From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, August 30, 2004 12:14 PM
To: [Redacted]
Subject: RE:
Dear [Redacted],

FDA regulations do not specifically address the scenario you have described; however, informed consent is a continuing process, and if data is collected during a period for which informed consent has been appropriately obtained, I see no regulatory reason why the sponsor cannot use that data. However, if the subject feels very strongly about this, the sponsor may want to exercise judgment and not use the data, to demonstrate respect for the patient/subject. I hope this information is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
-----Original Message-----
From: [Redacted]
Sent: Thursday, August 12, 2004 11:35 AM
To: gcpquestions@oc.fda.gov
Subject:
Please provide FDA opinion of the following scenerio:
A subject, being unable to give consent, is enrolled in a clinical trial by his/her Legally Authorized Representative (LAR). After a period of time, while still enrolled in the clinical trial, the subject is now able to give the consent and is not interested in continuing participation in the trial and is not conducive to allowing the sponsor to use his/her the previously collected data.
The question: Can the Sponsor use the previously collected subject data?
Thank you for your response.

[Redacted]