From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, September 11, 2006 11:27 AM
To: [purged]
Subject: RE: CRF

Dear [purged]:

Thank you for the clarification.

There is no specific requirement in FDA's regulations to create an annotated case report form (CRF), nor does FDA's official guidance, the ICH E6, "Good Clinical Practice: Consolidated Guidance," mention "annotated" CRFs.

Sponsors may, of course, choose to develop an annotated CRF, for example, to ensure that all information captured on the forms is entered consistently into the database. While this would be in keeping with good clinical practice, there is no specific regulatory requirement to develop an annotated CRF.

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 14-B17
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.

From: [purged]
Sent: Monday, September 11, 2006 4:26 AM
To: OC GCP Questions
Subject: RE: CRF

Dear Carolyn,

Many thanks for your reply. An annotated CRF may be created as part of the database set up for a study. It is a blank copy of the study case report form that is annotated with the corresponding data set names and variable names that are created in the study database.

Kind regards,
[purged]

> From: gcp.questions@fda.hhs.gov
> To: amber_neve@hotmail.com
> Subject: RE: CRF
> Date: Wed, 6 Sep 2006 15:33:41 -0400
>
> Dear Ms. [purged]:
>
> Your question was forwarded to me for a response, but I need more
> information. Can you explain what you mean by "annotated" Case Report
> Form?
>
> 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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> Phone: 301/827-3340
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> 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, August 31, 2006 8:15 AM
> To: CDER DRUG INFO
> Subject: CRF
>
>
>
> Name: [purged]
>
> E-Mail: [purged]
>
> Comments: Please could you advise me whether an annotated CRF should be
> created for every drug trial?
>
>

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