From: Lepay, David on behalf of OC GCP Questions
Sent: Friday, July 25, 2003 6:27 AM
To: [redacted]
Subject: RE: Human Subjects Research Certification

Dear [redacted]:

FDA does not itself conduct certification programs and, at present, does not itself have an on-line GCP training program. Depending on your particular needs, there may be information of use to you on the NIH (http://www.nih.gov/) or OHRP websites (http://ohrp.osophs.dhhs.gov).

There also may be private or academic websites that contain materials of use in on-line education. However, again, these are not FDA sites and therefore we can not recommend or endorse any individual site.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs
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: [redacted]

Sent: Thursday, July 24, 2003 12:42 PM
To: gcpquestions@oc.fda.gov
Subject: Human Subjects Research Certification

Hi

Please forward the name of a website where we can receive online training and certification on Human Subjects Research, Good Clinical Practice and FDA Regulations for PIs and other clinical trial personnel.

Thank You,
[redacted]