From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, September 12, 2006 1:55 PM
To: [purged]
Subject: RE: Follow-up on request for assistance in clarifying the difference between FDA and ICH GCPs

Dear Ms. [purged]:

This is in response to your e-mails dated 9/12/06 and 9/7/06.

In answer to your question, sponsors, monitors, clinical investigators, and contract research organizations in that conduct or assist in the conduct of clinical studies for drugs, biologics, and medical devices in the United States must comply with the Food and Drug Administration's (FDA's) regulations for the conduct of such studies. Likewise, Institutional Review Boards (IRBs) that review and approve these studies must also comply with FDA's regulatory requirements. FDA's regulations are found in Title 21 of the Code of Federal Regulations (21 CFR). I have listed the specific sections that apply to clinical investigations below:

21 CFR 50: Protection of Human Subjects (Informed Consent)
21 CFR 56: Institutional Review Boards
21 CFR 54: Financial Disclosure by Clinical Investigators
21 CFR 312: Investigational New Drug Application
21 CFR 320: Bioavailability and Bioequivalence Requirements
21 CFR 812: Investigational Device Exemptions

Regulations are enforceable under the Federal Food, Drug and Cosmetic Act. As part of FDA's bioresearch monitoring program, FDA sends its own field investigators out to inspect sponsors, monitors, clinical investigators, and IRBs to ensure that these establishments have followed FDA's regulations during the conduct of the studies. Should FDA's field investigators uncover any deviations from the regulations, then FDA can take enforcement action. Enforcement actions include sending a regulatory letter to the firm, and administrative sanctions (e.g., disqualification of a clinical investigator; requiring an IRB to withhold approval of new studies or directing that no new subjects be added to ongoing studies). FDA may also refer cases for criminal prosecution.

FDA guidance, on the other hand, is NOT enforceable. Guidance represents FDA's current thinking on a particular topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Alternative approaches may be used if the approach satisfies the requirements of the applicable statutes and regulations.

With respect to ICH, I can tell you that FDA has been part of the ICH process since its inception. The ICH E6, Good Clinical Practice: Consolidated Guidance, has been adopted as official agency guidance. When ICH E6 was developed, it was agreed that there might be differences in some national GCP requirements between the U.S., the EU, and Japan. For example, ethics committee requirements were more detailed in the U.S. than the EU and Japan --- and EU and Japanese representatives did not believe at that time that they were able to adopt all U.S. regulatory requirements for IRBs/IECs as part of ICH.

The bottom line, then, is that ICH E6 has been adopted as guidance in the U.S. U.S. regulatory requirements (i.e., FDA regulations) must be met for studies conducted in the United States; in some areas, these are more detailed [and, in fact, in a few areas less detailed --- for example, FDA regulations do not address clinical trial auditing] than ICH E6.

Links to FDA's GCP regulations and guidance can be found on FDA's GCP webpage: http://www.fda.gov/oc/gcp .

I hope this helps to clear up your confusion.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 14-B17
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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.

From: [purged]
Sent: Tuesday, September 12, 2006 10:46 AM
To: OC GCP Questions
Subject: Follow-up on request for assistance in clarifying the difference betweeen FDA and ICH GCPs

Dear Sir or Madam,

I am writing to follow up on my September 7th inquiry in which I asked for clarification of the differences between the GCPs developed by the FDA as compared with those created by the ICH (see my message below). I would greatly appreciate it if you could respond to my email at your earliest convenience.

Thank you very much.

Kind regards,

[purged]

-----Original Message-----
From: [purged]
Sent: Thursday, September 07, 2006 2:48 PM
To: 'gcp.questions@fda.hhs.gov'
Subject: Request for assistance in clarifying the difference betweeen FDA and ICH GCPs

Dear Sir or Madam:

I am an independent research librarian who supports the information needs of regulatory affairs professionals in the healthcare industry. I am currently conducting research on the difference between the GCPs developed by the FDA as compared with those created by the ICH. I would appreciate any clarification you can provide on this issue. If there is a difference between the two sets of standards, I would also like to know which standards a sponsor should comply if a clinical trial is being conducted in the US.

Thank you very much in advance for your time and assistance on this matter.

Kind regards,

[purged]