**Study: IRB #: PI:**

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| --- | --- | --- | --- | --- | --- |
| **Participant ID:** | |  | **Participant Initials:** | |  |
| **IRB Approval Date** | **Consent** | N/A | **IRB Expiration Date** | **Consent** | N/A |
| **Assent** | N/A | **Assent** | N/A |
| **PPF** | N/A | **PPF** | N/A |
| **Date Participant/LAR Signed: (DD/MMM/YYYY)** | **Consent** | N/A | **Time Participant/LAR signed:**  **24 Hour Clock**  **(01:00-24:00)** | **Consent** | ☐ N/A |
| **Assent** | N/A | **Assent** | ☐ N/A |
| **PPF** | N/A | **PPF** | ☐ N/A |
| **Is this the most recent version of the IRB approved form?** | | | Consent:  YES  NO  N/A  Assent:  YES  NO  N/A  PPF:  YES  NO  N/A | | |

|  |  |  |
| --- | --- | --- |
| **Person obtaining consent should check below to indicate completion of each task for Informed Consent, Parental Permission, and Assent:** | | |
| Yes | The informed consent form, PPF and Assent (if applicable) were signed before any research procedures were performed above and beyond routine standard of care. | |
| Yes | The participant/parent(s)/guardian were given the opportunity to read the consent and ask questions. | |
| Yes | The participant/parent(s)/guardian were consented in their primary language. | |
| Yes | The participant/parent(s)/guardian verbalized understanding of the informed consent information. | |
| ☐Yes | The participant/parent(s)/guardian were consented voluntarily. | |
| Yes  N/A | **If applicable,** the participant is capable of reading the Assent form and has signed the Assent to take part in this study. | |
| Yes  N/A | **If applicable,** the participant is not capable of reading the Assent form, but the information was verbally explained to him/her. The participant signed the Assent to take part in this study. | |
| Yes  N/A | **If applicable**, the protocol defined contraceptive was discussed with the participant/parent(s)/guardian. Please list the participant’s agreed upon method of contraceptive: | |
| Yes | A copy of the signed consent(s) form(s) were given to the participant/parent(s)/guardian. | |
| Additional consent details (include any details for obtaining non-english speaking consent): | | |
| **Name of person obtaining consent:** | |  |

Signature of Person Obtaining Consent Date