From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, July 11, 2005 1:46 PM
To: [purged]
Subject: RE 1572 and Informed Consent

Dear [purged]:

Both of your e-mails to the GCP Questions e-mail account and your e-mail to CDER DRUG INFOR, were forwarded to me for a response.

Question 1: You asked, "Is it essential that we always use the most recent version of the form, (03/05) as on top it is mentioned "Expiration Date: January 31, 2006"? If yes, which action should we take in case we didn't do this? Is there a way I can receive automatically a message that a new version has been created?"

Answer 1: The date on the form refers to the Office of Management and Budget's (OMB's) time frame during which FDA may collect information contained in this form. FDA does not expect sponsors to ask clinical investigators to routinely "update" forms previously submitted simply because the OMB expiration date has changed.

There is no way to automatically be notified that a new version of the 1572 has been created. I would suggest, however, that at the time you need to complete a new form, you visit FDA's Forms Distribution Page (http://www.fda.gov/opacom/morechoices/fdaforms/cder.html) and download the most recent version posted there.

Question 2: You asked, "Patients are included in a long-term follow-up study in which they have the opportunity to continue to take the study medication until marketing authorization. As the marketing approval is postponed, this will have implications on further treatment. To avoid that the patient will need to be put on a treatment interruption, there is a back-up plan. (patient continues without being in an actual trial). An addendum to the SIS/ICF is now being created. Is there any specific information this consent should contain???????"

Answer 2: Your statement that a patient "continues without being in an actual trial," is not correct. Because the product is investigational (and there is no certainty that a particular product will indeed be approved), subjects who continue to receive an investigational product are still considered to be participating in a clinical trial. The practice you have described would probably qualify as an open label protocol or a treatment IND. I have pasted

descriptions from FDA's Information Sheets about "Open Label Protocols" and "Treatment INDs" into this e-mail for your convenience.

"OPEN LABEL PROTOCOL OR OPEN PROTOCOL IND
"These are usually uncontrolled studies, carried out to obtain additional safety data (Phase 3 studies). They are typically used when the controlled trial has ended and treatment is continued so that the subjects and the controls may continue to receive the benefits of the investigational drug until marketing approval is obtained. These studies require prospective Institutional Review Board (IRB) review and informed consent.
"TREATMENT IND
"A treatment IND [21 CFR 312.34 and 312.35] is a mechanism for providing eligible subjects with investigational drugs for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. A treatment IND may be granted after sufficient data have been collected to show that the drug "may be effective" and does not have unreasonable risks. Because data related to safety and side effects are collected, treatment INDs also serve to expand the body of knowledge about the drug.

"There are four requirements that must be met before a treatment IND can be issued: 1) the drug is intended to treat a serious or immediately life-threatening disease; 2) there is no satisfactory alternative treatment available; 3) the drug is already under investigation, or trials have been completed; and 4) the trial sponsor is actively pursuing marketing approval.
"Treatment IND studies require prospective IRB review and informed consent. A sponsor may apply for a waiver of local IRB review under a treatment IND if it can be shown to be in the best interest of the subjects, and if a satisfactory alternate mechanism for assuring the protection of human subjects is available, e.g., review by a central IRB. Such a waiver does not apply to the informed consent requirement. An IRB may still opt to review a study even if FDA has granted a waiver. "

As for what the informed consent document should include, it would need to contain all of the information required by 21 CFR 50.25. The major difference between an informed consent document used earlier during the study and an informed consent document that would allow subjects to continue to have access to the investigational product would probably be that the sponsor would be more likely to have, and able to include, additional information related to the product's efficacy and safety.

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)
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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: Thursday, July 07, 2005 4:31 AM
To: gcpquestions@oc.fda.gov
Subject: 1572 question

Dear,

I have a question with regard to the form 1572.

Is it essential that we always use the most recent version of the form, (03/05) as on top it is mentioned "Expiration Date: January 31, 2006".

If yes, which action should we take in case we didn't do this?
Is there a way I can receive automatically a message that a new version has been created?

Thanks for your response

Kind Regards
[purged]

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and to delete the email and all attachments from your system.

[purged]

-----Original Message-----
From: [purged]
Sent: Thursday, July 07, 2005 2:54 AM
To: gcpquestions@oc.fda.gov
Subject: Importance

Consider the following case:
Patients are included in a long-term follow-up study in which they have the opportunity to continue to take the study medication until marketing authorization.
As the marketing approval is postponed, this will have implications on further treatment. To avoid that the patient will need to be put on a treatment interruption, there is a back-up plan. (patient continues without being in an actual trial). An addendum to the SIS/ICF is now being created.
Is there any specific information this consent should contain???????
Is it possible to answer this without the shortest delay.
Thanks.
[purged]

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