

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question regarding eConsent and chat function
Date: Wednesday, April 29, 2020 1:49:00 PM
Attachments: [REDACTED]

Hi [REDACTED] –

Here is an excerpt of the guidance (below)... but, as you state, the document does not say how to document the “chat”

This may be accomplished by in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing, or a live chat with a remotely located investigator or study personnel. When live chat or video conferencing is used during the eIC process, investigators and study personnel should remind subjects to conduct the eIC discussion in a private location to help ensure privacy and confidentiality.

We generally say that when the regulations are silent, institutions and sites have the freedom to develop their own standard operating procedures to resolve a particular situation. In your case, this would seem appropriate. However, I would like you to reach out the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on electronic records in clinical trials. They can give you additional advice.

Stay safe and healthy,
Doreen

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From: [REDACTED]
Sent: Wednesday, April 29, 2020 9:56 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Question regarding eConsent and chat function

Good morning,

I'm hoping that you can help me with a couple of questions related to electronic informed consent platforms and the use of a chat function to facilitate the consent process. I reviewed the guidance document Use of Electronic Informed Consent – Questions and Answers but didn't find that this issue was directly addressed.

When a "chat" function is built into an electronic consent platform so that potential subjects can ask questions and have them addressed before signing consent, do the chat records need to be maintained and for how long? My instinct is yes, but a client raised the point that investigators do not necessarily keep a record of each question asked and response provided during a more traditional face-to-face consent process, instead they may have a more general consent note that indicates that any questions a subject had were responded to. Instead of maintaining a copy of an electronic chat conversation, would it instead suffice to have a check box at the end of the electronic consent where a subject can confirm that all questions have been answered to their satisfaction?

Thank you in advance for any advice you can provide.

Best regards,

