



University of Pennsylvania Guidance on Remote Consent Discussion and Documentation

In the event of a health pandemic (i.e. COVID-19 declared on March 11, 2020) documenting consent from subjects utilizing methods other than pen and paper will be permitted.

NOTE: Guidance applies to all non-Penn Medicine and non-Penn Dental Schools within the University of Pennsylvania. This guidance only applies to non-HIPAA and non-FDA regulated research. If you are conducting HIPAA /FDA regulated research, please review the Penn Medicine guidance.

CONSENT DISCUSSIONS

If infection control prevents direct in-person communication with a participant, an audio or video call can be set up with the study team and participant. The protocol should delineate a standard process to:

- Identify who is on the call
- Review the informed consent with the participant by the investigator or their designee and respond to any questions
- Confirmation by the investigator that the participant is willing to participate

Note: An impartial witness should be considered to be included in this process if the participant may not have capacity to provide informed consent or may have other cognitive issues.

Options for Consent Discussions

1. **Phone Call**
2. **Video Call** (e.g., Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Skype, Zoom, or other private video conferencing software)

CONSENT DOCUMENTATION

A standard process should be set up to delineate how consent will be documented. The protocol should delineate which options will be utilized to document consent, once the consent discussion has taken place.

For minimal risk studies that involve no procedures for which written consent is normally required outside of the research context, teams may consider requesting a waiver of documentation of consent from the IRB.

Options for Distributing the Consent for Signature

1. **Qualtrics:** Teams can use Qualtrics to distribute and document consent via certification, or have participants electronically sign. Please see: www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/specialty-questions/signature
2. **DocuSign:** If teams have access to DocuSign, they may utilize it to distribute the consent and have participants electronically sign: <https://www.docusign.com>



3. **Penn Box:** Consents may be shared with participants via Penn Box, signed in their preferred method, and re-uploaded to Penn Box or emailed to the study team
4. **E-Mail:** Consents may be emailed to participants, signed in their preferred method and then emailed back to the study team for signature.
5. **Posted Mail:** Consents may be mailed, signed by the participants, and then mailed back to the study team for signature. *Note: This is not recommended during the COVID-19 pandemic to minimize the spread of infectious disease.*

Note: If following Good Clinical Practices, a consent note should be drafted to explain the difference in signature dates between the research participant and the study team, if applicable.

Options for Consent Documentation

1. Wet signature, the participant scans the signed consent and sends it to the research team via Penn Box, e-mail, or posted mail.
2. Wet signature and the participant sends the research team a picture of the signature page via Penn Box, e-mail, or posted mail.
3. Adobe Acrobat electronic signature and the participant sends the signed consent to the research team via Penn Box, e-mail, or posted mail.
4. DocuSign
5. Qualtrics