From: Toth-Allen, Jean
Sent: Thursday, June 22, 2006 11:12 AM
To: [purged]
Subject: RE: Serious Adverse Events and the "30 day Rule"

Dear [purged],

Thank you for your inquiry regarding follow-up of study subjects.

FDA regulations regarding clinical trials (21 CFR Part 312 for pharmaceuticals and Part 812 for devices) contain requirements regarding the investigational plan that include adequate follow-up of study subjects as pertinent to the nature of the study. There is, however, no requirement that I am aware of for follow-up beyond what would be considered the end of subject participation in a study as defined in a specific investigational plan.

The only issues with regard to clinical trials that have a 30 day timeframe that I am aware of are with regard to start of an IND/IDE study or restart of an IND study after a clinical hold. The former references the fact that an IND/IDE study may be started if the applicant has not heard from FDA 30 days after notice of receipt of the application. With regard to clinical holds, 21 CFR 312.42(e) requires FDA to respond to a sponsor's written request for removal of the clinical hold within 30 days of receipt of the request. The regulation, however, notes that, despite the 30 day requirement, a sponsor cannot restart a study that FDA placed on clinical hold without receipt of FDA notice that the hold has been lifted.

The title of your e-mail concerns me, as it implies there is some connection between a serious adverse event and your question about study subject follow-up beyond the end of the subject's participation in the study. If a clinical investigator and/or sponsor receives evidence of adverse events that could impact study subjects whose participation in the study is complete, there would of course be an obligation to inform the affected individuals and take appropriate actions as warranted. Such a circumstance would have no time limit, however.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: [purged]
Sent: Tuesday, June 20, 2006 3:32 PM
To: OC GCP Questions
Subject: Serious Adverse Events and the "30 day Rule"

Good afternoon:
Can you provide the regulation or guidance that requires investigators
to follow subjects for 30 days after their participation in an FDA
regulated trial has ended?
Thanks!
[purged]