



Penn Medicine / Penn Dental / UPHS (HIPAA Covered Entities) 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.

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.).

Investigators within Penn Medicine and Penn Dental must utilize platforms that are compliant with the following regulations, under the circumstances noted below:

- HIPAA regulations, when the study involves the collection or generation of patient data;
- Good Clinical Practice (GCP) when the study is a clinical trial; and
- FDA regulations (e.g., 21 CFR Part 11) when the research is FDA regulated (i.e., meets the definition of a clinical investigation).

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
- Confirm that the participant has verbally verified they are willing to participate, that all questions have been answered, and that the consent form provided at the time of the call has been signed and dated by the patient.

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. Note: This is required by NJ state law.

Options for Consent Discussions and Remote Study Visits

- **Telemedicine Visits** – Switchboard / BlueJeans via PennChart may be used for studies in which clinical care is mixed with research or standard of care procedures or performed or research related procedures will be billed to insurance.
 - Consent should still be documented in PennChart as well via a note
- **Phone Call**
- **Video Call:** There are several different options available when it comes to video conferencing in support of the consent process and/ or for research visits:



- **Zoom** - The University has an enterprise Zoom agreement, which covers PSOM faculty, staff and students. You can automatically get an account by following the instructions at <https://www.med.upenn.edu/dart/zoom>.
 - **NOTE: the Zoom cloud recording service is not HIPAA compliant.**
- **Microsoft Teams** - Microsoft Teams is available through your Penn Medicine email. *This solution is the preferred solution for UPHS employees.* PSOM faculty and staff with @upenn.edu email addresses can also get access to Microsoft Teams through Penn O365.

Please note that Zoom and Microsoft Teams options are not appropriate for patient care. However, they are appropriate for research, education, and administration purposes. For further information on their use with PHI please refer to the following [guidance](#)

Please check with your local IT service provider before using these applications for recordings as there may need to be additional protections in place or one platform may be more appropriate than another. If one must record a meeting where PHI will be discussed, only do so from a UPHS or PMACS managed computer and record that meeting locally. The recording can then be moved to another HIPAA-compliant location, like a UPHS or PMACS file share, Penn+Box or Penn Medicine OneDrive.

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.).

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- HIPAA regulations, when the study involves the collection or generation of patient data;
- Good Clinical Practice (GCP) when the study is a clinical trial; and
- FDA regulations (e.g., 21 CFR Part 11) when the research is FDA regulated (i.e., meets the definition of a clinical investigation).
 - For FDA regulated studies: The FDA maintains that while an Electronic Medical Record System (EMR) does not need to meet part 11 guidelines, if it is being utilized for a research activity such as consent, the signatures must meet part 11 compliance.

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 and an alteration to HIPAA authorization from the IRB.

Options for Consent Documentation

Electronic Options	Part 11 Compliant for FDA regulated studies
<ul style="list-style-type: none"> • REDCap: Recommended for any study not being conducted under an IND or IDE <ul style="list-style-type: none"> • May be used to document consent, including sending a consent and obtaining an e-signature. • May be used to generate a REDCap link to document attestation and understanding after the consent discussion <p>The application is:</p> <ul style="list-style-type: none"> • HIPAA compliant • Has easy self-service workflows to upload the consent and manage sending to participants • After the participant signs the document is accessible to research team for additional signature <p>NOTE: Team's must have active REDCap and PMACS accounts</p>	<p>No</p>
<ul style="list-style-type: none"> • DocuSign: Recommended for IND and IDE trials <ul style="list-style-type: none"> • Penn Medicine has a limited number of licenses for DocuSign which are reserved for studies under a Penn held Investigational New Drug (IND) or Investigational Device Exemption (IDE) application. • The application is under a business associates' agreement (BAA) and is HIPAA compliant. • If you think your trial qualifies for using the application please contact the Office of Clinical Research. • For non-Penn held INDs: If the research team or sponsor holds a license for DocuSign and has a BAA in place for the study, DocuSign may be used. Please check with OCR or ORS to confirm a BAA is in place, prior to using. 	<p>Yes</p>
<ul style="list-style-type: none"> • MyPennMedicine: Recommended for studies involving Penn Medicine patients with active MPM. <ul style="list-style-type: none"> • Consent verbiage can be added into a correspondence / message to the participant and then sent to the participant, as a means of consent documentation. A participant can attest to the consent or be sent a direct message. 	<p>No</p>

<ul style="list-style-type: none"> • Consent form can also be uploaded into MPM by the PennChart research team and directed to participant and managed by the research team themselves. • Participant can sign within the MPM application and route back as would standard clinical consents. Both participant and team have access to the consent. • HIPAA compliant • Allows for direct messaging back and forth with the participant • The study team can engage in survey or other MPM directed activities • Not advisable for obtaining LAR consent 	
<ul style="list-style-type: none"> • Epic/ PennChart: Recommended for studies that are using PennChart for enrollments and ordering <ul style="list-style-type: none"> • Contact PennChart Research team or OCR for build • Appears within the PennChart research record • Requires touch pads • Works best for electronic consent when subject is in person or on site • Consent lives within the PennChart record and can be sent electronically to the patient/ research subjects • HIPAA compliant 	No
<ul style="list-style-type: none"> • iConnect App Bakery: Recommended for studies where the population and study lends itself to smartphone application use <ul style="list-style-type: none"> • This is a DIY web-based, research study app builder that requires no programming. • HIPAA compliant • Participants download the app and use it to sign consent copy automatically back to the study team • App specifications are built through a web interface. Apps created are compatible for both iOS and Android, and can be added to the Google and Apple app store within a very short time frame. • The vendor company, TrialX, has an existing BAA with Penn Medicine, removing the need for research teams and departments to have their own. Learn more here: https://trialx.com/appbakery. Contact the Office of Clinical Research to set up a demo. 	No
Non-Electronic Options	Part 11 Compliant for FDA regulated studies
<ul style="list-style-type: none"> • Posted Mail: Recommended when infection control concerns are low <ul style="list-style-type: none"> • Consents may be mailed and signed by the participants, and then mailed back to the study team for signature, 	Yes

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| <ul style="list-style-type: none">• Usually paired with a consent discussion occurring via phone/video call or telemedicine visit.• If the consent cannot be mailed back, it can be returned to the study team via a scan and upload to PennBox or another electronic system, such as MPM, or it can be emailed back by the participant to the team if they are aware of the potential risks of email not being secure.• A consent note should be drafted to explain the difference in signature dates between the research participant and the study team. | |
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Questions about what should go into your IRB protocol or application? Contact the IRB at PROVOST-IRB@pobox.upenn.edu or call 215-573-2540.

Questions and feedback about available applications and their compliance with different regulations? Please contact the Office of Clinical Research at psom-ocr@pobox.upenn.edu or call 215-662-4484.