Patient Informed ConsentFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, September 23, 2002 11:18 AM
To: [purged]
Subject: RE: Patient Informed Consent

There is no regulation that states the grade reading level for informed consent forms.Generally, one strives for a 6th to 8th grade reading level unless there is a compelling reason to go lower (for children) or higher (for medical student subjects). Hope this helps.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Friday, September 20, 2002 12:32 PM
To: 'gcpquestions@oc.fda.gov'
Subject: Patient Informed Consent

Is there a regulation that states what the grade level should be for Patient Informed Consent?
Thanks You.