From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, November 07, 2006 10:34 AM
To: [purged]
Subject: RE: guidelines about facilities for phase 1 clinical trials

Dear [purged]:

Your e-mail requesting guidance on physiological monitoring of subjects who are participating in a Phase 1 study was forwarded to me for a response. Unfortunately, FDA's guidance on "Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-derived Products" [http://www.fda.gov/cder/guidance/clin2.pdf] does not address this issue, nor could I find any other relevant guidance on our website.

Thus, I suggest that you contact the review division responsible for reviewing the drug under study directly, as they may be able to provide you with specific advice as to how the subjects should be monitored. If you need assistance in obtaining the telephone number for that review division, let me know.

I'm sorry I cannot be more helpful.

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
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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.

From: [purged]
Sent: Monday, October 16, 2006 11:43 AM
To: OC GCP Questions
Subject: guidelines about facilities for phase 1 clinical trials

Do you have the guidelines on the physiological monitoring on subjects in a phase 1 unit and how the environment should be monitored?
Thanks very much.

[purged]