From: Lepay, David on behalf of OC GCP Questions
Sent: Saturday, October 18, 2003 6:31 AM
To: [Redacted]
Subject: RE: Investigator's Signature on Consent

Dear Ms. [Redacted]:

There is no FDA regulation that requires the investigator to sign and date the informed consent document. This may be part of an SOP on the part of either the sponsor or institution(s) --- in which case we would expect the SOP to be followed. Also, the ICH Consolidated Good Clinical Practice guideline (which is official FDA guidance but not regulation) suggests that the written informed consent form should also be signed and personally dated "by the person who conducted the informed consent discussion": see ICH GCP Guideline section 4.8.8, accessible from our GCP website www.fda.gov/oc/gcp through the link to "Guidances and Information Sheets" and hence to ICH E6.

Please note also that if a short form written consent document is used (as described in 21 CFR 50.27), there must be a witness to the oral presentation: in this case, the witness shall sign both the short form and a copy of the summary and the person actually obtaining the consent shall sign a copy of the summary.

I hope this addresses 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

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, October 17, 2003 11:09 AM
To: gcpquestions@oc.fda.gov
Subject: Investigator's Signature on Consent

I am trying to research regulations and guidelines regarding the Investigator's signature on the informed consent document (requirements, dating/timing, etc.). I would appreciate any reference to go to for this information. I would like the printed material to back details/facts. I have information regarding subject signature & date and the signature & date of person obtaining consent, but not for Investigators signature & date as required by some IRBs.

Thank You,
[Redacted]