From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 04, 2003 2:03 PM
To: [Redacted]
Subject: RE: Translated ICF
Dear [Redacted], FDA regulations do not specify any method for certification of the accuracy of consent document, CRFs, or other subject information. I understand that some State laws or institutional policies may specify the need for some type of certification. Thus, back translation to English may be a recommendation or an institutional or State requirement. I hope this is helpful to you.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, HF-34, 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: Wednesday, April 02, 2003 10:49 AM
To: 'OC GCP Questions'
Subject: RE: Translated ICF
Hello,

For consent documents translated to another language, what is the requirement for certification of accuracy?
Is back translation to English a recommendation or requirement?

Does the same standard apply to translated CRFs and other subject information, such as diaries?

Thanks,

[Redacted]