

## Consent Process Examples

### Telephone Consent Process to Obtain a Signed Consent Form

**Description:** Though a signed consent form may be necessary before beginning study procedures, it may be acceptable to obtain consent over the phone or via video conferencing before the first study visit. For example, such an alternative may be appropriate when the individual is unable to visit the study site to sign the consent form, or if the screening procedures for a clinical investigation require prior activity, such as fasting, that requires consent but does not require a visit to the study site. This example illustrates the steps a study team might take to obtain consent via telephone prior to the first study visit. ***The IRB must first approve a consent process that outlines this procedure. The details of the procedure to obtain consent can be provided on the Consent Process page of the New Study Application in ERICA.***

1. **Provide the participant with all the required information about the study in a language the participant understands.** Send a copy of the consent document to the participant via email, mail, or fax. Secure an interpreter for the telephone conversation, if needed.
2. **Give the participant an opportunity to ask questions before providing consent.**
  - a. Ensure the individual has enough time after receiving the consent form to read it before the scheduled telephone call.
  - b. Call the individual to discuss the study, highlighting each section of the consent form.
  - c. If the individual has questions about the study, the study team should ensure an appropriate individual is available to answer those questions.
3. **Give the participant enough time to consider being in the study.** Inform the individual that if they would like to take more time to consider the study, another telephone call can be scheduled.
4. **Document that the participant's consent was obtained before beginning study procedures.**
  - a. Ask the individual 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 the interaction:
    1. When the consent form was sent
    2. When the telephone call was made
    3. What was discussed during the phone call
    4. When the partially signed consent form was received by the study team
    5. When the partially signed consent form was signed by the person obtaining consent (the person obtaining consent should sign the form and date it for the day it was signed, not the day the phone call was made)
    6. When a copy of the fully signed consent form was given to the participant
  - c. Study procedures may begin once the signed copy is received.

5. **Give a copy of the signed consent form to the participant.** 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.