**Study:**  **IRB #:**  **PI:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant ID:** |  | **Participant Initials:** |  |
| **IRB Approval Date**  | ☐ N/A | **IRB Expiration Date**  | ☐ N/A |
| **Is this the most recent version of the IRB approved form?** | [ ]  YES [ ]  NO [ ]  N/A |

|  |  |
| --- | --- |
| **Participant’s Primary Language:**  |  |
| **Interpreter Information:**[ ]  N/A because thePerson Obtaining Consent is fluent and qualified to obtain consent in Participant’s Primary Language*Ensure documentation of their qualification is in the study record.* | **Name of Interpreter:** |  |
| **Interpreter Affiliation:**  | [ ]   | **Interpretation Company***Provide company name* |  |
| [ ]  | **Interpretation Service internal to the organization***Provide the service/department name* |  |
| [ ]  | **Other qualified interpreter***Briefly describe their affiliation. Ensure documentation of their qualification is in the study record.* |  |

**Select the Non-English Consent Document & Process used:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  | **Short Form Consent Document & Process** Translated Short Form in Participant’s Primary Language *partnered with* A Full Consent Form in English |  | [ ]  | **Fully Translated Consent Document & Process**A Full Consent Form Translated in Participant’s Primary Language |
| *Fill out this column to document the Short Form Consent Process. Leave blank if not using.* |  | *Fill out this column to document the Full Translation Consent Process. Leave blank if not using.* |
| **Name of independent witness to the consent process:** *This person must speak English and the Participant’s Primary Language.* |  |  | **Date Participant/LAR signed the Fully Translated Consent Form:** | **(DD/MM/YYYY)** |
| [ ]  | Interpreter is acting as witness. |  | **Time Participants/LAR signed:****24 Hour Clock (01:00-24:00)** | [ ]  N/A |
| **Date Participant/LAR signed the Short Form:** | **(DD/MM/YYYY)** |  | **Date Person Obtaining Consent signed the Fully Translated Consent Form:** |  |
| **Time Participants/LAR signed:****24 Hour Clock (01:00-24:00)** | [ ]  N/A |  |  |
| **Date Witness signed the Short Form:** |   | [ ]  Remote attestation for witness |
| **Date Person Obtaining Consent signed the Full English Consent Form:** |  |  |
| **Date Witness signed the Full English Consent Form:** |  | [ ]  Remote attestation for witness |

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| --- |
| **Person obtaining consent should check below to indicate completion of each task for Informed Consent:** |
| [ ] Yes | The informed consent form was signed before any research procedures were performed above and beyond routine standard of care. |
| [ ] Yes | The participant was given the opportunity to read the consent and ask questions. |
| [ ] Yes | The participant was consented in their primary language. |
| [ ] Yes | The participant verbalized understanding of the informed consent information. |
| ☐Yes | The participant was consented voluntarily.  |
| [ ] Yes [ ]  N/A | **If applicable**, the protocol defined contraceptive was discussed with the participant. Please list the participants’s agreed upon method of contraceptive: |
| [ ] Yes | A copy of the signed consent form was given to the participant. |
| [ ] Yes [ ]  N/A | **If remote attestation is used for the witness to the Short Form Consent Process:** *This should be used in situations when the witness participated remotely and cannot provide a signature on the consent documents.* The witness signature statement was read aloud to the witness and the witness gave verbal or written attestation, without providing a signature.  |
| Additional consent details: |
| **Name of person obtaining consent:** |  |

Signature of Person Obtaining Consent Date