From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, December 26, 2006 9:12 AM
To: **[Redacted]**
Subject: RE: 1572 completion

Dear Ms. **[Redacted]**:

The 1572 can be printed as a double-sided document or as a 2-page document; either one is acceptable. We recommend stapling the pages together if a site prints it on 2 pages, so that there is no question about the contents of the form that the investigator signs.

The investigator should sign the form and provide the original to the sponsor, per 21 CFR 312.53(c). The regulations are silent with respect to maintaining a copy at the investigator's site, but we would encourage each investigator to do so, thereby ensuring that each investigator has a record of the commitments that he/she is making with respect to conducting the study (see 21 CFR 312.53(c)(1)(vi) and (vii)).

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
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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.

From: **[Redacted]**
Sent: Saturday, December 23, 2006 2:50 PM
To: OC GCP Questions
Subject: 1572 completion

Is the 1572 supposed to be a separate 2 page document or a double-sided document? How should it be signed/dated and filed at sites?

[Redacted]