

Remote Consenting Options

Minimal Risk Studies

Waiver

Using a waiver to document consent in a minimal risk study, is still a process for obtaining consent. Therefore, the script, protocol, etc. must still include ALL of the required, standard elements of the informed consent process.

Can potentially be used for:

- Phone screens (verbal consent)
- Online consent (click to consent – different from electronic consent)
- Requesting a participant to fast prior to obtaining written consent
- Complete study participation (examples: interviews, surveys)

Cannot be used for studies with activities that require signed permission outside of the research context:

- Blood draws (home draw kits may be an exception, but this should be confirmed with the IRB)
- Medical records (HIPAA has no provision for verbal authorization)

Justification to the IRB: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Phone Call + Electronic Signature

Minimal risk studies that do not qualify for a waiver to document consent, can use a phone call combined with electronic signature as an alternative.

Process:

- Once a participant agrees to hear about the study, the consenting party (investigator or coordinator) calls the participant to discuss the research and go through all key elements of the consent. The consent form and/or other study materials may be emailed to the participant for review prior to the call.
- If the participant agrees to join the study, the consenting party sends the participant the consent form via REDCap for electronic signature.
- The participant will receive an email with a link to initiate the electronic consent process within REDCap. The participant must sign and submit the form.
- The signed consent document is stored securely in REDCap.
- The consenting party must document that they consented the participant. Some options are:
 - A note to file in the participant record
 - Signing an electronic attestation in REDCap

- Going back into the participant's consent to complete the fields on the electronic consent form

Greater Than Minimal Risk Studies

Video call + Electronic Consent

Obtaining consent through a video call and electronic consent may be used for greater than minimal risk, interventional studies.

Process:

- Once a participant agrees to hear about the study, the consenting party (investigator or coordinator) sets up a virtual meeting with the participant using one of Pitt's approved platforms (Zoom, Skype, Microsoft Teams) to discuss the study and go through all key elements of consent. The consent form and/or other study materials may be emailed to the participant for review prior to the call.
- If the participant agrees to join the study, the consenting party sends the participant the consent form via REDCap for electronic signature.
- The participant will receive an email with a link to initiate the electronic consent process within REDCap. The participant must sign and submit the form.
- The signed consent document is stored securely in REDCap
- The consenting party must document that they consented the participant. Some options are:
 - A note to file in the participant record
 - Signing an electronic attestation in REDCap
 - Going back into the participant's consent to complete the fields on the electronic consent form

Remote Consenting Platforms

Platform	Capabilities	Additional Actions	Things to know
REDCap	e-consent (signature capture)	Must be combined with a phone or video call	<ul style="list-style-type: none"> • Pitt vetted/hosted • Available to any Pitt/UPMC employee for research purposes • Participants do not need to have an account • Participant verifies consent before signing • Records are stored securely behind Pitt firewall • Able to upload different types of consent (pdf, video) • Set up can be cumbersome for some users • Pitt doesn't have all of the plug-ins/extras that would make it more visually appealing to participants (hover-overs, avatars, etc.) • Works best on a desktop, laptop, or tablet
DocuSign	e-consent (signature capture)	Must be combined with a phone or video call	<ul style="list-style-type: none"> • Can be accessed by the participant in a web browser (no install required on the participant side) • Requires coordinator to have a Pitt account • Verification performed by IP address • Works best on desktop or laptop
Zoom	Videoconferencing for face-to-face discussion	<p>Need to set up separate process for secure storage of consent records</p> <p>Must be combined with e-consenting option to capture signature</p>	<ul style="list-style-type: none"> • Can be accessed by participant in a web browser (no install required on the participant side) • Accessible via Pitt account, sponsored Pitt account, or web browser • Allows for face-to-face interactions • Security concerns do exist but can be mitigated by following the University's best practices for conducting a Zoom meeting