From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, April 13, 2004 1:06 PM
To: [Redacted]
Subject: RE: Query regarding Informed Consent Form

Dear [Redacted],

Thank you for your inquiry. I apologize for my delay in replying; I was out of the office several days last week and am only now getting to reply to your message.

The regulations governing the conduct of clinical studies and informed consent do not prohibit the signing and dating by the subject of two identical informed consent documents. I am curious, though, as to why this would be a necessary practice. The FDA has long accepted identical copies (known as "certified" copies since the publication of the ICH E6 Consolidated Guidance and the FDA Guidance for Industry Computerized Systems used in Clinical Trial) of records, including the informed consent document, as representative of the original documents. Our sanctioning this practice may very well be based on the same reason(s) you have elected to have subjects sign two original, identical informed consent documents. That is, to make certain records are available for the sponsor's and the clinical investigator's/staff's use. FDA understands that some hospitals engage in the practice of preparing microfilm/microfiche of medical records while archiving the original records. Likewise, records may be stored at kept by both the sponsor and the clinical investigator, necessitating the creation of a copy. FDA's position on this has been that it will accept the copy version of the record provided the copy of original information has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original.

I hope this information is helpful to you. Should you have any additional questions, please feel free to call or write our office again.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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: Friday, April 02, 2004 11:47 PM
To: GCPQuestions@OC.FDA.GOV

Subject: Query regarding Informed Consent Form

Is it acceptable to get the Informed Consent Form signed on two originals wherein one original is retained by the patient and the other original is kept in the hospital file? Please clarify.

Looking forward to a reply.

Thanks and best regards,
[Redacted]