From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, March 09, 2005 12:35 PM
To: [purged]
Subject: RE: English Translations in Foreign Clinical Sites

Dear[purged], I asked some of my friends who are more knowledgeable than I am on this topic. They said that when we plan to do a foreign inspection, we expect the sponsor to provide a translator to accompany our FDA field investigator. We do not expect the records to be translated into English. I hope this 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: [purged]
Sent: Tuesday, March 08, 2005 7:30 PM
To: BLee@OC.FDA.GOV
Subject: English Translations in Foreign Clinical Sites

Dear Bonnie:

I am hoping that you can address the following question for me, please. Is it necessary that clinical trial records in foreign countries be available in English, in addition to the native language? If not, how does FDA handle this during inspections?

As always, I truly appreciate your help!

Best regards,

[purged]