From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, May 27, 2004 3:15 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: FW: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted],

I am responding to both your 5/20 faxed inquiry and your email below. In the future, you can address good clinical practice inquiries to our general mail box at: gcpquestions@oc.fda.gov <gcpquestions@oc.fda.gov>.

We are currently in the process of developing guidance in the area of obtaining informed consent from subjects who do not speak English. In the description you have provided, it sounds as though your informed consent procedures could meet our requirements in that you have staff who can verbally communicate with the Mexican subjects, the consent form is translated into their language, and you have personnel available at all times to translate for these subjects. I am assuming that they would be otherwise competent to provide informed consent (e.g., meeting age and competency requirements). You did not mention, however, whether the IRB reviewing these studies has the necessary competence and membership to review the research in terms of its acceptability to the Mexican community from which subjects are drawn. 21 CFR 56.107(a). We would also expect the IRB to ensure that selection of subjects is equitable (21 CFR 56.111(a)(3)). As the regulations state: "In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as...economically or educationally disadvantaged persons."

I hope this information is helpful to you.

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, May 20, 2004 4:25 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: GCP Division:

We are a clinical trial site that is located in [Redacted]. While advertising for our trial, we have had some inquiry from Mexican nationals with the desire to participate in our studies. We have obtained an IRB approved Mexican Spanish consent form to use for subjects that do not speak English and it is our policy to have Spanish speaking staff in our facility at all times while a Spanish only speaking subject is here. We have been told by our IRB that the FDA is okay with us enrolling subjects that live in another country as long as they are here legally and we have the IRB approved IC in their language. We also have gotten direction from the IRS regarding stipend payment to these subjects.

I have searched your web site for this information in writing and have been unable to find it. Could you either let us know with an e-mail back to us that it is okay to enroll Mexican nationals with the guidelines spelled out above or let me know where this information is on your website.

Thank you,
[Redacted]