

Appendix B: 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