From: Toth-Allen, Jean
Sent: Monday, February 06, 2006 11:28 AM
To: [purged]
Subject: RE: G.C.P.'S

Dear Ms. [purged],

Thank you for your inquiry regarding guidance on good clinical practices (GCPs) for your cancer center.

In answering, I am making some assumptions that are not definitive in your message – e.g., I am assuming that the clinical trials in which your site participates are most probably pharmaceutical in nature but may also involve devices, or at least combination products, and that most, if not all, of these trials are FDA-regulated. Presently, the only guidance on GCPs with which FDA concurs is the ICH GCP consolidated guidance available at http://www.fda.gov/cder/guidance/959fnl.pdf. This document provides general guidance regarding the conduct of clinical studies. While it states it is specific to pharmaceutical studies, FDA believes the general sections of this document are applicable to all clinical studies.

However, this document does not provide guidance in writing enabling standard operating procedures (SOPs) for a clinical site, which it appears you are hoping to develop. There are a number of professional organizations which give workshops on the development of such documents and their websites include schedules of their up-coming courses as well as contact numbers for further information. These include the Association of Clinical Research Professionals (ACRP) at http://www.acrpnet.org, the Society of Clinical Research Associates (SoCRA) at http://www.socra.org, Drug Information Association (DIA) at (www.diahome.org), and the Regulatory Affairs Professionals Society (RAPS) at http://www.raps.org/x_raps/index.asp. There are also a number of for-profit organizations that provide such workshops as well, but FDA cannot recommend such organizations.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
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: [purged]
Sent: Friday, February 03, 2006 9:27 AM
To: 'gcpquestions@oc.fda.gov'
Subject: G.C.P.'S

HELLO, MY NAME IS [purged] AND I AM THE NEW CLINICAL TRIALS CORRDINATOR FOR OUR CANCER CENTER. I AM ATTEMPTING TO WRITE G.C.P.'S FOR OUR PROGRAM AND AM WONDERING IF THERE ARE ANY TEMPLATES OR GUIDELINES AVAILABLE, WHICH I COULD USE FOR AN EXAMPLE. THANKS, [purged] MY EMAIL ADDRESS IS [purged]

[purged]