From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 27, 2004 2:14 PM
To: [Redacted]
Subject: FW: FDA question

Dear [Redacted],

Your email about informed consent (below) was referred to our office for response.

"Legally authorized representative" is defined as "...an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." 21 CFR 50.3(l). It is State law that generally determines who can serve as a legally authorized representative; thus, there is no general answer to your questions as to whom can serve as a legally authorized representative.

FDA regulations state that "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative." See 21 CFR 50.20. FDA regulations at 21 CFR 50.27 describe the documentation requirements for informed consent. Both the verbal and written informed consent information must be in language understandable to the subject. Thus, if you know that you will be drawing subjects from a Spanish-speaking population, you will need to have the consent forms translated into Spanish and you will need to have a translator available to those subjects throughout the study. Your IRB requirements are consistent with our regulations.

I hope this information is helpful to you.

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: Lepay, David
Sent: Thursday, October 21, 2004 9:25 PM
To: OC GCP Questions
Subject: FW: FDA question

-----Original Message-----
From: Sherman, Linda A
Sent: Thursday, October 21, 2004 5:51 PM
To: ORA Contact Us

Cc: Lepay, David
Subject: RE: FDA question

David LePay of someone in his office can answer this best. However, an informed consent to be understandable must be in the language of patient. The IRB is correct. In fact, someone needs to check that the translation is accurate and not white-washed due to language barriers. The precedent is that I disqualified an investigator as the presiding officer on just such a case that the patients who only spoke an Asian dialect were not properly able to consent to the trial terms because they did not understand the fact that they could refuse to participate or understand what the trial was all about. If you have further questions, you may call me at 301-8273306.

LAS

-----Original Message-----
From: ORA Contact Us
Sent: Thursday, October 21, 2004 2:39 PM
To: Sherman, Linda A
Subject: FW: FDA question

Can you help with this question please --

-----Original Message-----
From: [Redacted]
Sent: Wednesday, October 20, 2004 2:19 PM
To: ORA Contact Us
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

Address: [Redacted]

Attn: [Redacted]

Phone: [Redacted]

URL: www.fda.gov/oc/ohrt/irbs/informedconsent.html

Comments: I received the documentation "A Guide to Informed Consent" and I have a question. Our IRB is mandating that we have the consents translated into our patient's language (for our community) based on this documentation they received from you. The handout titled "A Guide to Informed Consent - chapter 7" states that the Informed consent must be signed and dated by the subject or the subject's legally authorized representative. - What is the FDA's determination of a legally authorized representative (the subject's guardian, conservator, or other representative)? What is included in the other representative category? Is it a husband, wife, etc. or does this only apply to a minor (being that the parent is the authorized representative?)

Also - it states that to meet the requirements of 21 CFR 50.20 the informed consent document should be in language understandable to the subject (or authorized representative) - again, please define what the FDA means when they say authorized representative.

Our IRB is requiring that we offer spanish consents based on these statements above. Is it an FDA requirement that we have spanish consents and not have the consents interpreted to our patients?