From: Lepay, David on behalf of OC GCP Questions
Sent: Tuesday, December 30, 2003 12:38 PM
To: [Redacted]
Subject: RE: FDA Comments

Dear Ms. [Redacted]:
There is no FDA regulatory requirement for the investigator to sign or date the Informed Consent. With use of a Short Form, there are requirements for additional signatures; but I am assuming your query is not directed at those rare situations where a Short Form is used.

As you note, ICH does mention a signature of the person conducting the informed consent process. But ICH E6 is guidance in the U.S. and not an FDA regulatory requirement (and therefore not enforceable in the U.S.).

I hope this answers your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: [Redacted]
Sent: Tuesday, December 30, 2003 11:09 AM
To: 'CDER DRUGINFO'; gcpquestions@oc.fda.gov
Subject: RE: FDA Comments

Thanks for responding.

Yes, I am familiar with these already. Please note that my question is about the investigator having to sign the informed consent. Only ICH mentions signatures but the signatures are for the subject and the person conducting the consent process (which is typically delegated to someone and not the investigator). This question is in reference to the investigator having to sign also before the subject begins partipation.

Where in the FDA regs is this stated?

-----Original Message-----
From: CDER DRUGINFO [mailto:DRUGINFO@cder.fda.gov]
Sent: Thursday, December 18, 2003 1:40 PM
To: [Redacted]
Subject: RE: FDA Comments

Thank you for your message to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), one of the five centers within

the Food and Drug Administration (FDA).

Please refer to our Good Clinical Practice in FDA-Regulated Clinical Trials website at http://www.fda.gov/oc/gcp/ . If after reviewing this information you still have questions, please contact:

Email: gcpquestions@oc.fda.gov
Telephone: 301-827-3340
Facsimile: 301-827-1169

Sincerely,
Drug Information CY

-----Original Message-----
From: [Redacted]

Sent: Wednesday, December 17, 2003 4:04 PM
To: druginfo@cder.fda.gov
Subject: FDA Comments

Name: [Redacted]

Comments: I cannot find documentation to support the requirement that investigators have to sign the informed consent form before a subject participates in a trial. ICH GCP states that the subject and the person conducting the informed consent process needs to sign/date before particpating but what are the regulations for the investigator given that this task is typically delegated to someone else. Thanks.