From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, April 02, 2003 3:08 PM
To: [Redacted]
Subject: RE: Initials on consent forms

Dear [Redacted],

I can only speak to the requirements of informed consent that relate to FDA regulated trials. Our regulations (found at 21 CFR 50.27(a)) governing informed consent state:

"informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent."

You can find a copy of our regulations at the following url:
http://www.fda.gov/oc/gcp/regulations.html

I hope this is helpful to you.

Most sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-3340

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 nor otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, March 25, 2003 6:04 PM
To: gcpquestions@oc.fda.gov
Subject: Initials on consent forms

Hi FDA/GCP Staff
We are having a debate in our office as to whether non-FDA regulated trials need to initial consent forms on each page. It is my recollection that it is a GCP requirement--the intialing--though I can't find the reference. Can you direct me to where I might find it? Thanks for your help. [Redacted]