From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 20, 2003 3:48 PM
To: [Redacted]
Subject: RE: Non-English consents

Dear Dr. [Redacted],

We are currently having discussions with the Office for Human Research Protections (OHRP, formerly OPRR) about the correct policy related to informed consent for non-English speaking individuals. While both the HHS and FDA regulations contain substantially the same requirements pertaining to informed consent (that is, that information that is given to the subject or the representative shall be in language understandable to the subject or the representative (21 CFR 50.20) and that informed consent be appropriately documented (21 CFR 50.27), the interpretation of this language has differed. We are now working to come up with a common policy for obtaining and documenting consent from non-English speaking subjects and representatives. Although we have not reached closure on this issue, I can tell you what we think may be the appropriate solution to the problem you have described.

First, when there is a reasonable expectation that the prospective subject population for a proposed research protocol will include groups of subjects who do not understand English, the investigator should obtain, and the IRB should review and approve, an appropriately translated "long-form" informed consent document, or short form written consent document and written summary at the time of the IRB's initial review. In general, subjects who do not understand English should be presented with written consent documents and oral information in a language and at a comprehension level understandable to them throughout all phases of the research. Furthermore, an individual should be available to such subjects to translate information for and from the subjects throughout the course of the research.

We recognize that there may be occasions when an investigator may be faced with circumstances where (1) an individual who does not understand English is eligible for an approved research protocol; (2) enrollment of a subject speaking a particular language was not reasonably expected; and (3) therefore, the investigator does not have a written translation of the "long form" informed consent document or a translated written summary. In this case, the person obtaining consent may present an IRB-approved translated short form written consent document stating that the elements of informed consent required by FDA regulations at 21 CFR 50.25 have been presented orally to the subject or the subject's legally authorized representative. There must be a witness to the oral presentation. At the time informed consent is obtained, the IRB-approved English version of the written summary of what is to be said to the subject or the representative, or the IRB-approved English "long form" written consent document may be given to the subject or the representative. The short form written consent document is to be signed by the subject or the representative. The witness must sign both the short form and a copy of the written summary; the person actually obtaining consent must sign a copy of the written summary; and a copy of the written summary must be given to the subject in addition to a copy of the short form. (In each case the written summary could also be the IRB-approved English version of either the written summary or the "long form" written consent document.) The regulations describe these requirements at 21 CFR 50.27(b)(2). THE TRANSLATED WRITTEN SUMMARY MUST BE PROVIDED TO THE SUBJECT OR THE REPRESENTATIVE WITHIN A REASONABLE TIMEFRAME AFTER ENROLLMENT. Depending upon the nature of the study, we believe that reasonable would be less than one month.

While I cannot say with any certainty that OHRP will change its policy to the one that I have described above, this policy is one that we (FDA) believe supports the existing regulatory requirements. Also, as I indicated, we are cognizant of the discrepancy between our policies and are committed to uniformity. Thus, at a minimum you ought to be aware that it is likely that there will be a change in the policy described by OPRR.

While I am sympathetic to the cost of translation services, I believe that it is the cost of doing research to ensure that subjects are not categorically excluded from research due to an inability to speak English (or due to their parents' inability to speak English) and that informed consent is obtained from subjects in language they can understand. I believe that Spanish is the second most common language in this country and therefore it is reasonable to expect that in an area with a heavy Hispanic population, it may be necessary to translate many of your consent documents. Your IRB needs to consider whether it can ensure that the selection of subjects is equitable (21 CFR 56.111(a)(3)) in research it approves; it can do this in part by requiring a translation of the consent documents so that Spanish-speaking individuals are not excluded from the research.

I hope this information is helpful to you.

Sincerely,

Bonnie

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-----Original Message-----
From: [Redacted]
Sent: Friday, August 08, 2003 4:25 PM
To: gcpquestions@oc.fda.gov
Subject: Non-English consents for children with cancer

Gentlemen:

I am a [Redacted] at [Redacted] in the [Redacted]. My institution is a member of the [Redacted] and I am the principal investigator for our group. As you know, [Redacted] has a very high percentage of Hispanic individuals and many of the parents of our children do not read, and sometimes do not understand, English very well. [Redacted] has a very large number of protocols available for the treatment and study of childhood cancer. The informed consent forms are very long and detailed (often 15-20 pages). OPRR regulations allow for a short Spanish consent form which basically states that the individual understands the study and that the details have been translated for him/her on an individual basis. This has been our policy until recently.

My IRB has apparently been cited in the past by the FDA for not having direct Spanish translations for other types of protocols. They are now insisting that we have a direct complete translation of every consent form. Since my small division has no one who can do these translations and we cannot afford a translation service, I am in the position of having to deny access to these studies (which are considered to be the ideal and state-of-the-art way to treat any child with cancer if a study is available) to all children and adolescents whose parents are not literate in English. My institution, as well as [Redacted], pride ourselves in offering the best of care to all children, but I can no longer do this. [Redacted] provides consent forms for all studies, but they have no translations available. Their policy is to follow the OPRR regulations.

Can you please clarify this situation for me and my IRB (or, if necessary for [Redacted])?

I appreciate your help.

[Redacted]