



University of Pennsylvania Guidance on Remote Consent Discussion and Documentation

IRB SOPs permit documenting consent from participants utilizing methods other than pen and paper. This guidance outlines expectations surrounding remote consent processes and documentation.

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 or doing research with Penn Medicine/Dental patients, please review the Penn Medicine guidance.

REMOTE CONSENT PROCESS

The IRB application or standalone protocol should describe the consent discussion, i.e., the process that will be used to review the IRB approved informed consent document with the participant and obtain their verbal consent or permission. This description should include the medium / platform used (e.g., phone, Zoom video conferencing, etc.).

An audio or video call may be set up with the study team, participant and (if desired by the participant) an additional participant such as next of kin. A standard process should be set up 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

The IRB may approve a process that allows the informed consent document to be delivered by mail, facsimile or electronically to the potential subject or the potential subject's legally authorized representative.

The investigator should describe the method of 1) sending the consent document to the participant and 2) documenting signed consent, including the medium / platform used (e.g., mail, fax, DocuSign, etc.).



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: 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