From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, December 17, 2004 3:26 PM
To: [Redacted]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted], I apologize for the delay in getting back to you. Informed consent is a process that continues throughout a research study. In fact, I have found it useful to consider the informed consent process a conversation that begins when a subject is deciding whether to become involved in a study and continues as more is learned about the product and/or disease. It is not a one time event and as new information is obtain it ought to be provided to the subject. Informed consent involves not only giving information, but also making sure the subject understands that information, has an opportunity to ask questions, and voluntarily agrees to participate, or continue to participate in a study. If information becomes available that could affect a subject's decision to stay in the study, that information needs to be provided to the subject. Even if the study has concluded, if information becomes available that could have a significant impact on a subject, the Institutional Review Board (IRB) may decide that information should be provided to the subject. It would be up to the IRB to determine whether subjects need to sign a new or supplemental informed consent form. I hope this information is helpful to you.

Happy Holidays,

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-----

-----Original Message-----
From: [Redacted]
Sent: Tuesday, November 09, 2004 1:36 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Consent/ reconsenting, should consenting only be done to initiate a pt. into a study? Reconsenting-When changes occur in a study that may affect a pt.s particpation, should they be informed by reconsenting? If not reconsenting then is an addendum to the consent done or is a memo to the pt. sufficent? If accurral to a study is closed, is the consent dead too?