IRB#: Protocol #: Participant Name­­­­­­­­­­:

Date of Birth: Medical Record #:

Please **INITIAL** next to **“Yes” or “No”** by each line as appropriate **(if “No,” an explanation MUST be provided in the notes**

**section below). (HIPAA Authorization is not required for all studies – if it doesn’t apply, please remove it from the statements below – also remove this sentence prior to use.)**

|  |  |  |
| --- | --- | --- |
|  Yes |  No | Participant and/or the participant’s legally authorized representative (LAR) was given a copy of the consent document/HA to read. |
|  Yes |  No | Ample time was provided for reading the consent document/HA, and the participant (or participant’s LAR) was encouraged to ask questions. |
|  Yes |  No | All questions and concerns were addressed to the satisfaction of the participant (or participant’s LAR) prior to signing the consent document/HA. |
|  Yes |  No | The PI or Sub-I was available for questions prior to the subject signing the consent/HA. |
|  Yes |  No | The subject (or subject’s LAR) agreed to participate in the study and signed/dated the consent document/HA. |
|  Yes |  No | A copy of the signed consent document/HA was provided to the participant (or participant’s LAR).❑ Verbal consent was obtained (per IRB approved consent process). Documentation of the process and the individual(s) witnessing the process is described below. |
|  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/HA was placed in the participant’s medical record.  |

The details of this research study were discussed with the participant (or participant’s LAR), including an explanation of all of the elements of the consent document. The IRB-approved consent document was signed and dated by the participant (or participant’s LAR). No activities specifically related to the research were initiated until after the execution of the consent document. The principal investigator was notified of the participant’s consent to be enrolled in the study.

Consent Form:

The participant (or participant’s LAR) signed consent document version on

 *(date)* at *(time)*.

HIPAA Authorization:

The participant (or participant’s LAR) signed HIPAA Authorization version \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(date)* at \_\_\_\_\_\_\_\_\_\_\_\_\_ *(time).*

Notes­­­­­­:

Signature of Person Obtaining Consent Date Time