From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, July 07, 2006 3:34 PM
To: **[Redacted]**
Subject: RE: transfer of drug

Hi, **[Redacted]**,

I'm sorry to have taken so long to get back to you.

I think your question raises some other issues, but there isn't enough information in your e-mail to provide a clear answer.

If the product under study is, for example, an approved drug that is commercially available, then yes, it's probably okay for the sponsor to "waive" the requirement and allow the CRO to obtain the drug from another source.

If it's an investigational product, then there could be other issues. For example:

--If the CRO (that has taken on the sponsor's obligations) was compounding the drug from raw materials, and was provided enough "raw" material to produce the amount of study drug needed, how come they ran out?
--Could the investigational drug that was used with other study subjects have been superpotent (i.e., was the drug compounded correctly, or was there some error)?
--If they obtain the raw material from another source, how will the CRO ensure that it is being compounded correctly (this time)?
--Even if the CRO obtains "finished" product from another source, might there be bioequivalence/bioavailability issues?

I'm sure there are other questions that could easily be raised but these are the things that sprang to mind.

As for whether a protocol amendment would be needed, I would say yes, particularly if there is some manufacturing change or other question about production of the study drug that might be of interest to the review division.

Sorry I can't be more helpful.

Carolyn

From: **[Redacted]**
Sent: Monday, May 22, 2006 10:19 AM
To: Hommel, Carolyn - OC
Subject: transfer of drug

Hi Carolyn-

I'm hoping you can answer the following question for me. A sponsor filed an IND and transferred their obligations to a CRO. The sponsor states in the protocol that the CRO may not obtain the drug from a different source. However, the CRO has run out of drug, so the sponsor waived this limitation. Can the CRO obtain the drug from another institution? I would think that since the sponsor waived this, it is okay. Does a formal protocol ammendment need to be made?

Thanks...

[Redacted]