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| **CONSENT DOCUMENATION NOTE** |

@NAME@ was given the most recent IRB approved consent dated \*\*\* to read for the \*\*\* trial. The patient was alert & oriented and able to participate in the informed consent process. @NAME@ was given time to read and understand the consent form and then provided the opportunity to ask questions regarding the trial. All questions were answered by the study trial coordinator and/or investigator. The IRB was addressed with @NAME@ and information was pointed out on how to contact the IRB with questions. HIPAA information was also reviewed. After ample review with @NAME@, including, but not limited to the risks/benefits, other treatment options for treatment, & the subject right to withdraw from the study at any time, the subject consented to participate in the \*\*\* trial. The consent was then signed & dated by the appropriate study personnel and a copy of the consent given to @NAME@. The original consent form is kept in the participant's research files.