Consent Process Examples

Telephone Consent Process to Obtain a Signed Consent Form

- 1. Provide the participant with all of the required information about the study.
 - a. Send a copy of the consent document to the participant via email, mail, or fax.
- 2. Give information in a language the participant understands.
 - a. Secure an interpreter for the telephone conversation, if needed.
- 3. 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.
- 4. Give the participant enough time to consider being in the study.
 - a. Inform the individual that if they would like to take more time to consider the study, another telephone call can be scheduled.
- 5. Do not use exculpatory language in the consent process.
- 6. Document that the participant's consent was obtained before beginning study procedures.
 - a. Ask the individual if he/she would like to participant. 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 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
 - 5. When the partially signed consent form was signed by the person obtaining consent
 - 6. When a copy of the fully signed consent form was given to the participant
 - c. When you receive the partially signed consent form, 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.
 - d. Study procedures may begin once the signed copy is received.
- 7. Give a copy of the 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.