Informed Consent 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).**

_____Yes	_____No	Participant and/or the participant's legally authorized representative (LAR) was given a copy of the consent document to read.
_____Yes	_____No	The consent process occurred in a private, quiet area.
_____Yes	_____No	All risks, benefits, alternative treatments, confidentiality, and details of the above mentioned study were explained to the participant (or participant's LAR).
_____Yes	_____No	Ample time was provided for reading the consent document, and the participant (or LAR) was encouraged to ask questions.
_____Yes	_____No	The participant (or LAR) expressed an understanding of the study and consent process. All questions and concerns were addressed prior to signing the consent document.
_____Yes	_____No	The teach-back method was used to assess participant's comprehension of the consent document.
_____Yes	_____No	The participant (or LAR) agreed to participate in the study and signed/dated the signature page of the consent document.
_____Yes	_____No	A copy of the signed consent document and the University of South Alabama's Subject Bill of Rights document was provided to the participant (or participant's LAR).
_____Yes	_____No	No procedures specifically related to the study were performed prior to the participant signing the consent document.
_____Yes	_____No	The principal investigator was notified of the participant's consent to be enrolled in the study.

Consent Form:

The participant (or LAR) signed consent document version _____ on_____*(date)* at _____*(time)*.

Notes: _____

_____

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_____

_____
Name of Person Conducting Consent Process

_____ _____
Signature of Person Conducting Consent Process Date