From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, March 30, 2004 11:12 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE:

Dear Mr. [Redacted]:

Your questions about informed consent forms to CDER DRUGINFO were forwarded to me for a response.

You asked, "1. Is it an US FDA (CFR) recommendation that the ICF should include a statement that the investigator would contact the patient's family physician?"

Answer: The short answer is no; this is not required under FDA regulations, nor is it specifically addressed in FDA guidance documents. However, the ICH E-6 "Good Clinical Practice: Consolidated Guidance, Medical Care of Trial Subjects" (Subsection 4.3.3) states: "It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed." You may view the entire text of the ICH E-6 guidance, by visiting FDA's Good Clinical Practice webpage at http://www.fda.gov/oc/gcp.

2. Is it an US FDA (CFR) recommendation that the ICF should include the contact details of the IRB chairperson for the study patient to contact in case he / she has queries with regard to his / her rights as a study patient?

Answer: FDA's regulations require contacts for questions about the research, the research subject's rights, and in case of a research-related injury (21 CFR 50.25(a)(7)). The regulations do not specify whom to contact. The same person may be listed for all three. However, FDA and most IRBs believe it is better to name a knowledgeable person other than the clinical investigator as the contact for study subject rights. Having the clinical investigator as the only contact may inhibit subjects from reporting concerns and/or possible abuses.

You will find the entire text of the FDA regulations pertaining to the conduct of clinical investigations and human subject protection, as well as other references on our webpage also.

I hope this is 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 9C24
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.

-----Original Message-----
From: CDER DRUGINFO
Sent: Monday, March 29, 2004 6:22 PM
To: OC GCP Questions
Subject: FW:

-----Original Message-----
From: [Redacted]
Sent: Monday, March 29, 2004 10:09 AM
To: CDER DRUGINFO
Subject:

Sir,

Let me introduce myself. I am [Redacted].

I have two queries for which I have been trying to search the FDA website but haven't been able to locate the clarifications.

1. Is it an US FDA (CFR) recommendation that the ICF should include a statement that the investigator would contact the patient's family physician
2. Is it an US FDA (CFR) recommendation that the ICF should include the contact details of the IRB chairperson for the study patient to contact in case he / she has queries with regard to his / her rights as a study patient.

Can you please provide me the CRF section numbers where I can look up.

Thanks and regards,

[Redacted]