From: OC GCP Questions
To: [redacted]
Subject: Question and request for Guidance on 21 CFR 50.20
Date: Thursday, January 22, 2015 10:58:18 AM

Good morning –

FDA has a few guidance documents on informed consent that might be helpful to you. However none specifically addresses readability per se. They do however discuss that the language must be understandable to the subject. In order to meet the requirements of 21 CFR 50.20, the consent document must be in language understandable to the subject. When the prospective subject is fluent in English, and the consent interview is conducted in English, the consent document should be in English. However, when he study subject population includes non-English speaking people so that the clinical inves igator or the IRB anticipates hat the consent interviews are likely to be conducted in a language other than English, the IRB should assure that a translated consent form is prepared and that the translation is accurate.

Please see FDA's Information Sheet Guidance "Frequently Asked Questions" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm)

Also A Guide to Informed Consent –
Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet It states --

21 CFR 50.20 General requirements for informed consent

Except as provided in ß50.23, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The IRB should ensure that technical and scientific terms are adequately explained or that common terms are substituted. The IRB should ensure that the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend.

Although not prohibited by the FDA regulations, use of the wording, "I understand..." in informed consent documents may be inappropriate as many prospective subjects will not "understand" the scientific and medical significance of all the statements. Consent documents are more understandable if they are written just as the clinical investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the clinical investigator as "I/we." This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject consent, i.e., the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension.

Subjects are not in a position to judge whether the information provided is complete. Subjects may certify that they understand the statements in the consent document and are satisfied with the explanation provided by the consent process (e.g., "I understand the statements in this informed consent document)." They should not be required to certify completeness of disclosure (e.g , "This study has been fully explained to me," or, "I fully understand the study.")

Consent documents should not contain unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].

Lastly, FDA has a new draft guidance on informed consent. While it is still not final this document might also be helpful to you.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf It states --

3. Language Understandable to the Subject or the Legally Authorized Representative
The information given to the subject, which could include information provided orally during the consent interview or written information in the consent form, must be in language understandable to the potential subject or legally authorized representative (21 CFR 50.20). "Understandable" means the information presented to potential subjects is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms). In ensuring that information is understandable, it should be noted that more than one-third of U.S. adults, 77 million people, have basic or below basic health literacy.10 Limited health literacy affects adults in all racial and ethnic groups.11 In addition, more than one-half of U.S. adults have basic or below basic quantitative literacy12 and are challenged by numerical presentations of health, risk, and benefit data.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, January 21, 2015 3:08 PM
To: [redacted]

Cc: OC GCP Questions
Subject: RE: Question and request for Guidance on 21 CFR 50.20

Good afternoon [redacted],

I am referring your email to the Office of the Commissioner, Good Clinical Practice mailbox since your questions are agency level questions and not specific to drug studies. This is the link to their webpage:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.htm

Please feel free to contact me if you ever have human subject protection questions that are specific to FDA-regulated drug studies.

Regards,
Cathy

Catherine Parker, RN
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From [redacted]
Sent: Wednesday, January 21, 2015 12:56 PM
To: Parker, Catherine
Subject: Question and request for Guidance on 21 CFR 50.20
Importance: High

Ms. Parker,

Greetings and hope this finds you well.

I am involved in the process of revising my institution's IRB Policies and Procedures. While revising these policies and procedure documents related to Informed Consent Forms, I came across the following:

"The information given to poten ial research subjects must be understandable to them. Technical and medical terminology should be avoided or must be explained. The document must meet the following parameters:
1. **Effective January 2014**, the informed consent document should be directed at an individual whose reading skills are at the **7th grade level or below**. (Some current word-processing programs can automa ically calculate the reading level necessary to comprehend a given document via the "Readability" function of the grammar check command)
Technical and medical terminology should be avoided or must be explained in lay language. ***Please note that this new requirements (7th Grade reading level) applies to all new studies submitted on or after January 2014. Consent documents for existing studies will transition to the new reading level requirement at each Continuing Review OR during a major modification of consent documents (whichever comes earlier). "***

On inquiring on the origin of this requirement, I was made to understand that requirement was informed by 21 CFR 50.20, specifically, the section that says "…The information that is given to the subject or the representative shall be in **language understandable** to the subject or the representative."

MY QUESTIONS:

1. What does FDA mean when you say "language understandable" to the subject?
2. Does the consent "readability" as measured by the Microsoft Flesch-Kincaid Grade Level satisfy FDA's interpretation and requirement of "language understandability" ?
3. Are there any FDA Guidance Documents on Consent Readability?
4. What is FDA's position on Consent Readability, and specifically the requirement of the specific grade level?
5. What advice would you give to an institution that says that they require ALL subjects research documents, including informed consent documents, to be written at a 7th grade reading level because the population in which the institution operates in has low literacy levels?

I will highly appreciate your answers and guidance on the above questions.

Respectfully,

[redacted]