

**From:** [REDACTED]  
**Subject:** Question regarding eConsent and chat function  
**Date:** Thursday, May 14, 2020 11:31:25 AM  
**Attachments:** [REDACTED]

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**From:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Sent:** Thursday, May 14, 2020 11:12 AM  
**To:** [REDACTED]  
**Cc:** CDER OMP <[CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov)>  
**Subject:** Question regarding eConsent and chat function

Good morning –

Please see FDA Updated Guidance on COVID. <https://www.fda.gov/media/136238/download> Video conferencing in mentioned in Q 19.

FDA (OGCP) does not generally address small details or SOPs related to internal practices. When the regulations are silent, sites and institutions can develop their own SOPs to address a specific situation.

The updated COVID guidance does not address non-English speaking consents. I can tell you what this office has said in the past regarding non-English speaking subjects. Institutions may adapt to certain situations based on the COVID-19 pandemic. Please see below.

FDA's regulations require that the IRB must review and approve all English and non-English language versions of any consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a) and 21 CFR 56.111(a)(4)-(5)). When reviewing proposed informed consent procedures involving translation of written and oral information that is to be presented to subjects, FDA recommends that the IRB review, and if appropriate, approve procedures for ensuring that the translations will be prepared by a qualified individual or entity. The determination of what party is appropriately qualified to translate the informed consent document and the actual process to review and obtain the translated version is left to the individual IRBs to determine. I would recommend that you not only have appropriate procedures in place for doing so, but also maintain sufficient records of the actual process.

From FDA Information Sheet Guidance "Frequently Asked Questions" (available at [www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm)):

**51. Must informed consent documents be translated into the written language native to study subjects who do not understand English?**

The signed informed consent document is the written record of the consent interview. Study subjects are given a copy of the consent to be used as a reference document to reinforce their understanding of the study and, if desired, to consult with their physician or family members about

the study.

In order to meet the requirements of 21 CFR 50.20, the consent document must be in language understandable to the subject. When the prospective subject is fluent in English, and the consent interview is conducted in English, the consent document should be in English. However, when the study subject population includes non-English speaking people so that the clinical investigator or the IRB anticipates that the consent interviews are likely to be conducted in a language other than English, the IRB should assure that a translated consent form is prepared and that the translation is accurate.

A consultant may be utilized to assure that the translation is correct. A copy of the translated consent document must be given to each appropriate subject. While a translator may be used to facilitate conversation with the subject, routine ad hoc translation of the consent document may not be substituted for a written translation.

From FDA Information Sheet Guidance "A Guide to Informed Consent" (available at [www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#nonenglish](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#nonenglish) ):

### **Non-English Speaking Subjects**

To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. 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. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

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).

Although not clearly stated above, FDA's regulations require that a copy of the IRB approved written summary, of what is to be said to the subject or the representative when the short form is used, be provided to the subject or representative (see 21 CFR 50.27(b)(2)). In previous advice provided, FDA has indicated that a translation of the written summary (or the long consent form, if a written

summary has not previously been prepared) be promptly provided to the subject. Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. FDA believes that translation of the long form is critically important as a means of providing subjects an ongoing source of information understandable to them.

FDA notes that informed consent should be viewed as an ongoing process throughout the course of a subject's involvement in the research. Therefore, FDA recommends that whenever subjects who do not understand English are involved in research, appropriate interpreter services be made available throughout the course of the research.

Kind regards,

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Office of Clinical Policy and Programs  
Office of Good Clinical Practice (OGCP)  
U.S. Food and Drug Administration



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.

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**From:** [REDACTED]  
**Sent:** Tuesday, May 12, 2020 3:33 PM  
**To:** CDER OMP <[CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov)>; OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** RE: Question regarding eConsent and chat function

Good afternoon,

I'm hoping that you can help me with two additional questions regarding IRB review requirements when an electronic consent platform is used. I've included both OGCP and CDER OMP on this email as I'm not certain which office to direct these questions to.

1. "Use of Electronic Informed Consent – Questions and Answers" (Q12) indicates that investigators *"should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process. The investigator must obtain IRB approval for any subsequent modifications to the **study-related information** [emphasis added], whether electronic or in hard copy (see 45 CFR 46.109 and 21 CFR 56.109)."*

"Informed Consent Information Sheet – [Draft] Guidance for IRBs, Clinical Investigators, and

Sponsors” states that *“IRBs must review all materials used in the informed consent process. This includes recruitment materials and information provided in addition to the informed consent document (for example, a chart explaining what to expect at each study visit or a document explaining the costs to subjects). The IRB’s review is to ensure that information given to subjects as part of the consent process contains the elements identified in 21 CFR 50.25 and meets the requirements of 21 CFR 50.20 (see 21 CFR 56.109(a), 56.109(b), and 56.111(a)(4)).”*

My question is whether this requirement for IRB review of informational materials extends to support materials included in an eConsent platform that are not study specific; for example, a video explaining how to use the eConsent platform, a video explaining what a clinical trial is and what informed consent is, etc. Other than the “how to use the platform” video, the other videos or links would be to provide information akin to that which might be provided in brochures or websites that provide general information about participation in research, clinical trials, subject rights, etc.

2. My second question (really a series of questions) relates to translations. In a paper consent process, the IRB reviews and approves both the English consent document and all translations. In an eConsent platform that includes an audio plug-in that can “read” the consent form out loud to participants in English or multiple other languages, is it necessary to have the IRB review all of the possible translations or is the audio plug-in more like an “interpreter”? Does the use of a checkbox indicator that the subject understood the information provided and had the opportunity to ask questions and have them answered help? And finally, regarding the requirement that subjects are provided with a copy of the consent form, is it acceptable for this copy to be in English so long as the subject is able to access the audio at any time after signing?

Once again, many thanks for any clarification that you can provide.

Best regards,