From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, April 30, 2003 9:06 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: FDA question

Dear [Redacted], The short form is used rarely because it requires the same amount of information as a long form, but additionally requires a witness. Even when a short form is used, we would expect the written summary of the information provided to the subject to be in language the subject can understand. Thus, if the subject understands only Spanish, for example, then we would expect both the short form as well as the written summary to be in Spanish so that when both are given to the research subject, the subject is able to understand the information. Similarly, if a long form were used, we would expect that form to be translated into Spanish and given to the subject. While in some cases one can anticipate the potential enrollment of subjects who do not speak English into a study, in some instances, such a subject may present unexpectedly. In that case, where a translated copy of the consent information cannot be "taken off the shelf", the information can be presented verbally to the subject based on the English consent form while the consent information is translated into language the subject can understand. The subject cannot be considered to have entered the study (or begin any study-related activities) until after the translated documents have been executed. 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: CDER DRUGINFO
Sent: Friday, April 25, 2003 4:35 PM
To: OC GCP Questions
Subject: FW: FDA question

-----Original Message-----
From: [Redacted]
[Redacted]
Sent: Tuesday, April 22, 2003 9:19 AM
To: wmail@oc.fda.gov
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

Address:

Phone:

URL:

Comments: I am a [Redacted]for a pharmacetical company and have a question that I do need clarification on. We have been dealing with a few sites that are using the Short Form inform consent instead of fully translated version of the ICF. 21 CFR 50.27 provide a short form that can be used with the defined signatures and who has to be present.

My question is, under what conditions would you expect the Short Form ICF used and please enlightened me on how we (QA and clinical) can be more definitive on using a fully translated version of the ICF instead of using the Short Form? Your response to this question would greatly help us in ensuring the proper procedure to be used at site that have need of translated versions.

Thank you in advance for your consideration in my question.