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

Template contextual note for documenting the IC discussion in the study record

Template may be adapted or modified as needed.

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

A concise and focused presentation of the key information was provided. The details of this research study were discussed with the participant, including an explanation of all of the elements of the ICF. 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. The participant was given an opportunity to read the informed consent form in the participant's preferred language and to ask questions.

All questions and concerns were addressed to the satisfaction of the participant. The participant verbalized understanding of the information and agreed to participate prior to any study-related procedures. The participant signed and dated the currently approved main ICF [version]; other ICF(s) [version(s)] and the HIPAA Authorization form [version], as applicable, on [date and time] prior to any study procedures being conducted and received a copy of the signed forms.

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, translator, 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

Template contextual note for documenting the IC discussion in the EMR

Template may be adapted or modified as needed.

Initial Consent Discussion:

Dr. _____ and I met with participant _____to discuss consent for _____. The protocol was reviewed, including discussion of risks & benefits, that the treatment involves research, review of charges covered / not covered by study, medications/treatments used, procedures involved including optional procedures, confidentiality, time commitments involved, study contact list, the option to withdraw at any time, and required use of birth control (as applicable).
Alternatives to study participation were discussed and the participant was given reasonable time to consider participation in the study, in the absence of coercion or undue influence. The participant was offered an opportunity to ask questions and these questions were answered. The participant verbalized understanding of information presented.

The participant has signed the main informed consent form (ICF), _____ [version]; other ICF(s) _____ [version(s)] and the HIPAA Authorization Form [version], as applicable, in my presence, prior to any study procedures being conducted. Copies of the informed consent form(s) and HIPAA Authorization Form were given to the participant.

The ICF(s) and HIPAA Authorization Form were uploaded into the participant's electronic medical record. The signed and dated ICF(s) and HIPAA Authorization Form will be kept in _____. Every effort to maintain confidentiality will be employed.

Date: _____Time: _____
Other ICF(s), HIPAA Form Signature: Same date, time and signature as above

Reconsent:

Dr. _____ and I met with participant _____ to discuss reconsent for _____. Changes to the study, including any changes in risk, procedures, treatments, and time commitments were reviewed. The participant was reminded of the option to withdraw at any time. Alternatives to study participation were discussed again. The participant reasonable time to consider continued participation in the study in the absence of coercion or undue influence. The participant was offered an opportunity to ask questions and all questions were answered. The participant verbalized their understanding of the new information presented and indicated their wishes to continue the study.

The participant has signed the ICF in the presence of the researcher obtaining informed consent. A copy of the consent form was given to the participant. A copy was submitted to UNC Health Information Management for upload into the participant's electronic medical record. The signed and dated ICF will be kept in _____. Every effort to maintain confidentiality will be employed.

Date: _____Time: _____