From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, September 16, 2003 2:44 PM
To: [redacted]
Subject: RE: Web Based Training

Dear [redacted],

Although FDA does not offer web based training at this time, we are hopeful that in the near future, we will have such reference material. On-line references that are invaluable include the "ICH E6 Good Clinical Practice Consolidated Guideline", the "FDA Information Sheets for IRBs and CIs", and the regulations dealing with clinical studies (21 CFR 312, 21 CFR 50, 21 CFR 54, and 21 CFR 56). You can find all of these references on our GCP web site (www.fda.gov/oc/gcp). You might also want to visit the HHS Office of Human Research Protections (OHRP) "Educational" web site (http://ohrp.osophs.dhhs.gov/educmat.htm). You will find instructions on how to order a CD entitled "Investigators 101" and their IRB guidebook and video entitled "Protecting Human Subjects".

There are a number of professional organizations that offer training programs, however FDA does not endorse any particular training sponsor or course. You may want to consult with organizations such as (to name a few) PRIM&R, ARENA, SoCRA, and SQA (to name a few). I performed a search on google.com using the words "clinical investigator" and hit a large number of training references. You may find something suitable to your needs.

I hope this information is helpful to you. Please contact us again should you have any additional questions.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-6473

-----Original Message-----
From: [redacted]
Sent: Friday, September 12, 2003 8:02 AM
To: 'gcpquestions@oc.fda.gov'
Cc: [redacted]
Subject: Web Based Training

Sir/Ma'am,

I am about to join a research team overseas and I was trying to find out about any GCP web based classes that may be offered? THanks for the assistance

[redacted]