From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Tuesday, August 05, 2003 10:20 AM
To: [Redacted]
Subject: RE: GCP question

Dear Mr. [Redacted],
Thank you for your interesting question. The regulations regarding informed consent don't directly address the use of a subject's data after they have discontinued participation in the active phase of the trial. However, it seems clear that subjects should have a full understanding per 21 CFR 50.25, of the following from the informed consent process:

the purpose of the research
the expected duration of their participation
the extent to which confidentiality of records will be maintained
anticipated circumstances under which their participation may be terminated without regard to their consent

For the type of study you describe below, I would expect that the subjects would be told that the purpose of the study was to gather outcome data, and their participation would include gathering that outcome data even though it might occur long after their active participation. I would also expect they would understand that their active participation may be discontinued for the reasons you describe but that their data would still be collected. If the consent form and process adequately conveyed and addressed this information, it would seem that the subject's consent would be adequate to allow gathering this data.

I hope this is helpful. As I said the regulations don't directly address this issue but a consent form complying with 50.25 could/should be constructed to ensure it is suitable for the intended purpose and duration of the study.

Sincerely,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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: Tuesday, July 29, 2003 4:00 PM
To: 'gcpquestions@oc.fda.gov'
Subject: GCP question

Dear Good Clinical Practice Program staff:

I would greatly appreciate hearing your opinion regarding the following GCP related question.

Scenario: A clinical research subject participating in a trial involving treatment and the gathering of outcome data (survival status at end of study) is terminated from the study for reasons other than consent withdrawn, such as adverse events and/or treatment related decision to change from randomized treatment.

Question: Is the sponsor still able to gather the outcome data from this terminated subject (as described in the informed consent signed by the subject) at the conclusion of the study, which may be long after the patient terminated from the treatment? Or does the patient's termination from treatment invalidate the informed consent?

Obviously, its clear to me that for patient's who have withdrawn consent, the consent is invalid, but my feeling is that the group described above who have terminated from the treatment part of the protocol may still have their outcome status collected since the informed consent is still valid.

Thanks in advance for your help.

Sincerely,

[Redacted]