From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, December 27, 2006 12:14 PM
To: [Redacted]
Subject: RE: Dose Administration

Dear [Redacted]:

Per FDA's regulations at 21 CFR 312.60, "An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; FOR PROTECTING THE RIGHTS, SAFETY, AND WELFARE OF SUBJECTS UNDER THE INVESTIGATOR'S CARE; and for the control of drugs under investigation." [Emphasis added.]

In other words, it is the responsibility of the investigator to ensure that each subject can still appropriately and safely receive the investigational drug each time the drug is to be administered. Part of that decision would rest on evaluation of the subject's experience(s) related to the previous day's administration of the drug. Or, there may be toxicity or other concerns, related to the manner of administration that may require close observation of the subject when the drug is given. Depending on the subject's experience, there may be a need to provide ameliorating medication, suspend giving the investigational drug, or treat some reaction (and report it) before going forward. While the regulations don't specifically state how best to accomplish this, the investigator would remain responsible for the subject's welfare.

It's not altogether clear what prompted you to ask the question, but I hope this helps clarify the issues for you.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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: [Redacted]
Sent: Wednesday, December 20, 2006 8:45 PM
To: OC GCP Questions
Subject: Dose Administration

In a clinical trial if dose administration happen more than once to a single subject, should the investigator be present at each dosing session to check the

subject suitability before dosing? Or is it only necessary for him to be present at the first day of dosing?