From: OC GCP Questions
To: [redacted]
Subject: Inquiry
Date: Tuesday, March 25, 2014 9:24:37 AM

Good morning --

FDA does not have guidance specific to consenting deaf subjects, however, FDA's Guide to Informed Consent (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm) indicates that non-hearing or non-speaking persons may be enrolled in clinical trials but they must be able to communicate. FDA's regulations require that information given to the subject be in language understandable to the subject (21 CFR § 50.20). So in the case you describe, I would think a sign language interpreter is most appropriate. Every effort should be made to ensure the information is clearly understood. If the patient can also adequately make his/her self-understood, that is, ask questions, discuss concerns and indicate whether or not he/she wants to enter the study, then it may be possible to include he/her in the study. This may in part be dependent on the complexity of the study, as more complex concepts may be difficult to convey in such a situation. Also, you would want to make sure that the person can communicate with the research staff if issues occur during the course of the clinical study (for example-TTY phone).

If you believe adequate communication to achieve informed consent would not be possible then the patient should not be enrolled.

I hope this response will be helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions.

Kind regards,

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

-----Original Message-----
From: [Redacted]
Sent: Monday, March 24, 2014 10:31 AM
To: OC GCP Questions
Subject: Inquiry

I would like to know the agency's expectation for documented informed consent for a deaf subject.

Thanks!