From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, March 11, 2005 3:11 PM
To: [purged]
Subject: RE: Bioresearch Monitoring Program

Dear Mr. [purged]:

Your e-mail to the GCP Questions e-mail account was forwarded to me for a response.

Actually, the Food and Drug Administration's various Centers (Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition) issue assignments for inspections of institutional review boards (IRBs) and other bioresearch monitoring (BIMO) facilities (e.g., clinical investigators, sponsors, monitors, contract research organizations). The field investigators of FDA's Office of Regulatory Affairs (ORA) actually conduct those inspections. [I do not know the number of investigators that ORA dedicates to conducting BIMO investigations, but I have a call in to that office to find out. In the interim, I thought I would forward the information that I do have, in case you are close to your deadline. Once I hear from ORA, I'll let you know their answer.]

My office, the Good Clinical Practice Program, coordinates FDA policy related to good clinical practice (GCP) and human subject protection (HSP); provides leadership and direction through the administration of FDA's HSP/GCP Steering Committee; works with ORA to coordinate the GCP/HSP portion of FDA's BIMO program; contributes to international GCP harmonization activities; plans and conducts training and outreach programs; and serves as a liaison with the HHS Office of Human Research Protection (OHRP) and other federal agencies and external stakeholders committed to the protection of human research participants.

I have attached a couple of PowerPoint slides that depict findings related to IRB inspections in 2003. Let me know if you have questions about interpreting them.

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)
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Rockville, MD 20857

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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: Wednesday, March 02, 2005 11:52 AM
To: gcpquestions@oc.fda.gov
Subject: Bioresearch Monitoring Program

I am writing to you to inquire about the ORA's Bioresearch Monitoring Program. I am working on an assignment for my Monitoring Clinical Research class as [purged]. It is my understanding that your office conducts audits of IRBs to ensure compliance with federal regulations. I would like to know how many audits were conducted in 2003 and 2004 and also how many auditors the Program employs.

Thank you in advance for your time and assistance.
[purged]

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