From: Lee, Bonnie
Sent: Wednesday, June 30, 2004 9:41 AM
To: [Redacted]
Subject: FW: Please read my fax I sent last week, would appreciate guidance in resolving this issue.

Dear [Redacted],

Your email to David Lepay has been referred to me for response. In the future, if you have questions, I encourage you to submit them to our general question mailbox at GCPQuestions@oc.fda.gov in order to avoid delays in response.

FDA regulations do NOT specify that one must include the duration of the study in terms of months or years. Rather, they simply require that the consent form contain "...the expected duration of the subject's participation...." See 21 CFR 50.25(a)(1). Thus, if the expected duration of the subject's participation is for "as long as the treatment is working," then that information in the consent form would satisfy FDA's regulatory requirement. In fact, if the protocol also states this duration, it would seem inappropriate to say anything different in the consent form. I hope this is helpful to you and to your IRB.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
To: david.lepay@fda.hhs.gov <DLepay@OC.FDA.GOV>
Sent: Wed Jun 30 00:27:26 2004
Subject: Please read my fax I sent last week, would appreciate guidance in resolving this issue.

FAX MEMO:

June 23, 2004

To: David LePay, MD, PhD.
Director, FDA, Office for Human Research Trials
Fax: (301) 827-1169

Fr: [Redacted]

SUBJECT: FDA 21 CFR 50.25(a)(1), Expected elements of consent -- "...expected duration of study..."

In a [Redacted] study ([Redacted]) for the treatment of minors/adult patients with [Redacted], our informed consent's "expected duration of study" reads as follows:

"How long will my child/I be in this study?"
"Your child/you will be in the study for at least one month, and will continue receiving treatment as long as the treatment is working. Treatment will

continue as long as your child's/your disease does not get worse and there are no serious side effects. Also, we would like to continue to collect some medical information about how you are/your child is doing for as long as you are willing to let us."

The local reviewing IRB will not give us approval of an amendment for this study until we revise the consent to specifically state the subject's participation in months and years. We reviewed the protocol and told the reviewing IRB Office that we cannot find any stated time period (months or years), and the model consent matches the protocol's language.

This is not a new study and has been approved since 2002. We feel there is a liability issue if we ask patients/parents to sign a consent that states subject participation for a specific period of time, and it is unknown how long treatment will last.

We have also contacted the [Redacted] but would like to know how 21 CFR 50.25(a)(1) regulation is to be properly interpreted. Do you have any guidance on how the expected duration of study may be stated to reflect the protocol and resolve this issue with our IRB? Is the interpretation of the words "expected duration of study" meant to be only stated in months and years?

A written response is requested, please either e-mail me at [Redacted].

[Redacted] responded to my quiry and stated that we have no recourse but to close the study if we cannot obtain IRB acceptance.