From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Thursday, February 20, 2003 8:59 AM
To: [Redacted]
Subject: RE: screening labs for patients enrolling on study

Dear [Redacted],

We have guidance in the form of an information sheet on this exact topic. You will find it posted on our web site at http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening . In summary, informed consent must be obtained for any lab tests which are performed solely for study purposes. I would recommend consulting with your IRB on the possibility of a generic consent form. If you can't link to the guidance, let me know and I'll embed a copy in an e-mail.
Hope this is helpful.
Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Program

-----Original Message-----
From: [Redacted]
Sent: Thursday, February 13, 2003 11:57 AM
To: gcpquestions@oc.fda.gov
Subject: screening labs for patients enrolling on study

Where in the GCP guidelines does it address consenting patients prior to having any specific study labs done?
Our current practice is to draw a chem 14 on all patients prior to being seen by our oncologists. The question comes up for labs outside of the chem 14. For example, Lipase or triglycerides which may be needed to scrreen patients for various studies. Is it possible that a separate generic consent for "study puposes" be done to cover all labs? Any help would be appreciated.
[Redacted]