INFORMED CONSENT PROCESS NOTE
NON-ENGLISH SPEAKING PARTICIPANT

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

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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