From: OC GCP Questions
Sent: Thursday, December 31, 2015 11:32 AM
To: [redacted]
Subject: RE: ad hoc narration of procedure demo video by research staff

Hello,

FDA requires that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research.

Both the investigator and IRB 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 to them during the consent process, the subject's consent will not truly be informed and may not be legally effective. Perhaps the IRB may consider providing a copy of the transcript of the voiceover material (providing perspective relating the narrative to the visual in the video) which is translated to a language that is understandable to the subject during the consent process.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Thursday, December 24, 2015 12:59 PM
To: OC GCP Questions
Subject: ad hoc narration of procedure demo video by research staff

Good afternoon,

Our IRB is questioning whether IRB-approved translations would be required in a particular set of circumstances. Some of the studies we review use "demo videos" to show prospective subjects what is involved in participation. Many times, there is an English language voiceover describing the video, though the staff can certainly augment the content when viewing with a prospective subject. ***If a non-English speaking subject presents to the site, is it acceptable for the staff to provide an "ad hoc narration" of the video's content in a language understandable to the subject?*** Our IRB always requires a translation of the consent *document* into a language understandable to the subject, but we are wondering whether an IRB-approved translation of this type of video material would be necessary. Thank you for your consideration of this inquiry.

Best regards,

[redacted]