From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, September 03, 2003 8:18 AM
To: [redacted]
Subject: RE: clinical trials
Dear [redacted],

There is some information on our, the Good Clinical Practice Program's, homepage (www.fda.gov/oc/gcp) that may be of help to you. I suggest you look at information that's posted on the page entitled "Guidances and Information Sheets". I think the "ICH E6: Good Clinical Practice Consolidated Guideline" and the "FDA Information Sheets for Institutional Review Boards and Clinical Investigators" are especially helpful background references for you to review. You might also want to look websites of professional organizations that specialize in providing information on clinical research. Two organizations that immediately come to mind include PRIM&R (http://www.primr.org/), and the Association for Clinical Research Professionals (www.acrpnet.org). Good luck with your paper.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-3340

-----Original Message-----
From: [redacted]
Sent: Monday, September 01, 2003 3:21 PM
To: gcpquestions@oc.fda.gov
Subject: clinical trials

Dear Sir/Madam:

I am currently in a medical assisting program. I am gathering information on how to "assist with and coordinate clinical trials". Could you direct me to an area on your web site, or any web site, that would describe specific points on this issue. I am interested in learning specifically what my role would me in assisting with and coordinating clinical trials, as the topic of my research paper. Any assistance you can offer will be greatly appreciated.

Sincerely, [redacted]