From: Toth-Allen, Jean
Sent: Thursday, March 16, 2006 8:52 AM
To: [purged]
Subject: RE: FDA manual

Dear Ms. [purged]:

Thank you for your inquiry regarding the conduct of clinical trials.

FDA regulations regarding the conduct of clinical trials can be found in Title 21, Code of Federal Regulations (21 CFR). Part 312 covers pharmaceutical studies (both drugs and biologics) and part 812 covers devices. The most up-to-date versions of these regulations are available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. Hard copies are also available through the government printing office (information should be available on the GPO web site) as well as through commercial publishers.

There is also an ICH GCP guidance which FDA has adopted available at http://www.fda.gov/cder/guidance/959fnl.pdf. While it states is it specific to pharmaceuticals, we believe the general sections are relevant to the conduct of all clinical trials.

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: Friday, March 10, 2006 11:20 AM
To: OC GCP Questions
Subject: FDA manual

Dear Sir/Madam:

Does the FDA have a manual/regulation handbook, etc. with regard to the way
that clinical trials are to be done? If so, how can I obtain a copy.

Your prompt reply is greatly appreciated.

[purged]