From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, March 16, 2004 9:33 AM
To: [Redacted]
Subject: RE: ASSISTANCE PLEASE

Dear Ms. [Redacted],

Your e-mail to the GCP Questions e-mail account was forwarded to me for a response.

You asked: "(1) Is it necessary to translate (and back-translate) the full Information to Participants / Informed Consent document into the language of the participants - or is it satisfactory to translate (and back-translate) the abbreviated document?"

Answer: To meet the requirements of the Food and Drug Administration (FDA), set forth in Title 21 of the Code of Federal Regulation, Part 50.20 (21 CFR 50.20), the informed consent document should be in language understandable to the subject (or authorized representative).

When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2).

You also asked: "(2) Do the translations need a separate approval from the Ethics Committee or is it acceptable that the documents are approved within the scope of the application for the study?"

FDA regulations require that informed consent be "documented by the use of a written consent form approved by the IRB..." (21 CFR 50.27(a). The IRB reviews the information to be given to subjects to ensure that it contains all of the basic elements described in 21 CFR 50.25.

Because study protocols are often changed during the course of the study, the informed consent document is also often changed. Thus, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. While not required by FDA regulations, some IRBs stamp the final copy of the consent document with the approval date. The investigator then photocopies the consent document for use.

You can find additional helpful advice in FDA's "Information Sheets for IRBs and Clinical Investigators," which may be viewed on FDA's Good Clinical Practice website [http://www.fda.gov/oc/gcp]; click on "Guidances and Information Sheets."

You may also wish to consult the International Conference on Harmonization's "E6 Good Clinical Practice: Consolidated Guidance". Section 3.1.2 states:

"The IRB/IEC should obtain the following documents:...written informed consent form(s) and consent form updates that the investigator proposed for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects... and any other documents that the IRB/IEC may require to fulfill its responsibilities. The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed, and the dates for the following:
--Approval/favorable opinion;
--Modifications required prior to its approval/favoralbe opinion;
--Disapproval/negative opinion; and
--Termination/suspension of any prior approval/favorable opinion."

The ICH E-6 guideline is also posted in its entirety on FDA's GCP website.

I hope this information is helpful.

Sincerely,

Carolyn Hommel
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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, March 03, 2004 5:14 AM
To: gcpquestions@oc.fda.gov
Subject: ASSISTANCE PLEASE

To whom it may concern :

I cannot find any guidance on translations - please could you point me in the right direction?

We need to know :

(1) Is it necessary to translate (and back-translate) the full Information to Participants / Informed Consent document into the language of the participants - or is it satisfactory to translate (and back-translate) the abbreviated document.

(2) Do the translations need a separate approval from the Ethics Committee or is it acceptable that the documents are approved within the scope of the application for the study?

Many thanks for your help.
Regards
[Redacted]