## CONSENT PROCESS CHECKLIST

Subject Initials or ID: _____ Protocol: _____

☐ Initial Consent ☐ Re-consent ☐ Phone

*Initial below, if the statement below is not applicable indicate N/A and capture explanation in the progress note.*

**INITIALS**

_____ Subject/LAR was alert and oriented (to self, place, and time) and able to participate in the informed consent process (ask appropriate questions, repeat details, answer questions).

_____ Subject/LAR was given a copy of the currently approved consent form, HIPAA Authorization form (if applicable) and Consent Addendums (if applicable) to read prior to obtaining consent.
Consent/Assent IRB approved date: _____

_____ Ample time was given to the subject/LAR to fully read and understand information provided.

_____ Subject/LAR was given the opportunity to ask questions after reading the consent and other relevant information. All questions were answered to the subject's/LAR's satisfaction.

_____ Subject/LAR had the opportunity to decide if they wish to participate in the clinical trial free of coercion.

_____ Details of the consent form were reviewed with the subject/LAR in a private setting.

_____ Subject/LAR verbalized understanding of the purpose of the study, study procedures, risks, benefits, costs, compensation for participation (if applicable), alternative treatments, compensation for injury, who may access their personal health information, who they may contact if they have questions about the study and that participation is voluntary and they can withdraw from the study at any time without penalty.

_____ Subject/LAR consented to participate in the above listed clinical research study. Consent, HIPAA Authorization form (if applicable) and Consent Addendums (if applicable) were signed, dated, initialed (if applicable) and timed by the subject/LAR. All forms are complete and free of error and omissions.

_____ Consent was signed and dated by PI or designated research team member who obtained consent from the subject/LAR and study partner (if applicable) and is listed on the DOA as someone who may obtain consent.

_____ Details of the consent process were documented in an appropriate source document.

_____ Consent process was completed prior to any study procedures.

_____ HIPAA information reviewed with subject/LAR. Separate HIPAA Authorization form completed for OSU IRB approved studies.

_____ A copy of all signed forms was given to the subject/LAR and study partner (if applicable).

_____ Original signed forms were filed appropriately.

_____ Subject/LAR clarified with the CRC/CRS how they would like to be contacted and if messages may be left for them.

_____ _____

Person Obtaining Consent Signature & Date PI/Sub-I Reviewing Signature & Date