From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 30, 2004 10:17 AM
To: [Redacted]
Subject: RE: General question regarding an Informed Consent for an IDE study
Dear [Redacted],

There is no single answer to your question. When an IRB reviews a study and the consent process, the IRB could specify that after a certain period of time subjects ought to be reconsented. I don't think this happens often. More frequently, recruitment and consent is done in phases. That is, first, the patient may sign a consent form that permits the screening activities. Second, if the patient is eligible to participate in the study, the individual is presented with a consent form for the study itself. This two phase process links the consent form(s) to each activity and may help to avoid a long delay between signing the form and the activities (such as implantation of the device). It's important to remember that informed consent is a process that extends beyond the form. If that process is working effectively, then I would question the need to document the consent of the subject again if a certain number of days have elapsed. On the other hand, it would certainly seem prudent and a good "consent process" to re-review the information with the subject prior to device implantation to ensure that the subject understands that information, to respond to any additional questions, etc. Further, if, based on the nature of the study, you believe that subjects ought to be asked to provide consent again if 30 days have elapsed, that would be consistent with (although not required by) FDA's informed consent regulations.

I hope this information is helpful to you.

Sincerely,

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

-----Original Message-----
From: [Redacted]
Sent: Thursday, April 29, 2004 7:25 PM
To: gcpquestions@oc.fda.gov
Subject: General question regarding an Informed Consent for an IDE study

Dear Sir/Madam,

I work for [Redacted] company that sponsors several IDEs. We received a question from one of our clinical sites and in doing research on this topic, I can not find an answer. Please provide any guidance or link to information that pertains to this question:

"After Informed Consent is obtained from the patient, what time period is the IC document valid before the patient is actually enrolled into the study?"

We have an ongoing IDE that requires the Informed Consent to be obtained prior to any screening activities. Once the IC is obtained and the screening activities verify that the patient is suitable for enrollment into the study, the patient is randomized to receive either the control or study treatment. Occasionally, there is a delay from the time the patient is randomized until they are actually implanted with the investigational device. Does the patient need to be re-consented for the study if there is a lengthy time delay and how long is this consent actually valid? The assumption here is no more than 30 days, but we can not locate any facts to back this up.

Any help you can provide would be appreciated.

Thanks,
[Redacted]