Appendix C: 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: _____