From: Toth-Allen, Jean
Sent: Thursday, September 14, 2006 9:46 AM
To: [purged]
Subject: RE: Requesting Information Regarding Principal Investigator Transition at a site.

Dear [purged]:

Thank you for your inquiry regarding a change in clinical investigator at a clinical trial site. Please excuse my delay in responding to you.

When an institutional review board (IRB) approves the initiation of a clinical trial, they are approving the study as it will be conducted at the specific site. Therefore, they review the credentials of the designated clinical investigator as part of their review procedure. It is therefore important that the reviewing IRB approve the transition in clinical investigators before it actually occurs. The sponsor should retain a copy of the notice of IRB approval of this change.

For FDA-regulated clinical trials, sponsors are required to submit a progress/annual report (Title 21, Code of Federal Regulations - 21 CFR - 312.33 for pharmaceutical studies and 812.159(b)(5) for device studies). In addition, device study sponsors are required to supply a current investigator list to FDA at 6-month intervals [812.150(b)(4)]. A sponsor can choose to include notice of a clinical investigator change at a study site in such reports. Alternatively, the sponsor may choose to inform the reviewing division at FDA by phone, e-mail, or FAX immediately upon receipt of such information, particularly if the specific choice of trial clinical investigators was a concern to FDA reviewers when the original IND or IDE application was reviewed.

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.

From: [purged]
Sent: Tuesday, September 05, 2006 6:30 PM
To: OC GCP Questions
Subject: Requesting Information Regarding Principal Investigator Transition at a site.

What are the procedures that a sponsor must follow to ensure appropriate documentation when there is a change in principal investigator (i.e. due to illness or departure from job) during an ongoing clinical trial ?

Any information you could provide would be appreciated.