Consenting Blind and Illiterate Participants

If subjects cannot read the consent materials due to blindness, illiteracy, or the subject's legally authorized representative (LAR) is legally blind, the following consent process is followed:

- An impartial witness (someone who is not affiliated with the research team), such as a subject advocate, must observe the consent process. It is not recommended that family members serve as witnesses.
- The consent form must be presented to potential subjects orally.
- If potential subjects have access to equipment that can read the consent document for them, the research team must provide sufficient time and privacy for the participant to review the consent document independently.
- The study team must ensure that the consent process be transparent and meaningful. The potential subject, their representative, and the witness must have sufficient time to ask any questions.
- The subject signs and dates the consent form. If the subject is unable to sign and date the consent form, they should “make their mark” in the signature area of the consent form. If the participant’s LAR signs on the participants behalf the LAR will sign and date the form. The medical record (or study file if there is no medical record) should reflect whether the subject signed the consent form, made their mark, or the LAR signed on behalf of the participant.
- The witness signs and dates the consent form.
- Document the consent process in the medical record (or study file if there is no medical record) indicating that all relevant information was accurately explained; that the subject appeared to understood the provided information; and that informed consent was given freely.
- The study team member, who obtained the participant’s consent, signs and dates the consent forms.
- A signed copy of the consent form must be provided to the subject or subject's LAR.
- As required for any consent process, it is the study teams responsibility to judge the subject's comprehension of the consent process. It should be clear to the study team that the participant understands that participation is voluntary and that that they have the right to withdraw their consent at any time during the study. If the study team member doubts the subject's consent comprehension, they should not enroll the subject in the study.