AdventHealth **Research Department**: _____

Informed Consent Process Checklist Template

Instructions: ***This document must be revised as needed to follow the approved study protocol. For example, if the IRB did not approve the enrollment of vulnerable populations, references to LAR should be removed. If assent will be obtained, this must be included. Consider the process if using electronic and/or remote consenting. The person completing the form should be the person obtaining consent.***

Protocol #: _____ Site# _____ Subject ID#_____

Yes	No	Questions
☐	☐	Was Subject or Legally Authorized Representative (LAR) physically* and mentally able to provide consent? ****If the subject/LAR is physically unable to sign the consent document, an Impartial Witness must be present and sign the document.***
☐	☐	If consent process is conducted remotely: ☐ Identity of Subject or LAR was confirmed ☐ Subject or LAR confirmed all pages of the consent were visible
☐	☐	Was Subject or LAR given ample time to read the informed consent(s)?
☐	☐	Were all questions and concerns addressed prior to subject or LAR signing the informed consent(s)?
☐	☐	Did the subject or LAR sign the informed consent(s) prior to start of any study procedure? ☐ Confirmed each page initialed (N/A when using a Short-Form or if not required by the IRB approved consent.) ☐ Completed all optional sections of the consent form**.** (N/A when using a Short-Form) ☐ Subject or LAR signed and dated in the appropriate area
☐	☐	Was a Legally Authorized Representative (LAR) used?
☐	☐	Was the informed consent(s) presented in a language read and understood by the subject? For non-English speaking subject, please answer questions below. List language: _____ Was an interpreter used? ☐**Yes** ☐**No** ☐**N/A** Interpreter #: _____ Was a Short-Form used**?** ☐**Yes** ☐**No** If yes, Name of Impartial Witness:_____ ***Note:*** ***Impartial Witness is a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the entire consent process and reads the consent document and any other written information supplied to the subject as part of the consent process. This specifically excludes Research Personnel on the study. AdventHealth does NOT permit interpreters to act as a witness.***
☐	☐	Was a copy of the signed and dated informed consent document(s) provided to subject or LAR? Specify if other copies: _____
☐	☐	Was a signed copy of the informed consent(s) filed in the subject's medical record?

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Comments: **(This section may be used to capture any additional details not checked above. For example, other personnel or family members that may be present during the consent discussion or on the call if consent is completed remotely.)**

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Signature of person completing form: _____ Date:_____