From: Toth-Allen, Jean
Sent: Wednesday, September 06, 2006 1:15 PM
To: [Redacted]
Subject: RE: Question re subject with SAE

Dear Dr. [Redacted]:

Thank you for your clarification.

Some countries require that sponsors retain medical insurance for all study subjects and/or require that they treat any medical condition that might arise, whether or not related to the investigational product or related treatment. This is not so in the United States (U.S.). In the U.S., unless the sponsor has specified in the study protocol that study subjects be treated by study physicians, even if the medical issue is definitely unrelated to the investigational product or related treatments, the individual's personal physician would be considered responsible for medical care in this instance, whether or not the individual remained as part of the study or withdrew. Payment would then be made through the individual's health insurance/coverage as with their ordinary medical care. If emergency treatment is required, it would be expected to be given by whomever is available, including a physician who is part of the clinical study team, but such treatment would not be considered as part of the study. It would, however, be expected that the condition and its treatment be noted in the subject's study file, not matter who treated the condition and whether or not the subject withdrew from the study. If the subject withdrew from the study, no follow-up on the medical issue that was unrelated to the study would be expected.

If this study is occurring in [Redacted], as implied by the information below your name, you should check with your country's officials (most probably with the [Redacted]) as to what is expected in this regard. It is my understanding that [Redacted] has adopted some more stringent laws/regulations regarding clinical studies. Following what is customary in the U.S. would obviously not be acceptable if your country has different requirements.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Wednesday, August 30, 2006 11:35 PM
To: Toth-Allen, Jean
Subject: Re: Question re subject with SAE

Dear Jean,

All 3 questions are concerned with same subject.

Thanks and regards,

[Redacted]

On Wed, 30 Aug 2006 Toth-Allen,Jean wrote :
>Dear [Redacted],
>
>Your inquiry below was forwarded to us for a response. Could you please clarify if all 3 questions are with regard to the same subject or are they 3 different subjects.
>
>Thanks.
>
>Sincerely yours,
>Jean Toth-Allen, Ph.D.
>Good Clinical Practices Program
>OSHC, Office of the Commissioner, US FDA
>
>-----Original Message-----
> From: [Redacted]
><mailto:[Redacted]
>Sent: Tuesday, August 29, 2006 7:23 AM
>To: CDER DRUG INFO
>Subject: DrugInfo Comment Form FDA/CDER Site
>
>
>
> Name: [Redacted]
>
> E-Mail: [Redacted]
>
> Comments: Dear Sir,
>
>I need clarifications on following questions
>
>1.There is a subject with an SAE which is not related to study drug - who should bear the cost of treating SAE which is definetly not related to study drug?
>
>2. There is subject who has been withdrawn for the study after the SAE and subject was discharged form the hospital and SAE is still resolving. Who should bear the cost of the management of SAE till it resolves?

>
>3. Can sponsor refuse to pay for management of SAE till it is resovled as protocol states the subject will be followed upto 30 days after the study drug is stopped and SAE is not resolved yet and needs follow up upto another 3 months?
>
>
>Thanks and regards,
>
>[Redacted]