From: Beers Block, Patricia
Sent: Wednesday, December 13, 2006 6:52 AM
To: '**[Redacted]**
Subject: RE: 1572

Dear Ms. **[Redacted]** ,

We are frequently asked questions about how the 1572 should be completed and maintained; unfortunately, it's a question for which there is limited written guidance at this time. An important thing to remember is that one of the main purposes of the 1572 is to provide the sponsor with information about the clinical site and investigator qualifications which will enable the sponsor to establish and document that the investigator and site are qualified to conduct the study. The sponsor will need one signed version from each investigator charged with conducting/supervising the clinical trial. Rather than insisting that the investigator sign two documents, a better practice might be for your site to make a photocopy of the original, signed 1572 for your records.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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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: Wednesday, December 06, 2006 5:30 PM
To: OC GCP Questions
Subject: 1572

Some of my colleagues have been having two copies of the 1572 form signed by the PI, keeping one in the Regulatory binder and sending one to Sponsor. Is this an acceptable practice?

[Redacted]