From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, September 07, 2006 10:54 AM
To: **[Redacted]**
Cc: CDER DRUG INFO
Subject: RE: 1572

Dear Ms. **[Redacted]**:

Your question about whether an attachment to a 1572 needs to be signed and dated was forwarded to me for a response.

There is no regulatory requirement that an attachment to a 1572 be signed and dated. Thus, sponsors and clinical investigator sites are free to develop their own procedures for dating (and updating) such attachments.

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.

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, August 30, 2006 11:37 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: I work for a CRO and in one of my trials, i have encountered a unique issue that i would like to get resolved.

The research site submitted a Form FDA 1572 with an attachment listing all of the research sites and laboratory locations. Does the attachment have to be

signed and dated? if so, does the date the attachment was signed have to match the date on the Form FDA 1572?

Thanks!