From: Toth-Allen, Jean
Sent: Tuesday, February 07, 2006 11:11 AM
To: [purged]
Subject: RE: Good clinical practice

Dear [purged]:

Thank you for your inquiry with regard to definitions for good clinical practice (GCP) and standard operating procedures (SOPs).

Both of these terms are defined in the ICH GCP consolidated guidance available at http://www.fda.gov/cder/guidance/959fnl.pdf, the only guidance with regard to GCP with which FDA presently concurs. While this guidance states that it is specific to pharmaceutical studies, FDA believes the general sections of this document are applicable to all clinical studies.

GCP is defined in this guidance at 1.24 as:

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

SOPs are defined at 1.55 as:

Detailed, written instructions to achieve uniformity of the performance of a specific function.

Hope this is the information you need.

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: Monday, February 06, 2006 3:44 PM
To: gcpquestions@oc.fda.gov
Subject: Good clinical practice

Dear Sir/Madam,

I have an interview in a few weeks time which will have aspects of good
clincal practice and standard operating procedures in it.

I wonder if you have a definition of these two phrases and/or any examples
of either?

Many thanks

[purged]