From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, November 19, 2004 5:35 PM
To: [Redacted]
Subject: RE: Translation of informed consent documents

Dear [Redacted], The procedures you have described below appear to ensure that the translated materials are comparable to those reviewed and approved by your IRB and as such would appear to meet FDA reguirements. Hope this helps.

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: Tuesday, November 09, 2004 4:55 PM
To: FDA
Subject: Translation of informed consent documents

Obviously, translators are utilized when in-house staff lacks the knowledge or expertise to provide translations of study-related documents. It is our understanding that informed consent documents in any language as well as recruiting materials require IRB review/approval.

Our current process involves requiring a notarized certification letter from commercial translating services. In the event the translation is performed at the site we require an affidavit of accuracy. Our staff then compares the translated document to the approved English version by checking paganation and the number of paragraphs. When the documents are comparable the chair or co-chair approves the document(s) and the IRB "approval" is indicated on each page of the document(s).

In a recent conversation with a colleague, we were told the agency would accept an indication of acceptance rather than approval by the IRB.

Please advise.

Regards,

[Redacted]