

From: Hommel, Carolyn - OC on behalf of OC GCP Questions  
Sent: Friday, February 20, 2004 1:42 PM  
To: [Redacted]  
Subject: RE: informed consent  
Dear Ms. [Redacted]:

FDA's regulations require that the information provided to the subject be in language understandable to the subject (see 21 CFR 50.20). If the prospective subject reads, speaks, and understands English, that is sufficient (i.e., the informed consent process does not have to be conducted in both languages).

If the study is "focusing" on a particular ethnic population that speaks a specific language, then FDA would expect the IRB to have reviewed and approved a translated consent document in that language, and the site would need to have the translated consent document available, as well as a translator to assist in administering the consent to the non-English speaking subjects. Perhaps I'm missing something here, but if a subject asks to be consented in the target language, perhaps the individual is not as fluent in English as he/she first portrayed him/herself to be, and maybe is having second thoughts about having the information provided only in English? If the site has a translator available to assist in consenting the non-English speaking subjects (who speak the target language), might it not be reasonable to allow the individual to also utilize the translator's services?

You asked if a witness must be bilingual. FDA does not require a third person to witness the consent interview unless the subject or representative is not given the opportunity to read the consent document before it is signed (see 21 CFR 50.27)(b). A witness is required when a short form written consent document, stating that the elements of informed consent required by 21 CFR 50.25 have been presented orally to the subject or the subject's legally authorized representative (21 CFR 50.27(b)(2)). Considering that the witness "must be present to attest to the adequacy of the consent process and to the voluntariness of the subject's consent\*," it would be very difficult for the witness to make such an attestation if the witness does not speak and understand the subject's language. [\*See Final Rule, "Protection of Human Subjects; Informed Consent," Federal Register, vol 46, no. 17, January 27, 1981, Comment #52, pp. 8949-8950].

You may find additional helpful information in FDA's Information Sheets for IRBs and Clinical Investigators. These may be viewed online by visiting FDA's Good Clinical Practice website at <http://www.fda.gov/oc/gcp> . Click on "Guidances and Information Sheets," and then on "FDA's Information Sheets for IRBs and Clinical Investigators."

FDA recognizes that obtaining consent from non-English speaking subjects is a complex issue, and we are in the process of reviewing our policies and guidance related to informed consent and non-English speaking subjects.

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  
Phone: 301/827-3340  
Fax: 301/827-1169

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: [Redacted]  
Sent: Tuesday, February 03, 2004 8:39 AM  
To: gcpquestions@oc.fda.gov  
Subject: informed consent  
Hello, I have a question about informed consent.

If there is a study focusing on a particular ethnic population and consents are in both English and the target population's language, then:

1. If the prospective subject is bilingual and can read/write in both languages, but requests a non-English consent, does the witness have to be able to speak the language of the non-English consent, or is IRB certification of the translation sufficient to cover the witness in case the subject has a question about the consent?  
Or is the witness required to be able to speak/read the language of the non-English consent even if the subject understands English?

Thank you.