should be told that the subject is moving to receiving center and responsibility for the subject is being transferred to the receiving investigator/center. The receiving IRB should be informed that a subject under the protocol is being transferred to the new center and the investigator will be responsible for that subject beginning with date/study visit ##.

3. In such cases, Is site specific ICF need to be taken again?

As for re-consenting the subject, certainly the subject needs to be provided with the name of whom to contact at the new center for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject (both of which are required to be included in the informed consent document). In my opinion, it cannot hurt to review the consent document with the subject and provide him with a copy upon his arrival at the new center.

4. There is any regulatory obligation in such cases?

The sponsor needs to be informed of the move/transfer to assure that the subject (and any AEs) are not counted twice. If an AE is reported at the transfer center, but has not resolved by the time the subject arrives at the receiving center, then it would be important to ensure that the sponsor is aware that this particular AE has been reported but not yet resolved, to assure that it is not counted twice.

Good communication is going to be very important.

If the transferring center provides the subject's complete medical records and study file to the receiving center, this center would have the complete case history for the subject. The transferring center should retain a set of the records, and annotate the file as to the date when the subject moved to the new center. Likewise, the receiving center would document in the file when the subject arrives.

Generally, the IRB who reviewed the study at the site should assist in making these decisions. The

IRB's main responsibility is to ensure the safety, rights, and welfare of all study subjects within the studies they approve and all the concerns listed below need to be viewed in light of what is best for the rights and safety of all subjects who are or were part of the study.

I hope this information was helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, October 27, 2014 11:20 PM
To: OC GCP Questions
Subject: Question about transferring subjects from one site to another site

Dear Sirs,

I would like to know your input about transferring subjects from one site to another site in the same clinical trial.

We are facing a situation in one site conducting a clinical trial that requires an immediate transfer of subjects to another site, transfer would be temporary for 2 months and the study is active in a following study phase with phone contact visits for 3 years.
Subjects are underage and the number of subjects to be transferred is more than 700 subjects.

-We know that we should inform subjects and parents about the temporary transfer and obtain authorization from patients/parents to send his/her information to the transferring site, notify IRB and ask for the transferring approval

- We know that site should re consent the patient using the receiving site's current version of the study informed consent and prior to conducting any protocol-specific procedure, in this case the phone contacts.

-Transferring and receiving sites are close each other, (20 minutes by car) and site staff delegated at transferring site are already delegated at the receiving site because some site staff working at transferring site is working part time at the receiving site, and the principal Investigator of transferring site is sub-investigator at receiving site.
Considering the situation mentioned above, we are trying to find a simple way to do this transfer but following GCP and we have some questions:

- Can we transfer activities from the transferring site to receiving site?. or Have we have to transfer subjects following the points mentioned above, considering that the activity to do is a

phone contact study follow up?.

- Can we inform subjects/parents of the temporary transfer through a written letter sent by certified mail?. Is the re-consent process at the receiving site required?

- Can we talk about temporary transfer of activities rather than temporary transfer of subjects?.

- Is there any guide to transfer subjects from one site to another site?

- Any reference or experience transferring subjects?

- Any suggestions or advise to manage this temporary situation?.

Thanks in advance

Kind Regards,

[redacted]