From: OC GCP Questions
To: [redacted]
Subject: REB or Institute name
Date: Friday, February 10, 2017 1:50:00 PM
Attachments: [redacted]

Good afternoon --

I would recommend that you provide the official legal name of the institution on the 1572, in language understandable to the person(s) who will be reading it. If individuals who will be reviewing the form speak English, rather than the language of the clinical investigator who is completing the form, then it would be helpful to provide a translation.

FDA's regulations do not address what makes a translation or translator acceptable. Sites may use thus develop their own policies and procedures for ensuring that documents are appropriately translated when necessary. Documents, forms, or study records that are submitted to FDA for review would need to be translated into English for FDA staff, but again, the sponsor and sites may use their own procedures for accomplishing this.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, February 10, 2017 10:21 AM
To: OC GCP Questions
Subject: REB or Institute name

Dear Madam or Sir,

I have a question regarding the completion of the Form FDA 1572.

When completing the form if the IRB or institute has a name in another language does the name need to be translated to English?

Many thanks, [redacted]