**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 the  Person 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 | | |

|  |  |  |
| --- | --- | --- |
| **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