Human Subject Protection Program
Investigator Guidance
May 26, 2021

REMOTE CONSENT FOR RESEARCH: OBTAINING CONSENT AND DOCUMENTING CONSENT (ELECTRONIC CONSENT)

Overview

The purpose of this document is to provide guidance and resources for investigators who wish to use a remote consent process to obtain and/or document informed consent and HIPAA research authorization.

This guidance applies to investigators who wish to perform **one or more portions** of the consent (or assent) process for research remotely: the consent form discussion and/or electronic consent signatures.

Only approved CHLA remote applications may be used to conduct the consent conference and to obtain electronic signatures.

1. The IRB must review and approve the use of the remote consent process **for each study**. Investigators must submit an amendment in iStar to perform remote consenting if it is not already approved by the IRB. The details of the remote consent process must be described in the approved protocol (see sample text below).

2. It may not be possible in some situations to have an in-person discussion of the study with the participant and/or parent(s)/guardian(s)/representative(s), yet the criteria for a waiver of documentation of informed consent **cannot be met**. In this situation, IRB approval to use a remote consent process may be requested.

3. When a waiver of documentation of informed consent is not permissible, the remote consent process must resemble an in-person consent process. The procedures in the investigator guidance document, "Obtaining and Documenting Consent" **must be followed** for obtaining and documenting consent.

Important Notes:

☐ Only **IRB approved (stamped) versions of consent and assent forms** may be used to obtain and document consent. Word versions of consent and assent forms may not be used to create new consent documents in a remote application (e.g., REDCap).

☐ Study sponsors may require review and approval of the remote consent procedures **before** they are submitted to the CHLA IRB for approval. Check with the study sponsor to ensure copies of signed consent forms are acceptable in lieu of "wet" original signatures.

☐ If you will use a remote consent process for a study that is **under the review and oversight of another IRB**, ensure the Reviewing IRB has approved the process and procedures for the use of a remote consent process.

Remote Consent Process

1. The remote consent process (e.g., applications to be used, how consent signatures will be obtained) needs to be described in either the original protocol or an amended protocol that is approved by the IRB.

2. When approved by the IRB, obtaining and documenting written informed consent in these instances must involve a process that includes **one or more parts** of the consent (or assent) process remotely: a) consent (or assent) discussion, and/or b) electronic consent (or assent) signatures.

    ☐ If some or all of the consent **discussion process** will be remote, see "CHLA Approved Applications for Obtaining Remote Consent (Consent Conference)" below.

    ☐ If some or all of the consent **signatures process** will be electronic, see "CHLA Approved Applications for Documenting Consent (Electronic Signatures)" below.

3. When the research involves the discussion of Protected Health Information, the remote applications used must be HIPAA compliant. The remote applications listed in this guidance document are HIPAA compliant.

4. When research data are submitted to, or held for inspection by the FDA (i.e., clinical investigations of test articles – drugs and devices) the remote applications used for documenting electronic consent must be 21 CFR Part 11 compliant (Electronic Records). Contact the Sponsor to discuss acceptable remote applications for documenting informed consent and assent.

5. Below are sample statements that can be used to describe the remote consent process and how electronic consent signatures will be obtained in the study protocol. **Note:** The sample statements will need to be customized into paragraphs for the specific study.

Sample Statements for Describing a Remote Consent Process (Consent Conference) for Potential Participants

☐ The study team will reach out to the participant/parent or legal guardian via phone before the consent discussion to determine if they are interested in participation.

☐ If the participant/parent or legal guardian are interested in participating, the study team will make arrangements to email or mail the consent/assent forms, HIPAA authorization form and Experimental Subject's Bill of Rights to them before scheduling a conference call.

☐ The participant/parent or legal guardian will receive all documents in advance of the informed consent discussion.

☐ The participant/parent or legal guardian will be asked to read over the documents and make note of any questions to prepare for the call.

☐ Once the participant/parent or legal guardian has received and reviewed the forms, a conference call will be scheduled for the remote consent discussion.

☐ The study team will verify the identity of individuals to ensure the correct individuals are present for the consent conference (i.e., participant/parent or legal guardian).

☐ The informed consent discussion will be completed via telephone or video conference (using a CHLA approved, HIPAA compliant platform) just as would occur in-person. A link to the electronic signature platform will be sent prior to the conference call. The participant/parent or legal guardian will be asked to sign and date all forms before ending the call if they choose to participate. Instructions for returning the signed documents will be discussed.

☐ If additional time is needed for the participant/parent or legal guardian before signing the forms, an additional phone call or video conference will be scheduled.

Sample Statements for Describing Documentation of Consent (Electronic Consent):

☐ After obtaining informed consent, the participant/parent or legal guardian will be instructed how to sign the consent documents electronically. Only CHLA approved, HIPAA compliant platforms will be used to document electronic signatures. The correct areas for signatures and dates will be flagged to ensure all required signatures are obtained.

☐ The study team will ensure the consent/assent forms are signed by the correct individuals who participated in the consent conference (i.e., participant/parent or legal guardian).

