From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Thursday, February 20, 2003 10:11 AM
To: [Redacted]
Subject: RE: informed consent
Dear [Redacted],
FDA regulations for documenting informed consent are found at 21 CFR 50.27
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.27
and generally require informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative. The regulations are silent on the issue of additional documentation of the informed consent process. Some sites/sponsors/IRB may impose additional record keeping requirements, but this is at their discretion. If the study protocol, or the IRB requires additional documentation, then the CI must comply with the protocol and/or directions of the IRB.

I hope this information is helpful.

Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Program

-----Original Message-----
From: [Redacted]
Sent: Sunday, February 16, 2003 4:44 PM
To: gcpquestions@oc.fda.gov
Subject: informed consent

I am a clinical research nurse and am responsible for obtaining the informed consent from patients. Is it necessary for me to write a nursing note stating that the consent was obtained and the patient understood all the information, etc. even though our consents have a statement at the end for my signature which reads:
Person Conducting the Informed Consent Process_____?
Thank you for your help in clarifing this for me.

[Redacted]