From: Toth-Allen, Jean
Sent: Thursday, July 13, 2006 12:39 PM
To: [purged]
Subject: Clinical trial - screening

Dear Ms. [purged]:

Thank you for your inquiry regarding screening tests. Please excuse my delay in responding.

FDA has consistently stated that testing performed solely as screening for entry into a clinical trial is part of that clinical trial and cannot be performed prior to obtaining the potential subject's informed consent. There is written guidance in this regard in the FDA Information Sheets at http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening.

Conditions can be arranged, however, such that a potential subject will receive and sign a simple screening informed consent document prior to any actions taken as part of such screening procedures. The reference cited above includes details with regard to such informed consent documents and IRB review and approval of them. To avoid a double trip to your facility by those at a considerable distance, you can have the consent form available on an internet site or mail or FAX the form to the individuals selected. Since fasting is part of the screening procedure, a mechanism needs to be in place for your receipt of the signed informed consent document (by FAX or mail) prior to the subjects initiating their fasting for the screening procedure.

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.

----Original Message-----
From: [purged]
Sent: Friday, June 30, 2006 1:59 PM
To: CDER DRUG INFO
Subject: Clinical trial - screening

Name: [purged]

E-Mail: [purged]

Comments: we are clinical research site. We have recently had a sponsor audit and this issue has come up again: When a patient is asked to come in for a screening visit for a clinical trial, we ask them to come in fasting (if the protocol requires it). The auditor pointed out that we cannot do this as it is something that the patient does for the study prior to signing the consent form. We have an SOP at our site that this is acceptable. We have also had [purged] IRB address the issue too. They felt that it was acceptable to ask the patient to do this. Many of our patients come from some distance and it would be a burden for them to return the next day for the labs to be drawn. We also instruct our diabetic patients to go ahead and eat something if they are hypoglycemic that morning. Please advise us on how the FDA feels on this issue and how an FDA auditor would call this. Thanks, [purged]