From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 16, 2002 3:28 PM
To: [purged]
Subject: RE: Risk versus benefit

Dear [purged], I apologize for the delay in getting back to you. Your common sense reaction is the right reaction to have. Screening tests that are done either as part of common medical practice or to determine eligibility for a trial do not generally require informed consent. Further, it would certainly be unethical to repeat these trials, if they had already been done, unless there was some medical reason to repeat them. You do NOT need to repeat the tests. Rather, you need to keep the test results and they become a part of the case history which establishes that the patient was eligible to become a subject in a trial.

I think this is another example of the appropriateness of questioning the statement that "FDA requires....." particularly when subjects would be put at additional risk. Thanks for asking the question and doubting the statement.....

Bonnie

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-----Original Message-----
From: [purged]
Sent: Thursday, October 03, 2002 4:01 PM
To: GCPQuestions@OC.FDA.GOV
Subject: Risk versus benefit

The following scenario came across my email earlier this week from a research coordinator on our campus:

"The study requires some labs to confirm suitability (SMA-6, CBC, pregnancy test) that may have just been done or certainly would have been done within a

few hours of the time we see the patient in the ICU/CCU for enrollment in the study. According to the sponsor and the CRO, it is an FDA regulation that no information on the patient, specifically lab testing when we raised the issue at the Investigator Meeting, can be used as part of screening for suitability since the patient had not signed the study consent form at the time the tests were performed. They say we MUST repeat them or we are in violation of FDA regs."

I reviewed the information available at http://www.fda.gov/oc/ohrt/irbs/informedconsent.html as well as the applicable CFR and it is my feeling that if the labs were completed as part of the routine care that also happen to fulfill screening requirements, then those labs should be used instead of sticking the subject again. Can we get some guidance on this issue please?

Thank you for your attention and we look forward to hearing from you.

[purged]