From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 10:17 AM
To: [Redacted]
Subject: RE: Query regarding Translations

Dear [Redacted],

To meet the requirements of the Food and Drug Administration (FDA), set forth in Title 21 of the Code of Federal Regulations, Part 50.20 (21 CFR 50.20), the informed consent document should be in language understandable to the subject (or authorized representative). Therefore, any abbreviations should also be presented in a way that is understandable. This could result in English abbreviations not being abbreviated in other languages, a different abbreviation, or possibly no difference if the abbreviation is well known and unchanged in other languages. The most important thing to consider, however, is that the subject understands what he/she is reading.

I hope this information is helpful.

-----Original Message-----
From: [Redacted]
Sent: Saturday, September 04, 2004 10:25 AM
To: GCPQuestions@OC.FDA.GOV
Subject: Query regarding Translations

I have a query regarding translations of informed consent form. If an original informed consent form which is in English is translated into a local language and if there are some abbreviations in the translated document which has been left untranslated in English. Please confirm whether this document is acceptable as per ICH-GCP if it is approved by the [Redacted].

Thanks and best regards,
[Redacted]