Appendix A: Template checklist for documenting the informed consent discussion

Template may be adapted or modified as needed.

IRB Study #: _____ Participant Initials: _____ Study ID: _____

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	A concise and focused presentation of the key information was provided.
_____Yes	_____No	The details of this research study were discussed, including an explanation of the required elements of the ICF.
_____Yes	_____No	It was emphasized that study participation is voluntary, that the participant's clinical care would not be affected if study participation is declined, and that the participant may withdraw consent at any time.
_____Yes	_____No	The ICF was provided in the preferred language.
_____Yes	_____No	Ample time was provided for reading the consent document and questions were encouraged.
_____Yes	_____No	All questions and concerns were addressed to the satisfaction of the participant (or LAR).
_____Yes	_____No	The PI or Co-I was available for questions.
_____Yes	_____No	The participant (or LAR) reviewed the current IRB approved consent document(s) and agreed to participate. Specify ICF version and date/time signed below.
_____Yes	_____No	A copy of the signed consent document was provided to the participant and/or LAR.
_____Yes	_____No	No procedures specifically related to the study were performed prior to the participant signing the consent document.
_____Yes	_____No	A copy of the signed consent document was placed in the participant's research file. If a copy was also placed in the medical record, specify in Notes.

The participant or the participant's LAR signed the following consent documents (notations of date and time should indicate when the ICF was signed):

☐ Main Study ICF, Version: _____Date:_____Time: _____

☐ Other ICF, Specify: _____ Version: _____ Date: _____Time: _____

☐ Other ICF, Specify: _____Version: _____ Date: _____Time: _____

Additional Notes (may include):

- *People who were present during the consent discussion, such as the participant, an LAR, the person obtaining consent, relative(s), PI, study coordinator, interpreter, witness, etc.)*
- *any questions or concerns raised during the consent discussion*
- *use of a verbal consent process, LAR or the short form method*

_____ _____ _____

Signature of Person Completing the Form Date Time