From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 10:06 AM
To: [Redacted]
Subject: RE: Question concerning informed consent and translators
Dear [Redacted],

To meet the requirements of the Food and Drug Administration (FDA), set forth in Title 21 of the Code of Federal Regulations, Part 50.20 (21 CFR 50.20), the informed consent document should be in language understandable to the subject (or authorized representative).

When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2).

For valid consent, both the verbal and written information need to be in language the subject can understand. If the summary of the written information that would be given to the subject (as part of the short form process) has not been translated at the time the information is verbally given to the subject, it needs to be translated and provided to the subject in a reasonable timeframe. In the interim, we expect the english summary and the translated short form will be given to the subject.

I hope this information is helpful.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: Thursday, September 09, 2004 4:43 AM
To: gcpquestions@oc.fda.gov
Subject: Question concerning informed consent and translators

Dear Sir/Madam

Could you please confirm the FDA's position on the use of an interpreter to verbally translate an English language consent form into a patient's native language. Is this acceptable for the purposes of ensuring valid written informed consent. The patient and consentor would sign the consent form together with the interpreter.

yours sincerely
[Redacted]