MessageFrom: Toth-Allen, Jean
Sent: Thursday, January 26, 2006 12:26 PM
To: [purged]
Subject: RE: guide to good clinical practice in pdf format?

Dear Dr. [purged]:

Thank you for your inquiry regarding available GCP documents.

A guidance document regarding GCPs for pharmaceutical studies is accessible at http://www.fda.gov/cder/guidance/959fnl.pdf. The general principles found in this guidance document can be applied to clinical research across medical products. Hope you find the information provided in this document 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: Sunday, January 22, 2006 10:58 AM
To: gcpquestions@oc.fda.gov
Subject: guide to good clinical practice in pdf format?

Respected Sir/Madam,

I am studying for clinical research associate program in canada and would like to know where can i find gcp guidelines of the fda.

Is there some pdf program that i can download?

Regards
Thanking you in anticipation
[purged]