From: Lepay, David on behalf of OC GCP Questions
Sent: Monday, March 25, 2002 10:46 AM
To: [purged]
Subject: RE: Informed consents

Dear Ms. [purged]:
FDA Informed Consent regulations to not require that the investigator sign or date the Informed Consent statement. Rather, the Informed Consent must be signed and date BY THE STUDY SUBJECT.

ICH Good Clinical Practice standards, on the other hand, do recommend that the investigator sign the Informed Consent form; as a result, this provisions is often included in clinical trial protocols and SOP's. ICH GCP is official FDA guidance, but is not regulation in the United States. FDA would only enforce a provision for investigator signatures if this was incorporated (voluntarily) as part of a study protocol and was subsequently not followed (i.e., as a failure to follow the study protocol). The same clearly applies to a dated investigator signature: it is not an FDA regulatory requirement (but if included as a requirement in the protocol and/or by the IRB and was not followed, FDA could cite this).

I hope this answers your query without creating unnecessary confusion.

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

-----Original Message-----
From: [purged]
Sent: Friday, March 22, 2002 12:21 PM
To: gcpquestions@oc.fda.gov
Subject: Informed consents

Hello, i'm unable to find a clear answer....

Does the investigator need to date his signature on an informed consent form?
Per FDA regulations or is it left up to the individual IRB?

Thank you,

[purged]