From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, November 13, 2003 9:19 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: FDA Comments

Dear Ms. [Redacted]:

Your e-mail to CDER DRUGINFO was referred to me for a response.

21 CFR 50.20 states that "...The information that is given to the subject or the representative shall be in language understandable to the subject or the representative..." The regulations do not specify a reading level for the language used, nor am I aware of any FDA guidance that recommends a specific reading level. You might ask the clinical investigator to check with the IRB, in case the IRB has specific requirements or guidance on a recommended reading level.

Bear in mind, that while the consent form serves to document that the subject has agreed to participate in a study, the form itself is only one part of the consent process. The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject's questions, ensuring that the subject has comprehended this information, obtaining the subject's voluntary agreement to participate and, continuing to provide information as the subject or situation requires. To be effective, the process should provide ample opportunity for the investigator and the subject to exchange information and ask questions.

You may find it helpful to review FDA's Information Sheets for Institutional Review Boards and Clinical Investigators. In particular, Questions 34, 37, 40, 42, and 47 each contain some material pertaining to making the informed consent form itself understandable to subjects. You can view the Information Sheets on FDA's Good Clinical Practice website at http://www.fda.gov/oc/gcp . Once there, click on "Guidances and Information Sheets" in the middle column, and you'll be linked directly to the guidance page.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

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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: CDER DRUGINFO
Sent: Wednesday, November 12, 2003 2:43 PM

To: OC GCP Questions
Subject: FW: FDA Comments

-----Original Message-----
From: [Redacted]
Sent: Monday, November 10, 2003 5:49 PM
To: druginfo@cder.fda.gov
Subject: FDA Comments

Name: [Redacted]

E-Mail: [Redacted]

Comments: Can you please advise what the required (or recommended)reading level of an Informed Consent Doucument should be in order to comply with CFR 50.20. It is 'generally accepted" that the consent should be written at the 5th grade reading level, but I cannot find this stated in any of your documents. I would greatly appreciate your feedback.

Thank you!