Informed Consent Process

Determine:
Participant's preferred language
- Refer to EMR, or
- Ask participant/family

Non-English

Prepare for non-English Consent discussion
- Obtain fully translated consent (if available), **or**
- Obtain short form consent from IRB, **AND**
- Identify an interpreter

English

Assess:
Participant ability to consent

Participant can consent

Participant cannot consent and study is approved to consent LAR

Document in EMR:
Participant's inability to consent must be noted in EMR/Study records

Identify LAR
- Ensure LAR is appropriate to consent

Conduct Consent Discussion
- Provide Consent for review
- Discuss Study Protocol
- Answer questions
- Allow family consultation
- Provide time to decide
- Have interpreter present for non-English consent

Participant agrees to consent

Participant signs consent

Study Team signs consent
- Investigator/Coordinator signs consent
- Witness/interpreter* signs if non-English short form

If language line is used, enter interpreter employee ID in place of signature

Participant receives copy(ies)

Provide copy of the **signed**:
- Consent and
- HIPAA authorization

Document consent and enrollment in EMR:
- Upload signed consent and HIPAA authorization (if applicable)
- Insert a consent note documenting the consent process, including who was present during consent discussion