From: Toth-Allen, Jean
Sent: Friday, March 03, 2006 12:18 PM
To: [purged]
Subject: RE: Wet signatures

Dear [purged]:

Thank you for your inquiry about signature maintenance.

There is no FDA regulation in this regard. However, the ICH GCP guidance document, available at http://www.fda.gov/cder/guidance/959fnl.pdf, does include maintenance of a "Signature sheet" among the documents suggested for the actual clinical conduct of the trial - see 8.3.24. While this is not a requirement, this guidance document has been officially adopted by FDA and thus represents the agency's current thinking in this regard.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
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.

From: [purged]
Sent: Wednesday, March 01, 2006 2:58 PM
To: OC GCP Questions
Subject: Wet signatures

Is there a requirement that wet signatures be maintained at the Sponsor, Investigative site or both etc…

[purged]