

Telephone/ Video Consent Process to Obtain a Signed Consent Form

1. **Provide the potential participant with all of the required information about the study in advance.**
 - a. Send a copy of the IRB approved consent document to the potential participant via email, mail, or fax.
2. **Give the potential participant an opportunity to ask questions before providing consent.**
 - a. Ensure the participant has enough time after receiving the consent form to read it before the scheduled telephone/video visit.
 - b. Contact the participant to discuss the study, highlighting each section of the consent form.
 - c. If the participant has questions about the study, the study team should ensure an appropriate participant is available to answer those questions.
3. **Give the potential participant enough time to consider being in the study.**
 - a. Inform the participant that if they would like to take more time to consider the study, another time can be scheduled.
4. **Ensure that only study personnel approved to consent by the IRB are consenting the participant.**
5. **Document that the participant's consent was obtained before beginning study procedures.**
 - a. Ask the participant if he/she would like to participate. If yes, have the participant sign and date the consent form, then return it to you (via email, mail, or fax).
 - b. Write a note to file that documents everything about the interaction:
 1. When/how the consent form was sent
 2. When the telephone/ video visit was made
 3. What was discussed during the visit
 4. The subject's full legal name and date of birth were confirmed
 5. When the partially signed consent form was received
 6. When the partially signed consent form was signed by the person obtaining consent
 7. When a copy of the fully signed consent form (signed by subject and study personnel) was given to the participant
 - c. When the partially signed consent form is received, the person obtaining consent should sign and date it in real time, not the date the phone/ video visit was done.
 - d. Study procedures may begin once the signed copy is received.
6. **Give a copy of the fully signed consent form to the participant.**
 - a. Send a fully signed consent form via email, mail, or fax. A copy can also be given to the participant in person, if the participant will be coming in for a study visit.
7. **Per LLUH Policy, upload a copy of the fully signed consent form to the participant's record in LLEAP.**

For Non-English-Speaking Subjects:

1. **Give information in a language the participant understands.**
 - a. The potential participant will be provided a fully translated IRB approved consent in their language.
 - b. Secure an authorized interpreter for the conversation, if needed.
 - c. Interpreter will sign a note to file confirming the interpretation of the study with the potential subject. This should be attached to the final signed consent document.