From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, April 27, 2005 11:13 AM
To: [purged]
Subject: RE: FDA Form 1572

Dear Ms. [purged]:

The Food and Drug Administration (FDA) regulations do not specify that the Form FDA 1572 must be double sided, nor does FDA have a set policy on this. It's equally acceptable to use a double-sided form as it is to use a form printed on two pages. I'd recommend, however, that if a two page form is used, the pages should be stapled together so there is no doubt as to the form a particular investigator signed.

I hope this clears up your confusion.

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: [purged]
Sent: Tuesday, April 26, 2005 4:18 PM
To: GCPQuestions@OC.FDA.GOV
Subject: FDA Form 1572

One of our study coordinators recently attended a clinical research
coordinator workshop sponsored by [purged] and was told by
one of the workshop trainers that the FDA Form 1572 must be double-sided
and not printed on two pages. Is this an FDA policy and if so, could
you please refer me to the policy # ?

Thanks,
[purged]
4/26/05

[purged]