From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, March 03, 2006 3:03 PM
To: [purged]
Subject: RE: GCP

Hi [purged], It is a guidance; it is not a regulatory requirement. As with all guidances, it does not establish legally enforceable responsibilities. Instead, it describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. I hope this is helpful to you and that you are well and looking forward to the spring weather that I'm hoping is just around the corner!

My best,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Note new email address: Bonnie.Lee@FDA.HHS.GOV
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: [purged]
Sent: Friday, March 03, 2006 2:51 PM
To: OC GCP Questions
Subject: GCP

Hi
This is a basic question.
I've always been under the impression that the ICH/GCP document
was a guidance and was not a regulatory requirement from FDA.
Is that not so?
[purged]