From: OC GCP Questions
To: [redacted]
[redacted]
Subject: informed consent and acceptance of foreign data
Date: Wednesday, December 09, 2015 2:37:00 PM

Dear [redacted],
We recommend that you contact your project manager for your submission to determine whether submission and translation of the consent forms is required.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Tuesday, December 08, 2015 1:47 PM
To: OC GCP Questions
Cc: [redacted]
Subject: informed consent and acceptance of foreign data

To whomever:

We are preparing an NDA for a client that conducted several small studies outside the US (in a number of EU countries), and not under an IND. To support the NDA, we have prepared documentation to demonstrate compliance with the requirements of 21 CFR 312.120 (per FDA' March 2012 guidance document).

In addition to this documentation, which will be submitted with the NDA, is there a requirement/FDA expectation that all of the consents be translated into English and included in the NDA? We do not find any such requirement, and do not need it to document adherence to 312.120. However, we want to be sure that this is the case.

Kind regards,
[redacted]