☐ The consenting study team member will countersign the consent/assent and HIPAA forms and document the consent conference in the study files, being sure to document the name of any witnesses and the means of communication.

☐ Copies of the fully signed forms will be emailed or mailed to the participant/parent or legal guardian.

☐ All of the above steps will be completed prior to the start of any study procedures (e.g., screening procedures) with the participant.

☐ Be sure to also describe how subjects will have access to all of the consent related materials, including hyperlinks or other external documents throughout the lifespan of the study.

CHLA Approved Applications for Obtaining Remote Consent (Consent Conference)
These applications have been approved by CHLA to obtain remote research consent. Non-CHLA provisioned systems (such as those provided by USC) are not approved to obtain remote consent.

1. **CHLA Telehealth (Amwell):** Amwell may be utilized for research consent videoconferencing with CHLA patients.

2. **CHLA WebEx:** The CHLA version of WebEx may be utilized for research consent videoconferencing: chla.webex.com

3. **CHLA Zoom:** Not all versions of Zoom are HIPAA compliant. CHLA has a version of Zoom that is HIPAA compliant, and may be utilized for research consent videoconferencing at an additional cost.

How to Gain Access to CHLA Zoom (HIPAA Compliant):

☐ Open a Service Request ticket. Contact the Service Desk at 323-361-4444 or email CHLA Service Desk Help@chla.usc.edu.

➢ Request a **Business or Enterprise plan of Zoom**. They will enroll you using the agreement in place. Non-CHLA provided Zoom cannot be used for research consent videoconferencing.

➢ State that the request is for **research** purposes.

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4. **Phone:** Phone calls are permitted for simple studies.

Important Notes:

☐ While obtaining consent by phone is permitted, a videoconference using a CHLA approved application is the preferred method for protocols involving complex intervention/treatment study procedures.

☐ If a CHLA-approved interpreter is required, they can participate in the conference call using one of the CHLA approved applications.

Risk Mitigation Strategies for Obtaining Remote Consent

When using remote applications to obtain consent, investigators are advised to adopt as many of the following risk mitigation measures as possible to protect research participants and CHLA:

1. The potential participant/parent or legal guardian must receive copies of the consent and assent forms in advance of the consent discussion.

2. When sending the consent forms, include instructions to contact the investigator/research staff when consents are received.

Note: Only use secure methods to transmit consent forms via email.

- ☐ Verify the recipient before you send an email.
- ☐ Never email CONFIDENTIAL DATA without explicit approval.
- ☐ Password protect and encrypt any document that may contain confidential data.
- ☐ Use only CHLA email accounts. Add the word SECURE to the email subject to encrypt the email.

3. Use CHLA approved video calls to permit better assessment of participant comprehension, answer questions, and verify identity. If video calls are not possible due to technology limitations, phone calls are preferred in lieu of communicating exclusively via email with participants.

4. To ensure that participants are approached in a consistent fashion, a standard process should be used that will accomplish the following:

- ☐ Verification of who is on the call to ensure the correct individuals are present for the consent conference (i.e., participant/parent or legal guardian).
- ☐ Investigator reviews the informed consent/assent document(s) with the potential participant/parent or legal guardian and responds to any questions they may have.
- ☐ Confirmation by the investigator that the participant/parent or legal guardian is/are willing to participate in the research.

5. The person obtaining consent should document that they witnessed the subject sign the consent documents (if over video conference) for identity verification and record the date and time the consent forms were signed and when consent was documented in a detailed note to file.

6. Video or audio of remote consent conferences should not be recorded unless there is IRB approval for recording video or audio for consent conferences.

CHLA Approved Applications for Documenting Consent (Electronic Signatures)

These remote consent applications are approved by CHLA to document electronic research consent, HIPAA research authorization, and other research consenting forms (e.g., Experimental Subject's Bill of Rights). Non-CHLA provisioned systems (with the exception of USC's REDCap) are not approved to document electronic consent. One fully signed copy of each consent document must be included in the subject's records (copies are acceptable).

Interpreter Signatures: If a CHLA-approved interpreter is required and cannot document their presence, commonly because phone-based interpreters are used, the investigator must document the interpreter's ID number in a note-to-file.

1. **DocuSign:** CHLA provided DocuSign may be utilized to obtain signatures from the participant/parent or legal guardian, and investigator obtaining consent. To access DocuSign, open your account through the OKTA website.

How to Gain Access:

1. Your OKTA account will only grant you signing rights. You will need to request additional permissions via a Service Request to the CHLA Service Desk.
   - ☐ Login into chla.okta.com
   - ☐ Click the DocuSign tile.
   - ☐ This will auto create your account. It will allow you to <u>view and sign</u> documents under CHLA purview.

2. Open a Service Request ticket. Contact the Service Desk at 323-361-4444 or email CHLA Service Desk Help@chla.usc.edu.

   - ☐ Request to <u>increase your permissions to be able to send out requests for signatures and create PowerForms</u>.
   - ☐ State this request is for **research** consenting.

