



Informed Consent/Assent Process Documentation

Protocol Name: _____

Participant Name: _____

Medical Record #: _____

Please **INITIAL** next to "Yes" or "No" by each line as appropriate (if "No," an explanation **MUST** be provided in the notes section below).

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Participant and their parent/guardian were given a copy of the consent document to read.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The consent/assent process occurred in a private, quiet area.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	All risks, benefits, alternative treatments, confidentiality, and details of the above mentioned study were explained to the participant and their parent/guardian.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Ample time was provided for reading the consent and assent documents, and the participant and parent/guardian were encouraged to ask questions.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The participant and their parent/guardian expressed an understanding of the study and consent process. All questions and concerns were addressed prior to signing the consent and assent documents.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The teach-back method was used to assess comprehension..
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The participant and their parent/guardian agreed to participate in the study and signed/dated the signature page of their respective consent and assent documents.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	A copy of the signed consent and assent documents and the University of South Alabama's Subject Bill of Rights document was provided to the participant and their parent/guardian.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	No procedures specifically related to the study were performed prior to signing the consent and assent documents.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The principal investigator was notified of the participant's consent to be enrolled in the study.

Consent/Assent Forms:

The participant signed assent document version _____ on _____ (date) at _____ (time).

The participant's guardian signed consent document version _____ on _____ (date) at _____ (time).

Notes: _____

Name of Person Conducting Consent Process

Signature of Person Conducting Consent Process

Date