Question regarding Phase I trialsFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, December 12, 2006 4:08 PM
To: [purged]
Subject: RE: Question regarding Phase I trials

Dear [purged]:

FDA does not have any regulations pertaining specifically to Phase 1 trials; that is, sponsors and investigators who are involved in Phase 1 trials would be expected to comply with all of the applicable regulations that apply to clinical trials generally, as set forth in 21 CFR 312 (Investigational New Drug Application) or 812 (Investigational Device Exemptions). In addition, they would be expected to comply with the applicable, related regulations contained in 21 CFR 50 (Informed Consent) and 21 CFR 56 (Institutional Review Boards).

You may recall seeing news reports from a few years ago about a Phase 1 trial in which a healthy subject died. Because this is often the first time that a drug is being introduced into human subjects, these studies pose their own risks and challenges. Bear in mind that the primary objective of Phase 1 trials is safety (i.e., to identify common toxicities of the drug under study, and to establish a safe dose and schedule for administration). Thus, it is critical to ensure that your site has appropriate staff, well-qualified by training and experience, as experts who will carry out the study and supervise the administration of the test article, and who would be able to respond to any emergency situations that might arise.

I would also suggest that you might want to obtain legal advice regarding state or local laws or regulations (e.g., building codes, health and safety standards) that may apply to hospitals, clinics, medical offices and/or other facilities where Phase 1 studies are carried out.

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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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: Friday, December 01, 2006 10:15 AM
To: Lee, Bonnie
Subject: Question regarding Phase I trials

Good day Bonnie,
I've been trying to navigate the FDA's website to find the answer to my question, but I am not having any luck. I was wondering if you could help me out? My question is: If a site is going to conduct a Phase I trial, does this site have to follow any special requirements, or is there specific regulations regarding this issue? If you could point me in the right direction for this answer, I would be much appreciative!! Thank you!!
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