   How to Create Documents for Electronic Signature:

3. See the DocuSign Job Aid located on the CRSO SharePoint website. This job aid will assist investigators with creating documents for electronic signature.

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2. **REDCap:** The USC version of REDCap has a remote consent feature for documenting research consent. It is available to certain CHLA employees with approval.

How to Gain Access:

☐ Refer to REDCap Job Aids below to request access forms to obtain REDCap:
  - ➢ New Users
  - ➢ Current Users

☐ If you encounter issues, email Warren Gabrillo, iVIP Administrator at wgabrillo@chla.usc.edu. Explain that you need access to REDCap for research consenting.

☐ **Note:** Each iVIP account access needs to be renewed annually.

3. **Qualtrics:** This survey tool contains a remote consent feature for documenting research consent. CHLA has an enterprise license.

How to Gain Access:

☐ Contact your Department Administrator to complete a Request for User Access (RFUA) form.

☐ Send the completed form to this email address: CHLA Service Desk (Help@chla.usc.edu)

☐ Explain that you need Qualtrics access for **research**.

☐ See the CHLA SharePoint site for Qualtrics training and assistance.

4. **CHLA Email** – Only CHLA email accounts can be used to send secure documents.

Note: Only use secure methods to transmit consent forms via email.

☐ Verify the recipient before you send an email.
☐ Never email CONFIDENTIAL DATA without explicit approval.
☐ Password protect and encrypt any document that may contain confidential data.
☐ Add the word SECURE to the email subject to encrypt the email.

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5. **Physical Mail:** Documents can be sent by U.S. mail.

6. **CHLA Facsimile (Fax):** Only CHLA facsimile (fax) machines can be used to send secure documents.

Risk Mitigation Strategies for Documenting Electronic Consent

When using remote applications to document consent, investigators are advised to adopt as many of the following risk mitigation measures as possible to protect research participants and CHLA:

1. Verbal confirmation that the participant/parent or legal guardian have signed and dated the informed consent/assent document(s) in their possession.

2. Obtain the signed document by all parties prior to commencement of the study.

3. Documenting electronic signatures should include:

   ☐ Time of signature (time stamp)
   ☐ Typed/printed name of signer (in addition to signed name)

Requesting CHLA Approval to Use Other HIPAA Compliant Remote Applications

1. If the study calls for use of a remote application for obtaining and/or documenting consent **that is not listed above**, you will need to open a Technology Contract Review (TCR) Service Request (SR) ticket.

2. The TCR process is to approve the architecture and the security of the remote application.

3. For more details on how to create this TCR SR ticket, please see the TCR website: https://is.chla.usc.edu/trc/.

4. You can also contact the CHLA Service Desk by calling 323-361-4444 or emailing CHLA Service Desk Help@chla.usc.edu.

Part 11 Compliance (Electronic Records) for FDA Studies

Part 11 compliance validation of a remote application **is done individually for each study**. The certification of the study is required by the FDA and is performed by a third-party vendor.

1. CHLA IS **does not offer** any service for Part 11 compliance validation requests. Investigators are advised to communicate with the study sponsor to discuss acceptable Part 11 compliant remote applications or to identify a vendor that performs validation and certification for electronic consent.

2. If the sponsor provides a remote application that is not CHLA approved, the Technology Contract Review (TCR) may be required. For more information see this website: https://chla.sharepoint.com/teams/techreview/SitePages/Home.aspx

Compliance Tips for Remote Consent and Electronic Signatures

Below are compliance tips for ensuring informed consent is obtained and documented:

1. The remote consent process (e.g., applications used, how consent signatures were obtained) should be documented in each subject's source notes/note to file. A sample note to file is available on the CRSO SharePoint site.

2. Flag or highlight the correct signature and date lines for electronic signatures to ensure all required signatures are obtained.

3. Participants/parent(s) or legal guardian(s) should be instructed to retain signed copies of the consent documents for their own records.

4. All attempts need to be made to receive the originals or copies of the signed documents. If signed copies are not returned, the investigator may need to follow up with the participant/parent or legal guardian to bring back the signed consent to the research site at the time of the next visit. **Research procedures cannot begin until the documents are received, counter signed and dated.**

5. If the participant/parent or legal guardian cannot use the application for electronic signatures they can print consent forms and send them by mail or fax, or they can bring the documents in person to their next visit to clinic for counter signing and dating. **Research procedures cannot begin until the documents are received, counter signed and dated.**

6. Unless the criteria for a waiver of documentation of consent are met and approved by the IRB, documentation of consent is required (similar to in-person consenting). **If an investigator does not receive signed copies of consent documents for counter signing and dating, written informed consent from the participant/parent or legal guardian has not been obtained.**

7. The person obtaining consent should sign and date the appropriate signature lines with the current date when they receive the consent for signing, not the date they spoke with the participant/parent or legal guardian.

8. Ensure all signatures and dates are accurately documented. Any errors should be noted in the note to file and corrected appropriately.