From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, February 03, 2006 9:00 AM
To: [purged]
Subject: RE: GCP question

Dear Ms. [purged]:

This is not an FDA document.

Although the document quotes various guidances that do indeed appear on our website (e.g., the ICH E6, " Good Clinical Practice: Consolidated Guideline"), and includes a list of documents to be maintained by clinical investigators, as well as a list of "common deficiencies" that FDA has uncovered during inspections, I am not aware of any single document on our website that combines all of these materials.

Further evidence that this is not an FDA document is found on page 4, in the paragraph below the first "box" under the list. The paragraph opens, "The CHOP IRB functions in compliance with..." When I put "CHOP IRB" into Google's search engine, the "Children's Hospital of Philadelphia" came up. Perhaps that is the source of your document.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857
Phone: 301/827-3340
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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: Thursday, February 02, 2006 4:13 PM

To: gcpquestions@oc.fda.gov
Subject: GCP question

Hello: I'm trying to locate an fda website where I downloaded this pdf file.-I can't seem to recall where I got this document from.

Can you take a look and see if you can help me?

Thanks,

[purged]