From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Tuesday, February 11, 2003 4:21 PM
To: [redacted]
Subject: RE: human subject protection training

Dear [redacted],
We certainly applaud clinical investigator training programs and believe all clinical investigators should be trained appropriately.
The only mandate from FDA regarding training is found in the regulations which simply say sponsors must select only
investigators qualified by training and experience as appropriate experts to investigate the drug. We have not however
required or officially endorsed any particular training program or certification scheme for clinical investigators. While we support
many training activities through our outreach activities at meetings of non-profit organizations such as DIA, ACRP and PRIMR
we are not mandating specific training requirements beyond what the regulations imply. I hope this is helpful.
Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Program

-----Original Message-----
From: [redacted]
Sent: Tuesday, February 11, 2003 3:25 PM
To: gcpquestions@oc.fda.gov
Subject: human subject protection training

Please comment with regard to FDA's position on human subject protection training for researchers.
Our institution only participates in FDA-regulated research. It is my understanding that the NIH mandate for training is the only one
currently in existence. However, our IRB has chosen to require training
of all researchers, regardless of source of funding. We chose to
purchase the Investigator 101 CD ROM program, but offer our researchers the opportunity to attend a comparable
conference.
Do you foresee an FDA mandate for training?
Many thanks,
[redacted]