From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, December 10, 2002 3:40 PM
To: [purged]
Subject: RE: Continuing informed consent documentation

Dear [purged], As you can see, I'm trying to respond to my outstanding e-mails...again, my apologies for the delay in getting back to you. Although we all recognize the importance of informed consent as a continuing process, the focus of the documentation requirements in the regulations is on initial, rather than continuing, informed consent. That being said, we also frequently comment that if something is not documented, then you cannot know that it happened. Thus, if, as the regulations require, you provided a subject with, for example, "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation", it would seem reasonable that there would be some form of documentation that this occurred..it may be, for example, in a formal consent form or in a notation in the subject's medical records. It's also important to remember that State law plays an important part in determining what is required in terms of informed consent as well as its documentation. I am not aware of what Georgia law says. What your IRB auditing program is requesting is reasonable and certainly good practice--there is nothing to say that the IRB can only require what is in the regulations--you can and should exceed our regulatory requirements. I would respond to those investigators who ask for "chapter and verse" accordingly.

If you go to the ICH guidance document at:
http://www.fda.gov/cder/guidance/959fnl.pdf and read sections 4.8.2. and 4.8.11,I think that you will the language you seek to support your policy.

I hope this is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [purged]
Sent: Monday, October 21, 2002 11:23 AM
To: gcpquestions@oc.fda.gov

Cc: Shelia White
Subject: Continuing informed consent documentation

Good morning.
Our IRB auditing program is now its toddler years. As such, we are focusing on the informed consent process. One area that we address in our audits is the process of continuing informed consent. We are able to locate the initial documentation of informed consent but the medical record often doesn't notate the continuing informed consent. We request that the investigators document this information. Some of the investigators request the "chapter and verse" for this requirement.

We have searched the sites as best we can and were able to find some things but nothing absolutely concrete. Is there an FDA or ICH guideline or regulation that could help us with this? As always, thanks for your help!

[purged]