From: Toth-Allen, Jean
Sent: Thursday, March 09, 2006 9:27 AM
To: [purged]
Subject: RE: Clinical trial conduct question

Dear Dr. [purged]:

Thank you for your inquiry.

There is neither FDA regulation nor guidance that directly addresses this issue. If an investigator is still capable of overseeing the conduct of an on-going study and an appropriate sub-investigator can perform any subject-related study requirements, it would seem possible for that investigator to maintain his/her position. However, the study sponsor and/or the institution at which the study is conducted may weigh in differently in this regard. As far as future studies are concerned, that would appear to depend upon the nature of the disability, the particular role he/she can play in the study, and the policies and/or needs of the study sponsor and the institution at which the study will occur.

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: Wednesday, March 08, 2006 3:24 PM
To: OC GCP Questions
Subject: Clinical trial conduct question

If an investigator has been placed on full time disability (and cannot see
patients per disability agreement) is he allowed to remain a principal
investigator or subinvestigator? Is it permissible to accrue new clinical
trials?
Thank you,

[purged]