**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/AAssent: [ ]  YES [ ]  NO [ ]  N/APPF: [ ]  YES [ ]  NO [ ]  N/A |

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| --- |
| **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