From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, March 14, 2003 2:03 PM
To: [Redacted]
Subject: RE: screening tests prior to study enrollment

Dear [Redacted] ,

The examples that you have given in your email (below) are acceptable examples of procedures for which one can ask subjects about without documenting informed consent. These procedures involve minimal risk of harm to subjects and are not procedures for which written consent is normally required outside of the research context; further it would be impossible (or possible impracticable) to expect a potential subject to come to an appointment and wait until they have a full bladder or sit there until food they have eaten has metabolized. I hope this is helpful to you.

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

> -----Original Message-----
> **From:** [Redacted]
> **Sent:** Wednesday, March 12, 2003 11:24 AM
> **To:** gcpquestions@oc.fda.gov
> **Subject:** screening tests prior to study enrollment
>
> To Whom It May Concern:
>
> I have a question regarding the above topic. According to the "FDA Information Sheets," informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility. I understand that this would include any wash-outs or blood draws performed only for the research purpose of determining eligibility. I would appreciate if someone could comment on the following scenario:
>
> A potential subject calls an investigator and is interested in a study based on some limited criteria. The investigator sets up an appointment with the individual to do a screening to determine eligibility. When the subject arrives, the informed consent process takes place. Can the investigator, over the phone, prior to the appointment ask the subject to fast before they come in because blood will be drawn if the subject consents? What about asking the subject to have a full bladder when they come in in case a urine test has to be done to determine eligibility (and, again, the urine test will be part of the screening process and the subject will consent prior to it).
>
> Are the above examples acceptable (i.e., fasting and having a full bladder) to do prior to signing an informed consent for screening?
>
> Any advice you could provide would be appreciated. Many thanks,
> [Redacted]