From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, March 14, 2003 1:49 PM
To: [Redacted]
Subject: RE: Compliance Question - Protocol Deviations/Violations

Dear [Redacted], Unless an IRB has directed that all subjects who have ever been entered into a study must be advised of some new finding, there would be no reason to have a subject who has discontinued participation in a study sign consent forms that were revised after the subject withdrew from the study. I believe that your suggestions are good: that is, have the PI generate a note to the file to explain that the subject withdrew from the study before the two new informed consent forms were generated and depending upon the circumstances, provide the subject with the new information. The only time there may need to be some documentation of receipt of that information by the subject would be if the IRB required that all subjects who ever entered into the study be advised of that information. I hope that this is helpful to you.

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

-----Original Message-----
From: [Redacted]
Sent: Tuesday, March 04, 2003 4:27 PM
To: OC GCP Questions
Subject: RE: Compliance Question - Protocol Deviations/Violations

Dear Office of Compliance,

I have a question on which I need guidance.

Scenario: A study has 2 revisions to an ICF (both are providing updated safety information). A subject (at one of the sites) discontinued in Dec. 2002
due to lack of therapeutic response. The subject did not sign the revised, Amendment C ICF (version 2) prior to discontinuation. The site
had another ICF revision per the IND safety letters (version 3) and the subject didn't sign this ICF either.

The patient still returns to the clinic, and the SC thought it would be possible to have the former subject sign the 2 ICFs the next time.

I am a bit skeptical of this because the patient no longer a part of the study.

I suggest that the PI generate a note-to-file to explain that neither of these two ICFs were signed before withdrawal. I also said that the SC or PI
could provide the person with the information to be diligent, but could not require the person to sign.

The SC has agreed to not take action until she hears from me

about how to proceed.

Question: If a subject withdraws from a study prior to signing a revision of an ICF, should the investigative site (PI/SC) attempt to have the (now) patient return to the site to sign the ICF?

Please provide me with guidance on this issue.

FDA/OC Response:

Thank you very much.

Sincerely,
[Redacted]