Informed Consent Process Checklist

IRB Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approved Age Criterion for Subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Consent

was Obtained: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approval Period of the ICF Used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person Obtaining Consent

and Completing this Form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Yes No** | **Date** | **Staff Initials** | **Consent Note to File** (*for any of the items checked “No”;* i.e., handwritten changes, signatures missing, etc.) |
| 1 | Discussed study with potential subject, parent, and/or LAR. |  |  |  |  |
| 2 | Copy of ICF given to subject and time for review and discussion with family or others was provided. |  |  |  |  |
| 3 | The subject met all eligibility requirements (i.e., age, all inclusion criteria, and etc.) |  |  |  |  |
| 4 | The subject signed and dated the ICF. |  |  |  |  |
| 5 | The parent and/ or LAR signed and dated the ICF. |  |  |  |  |
| 6 | IRB-approved LAR provided permission for subject to participate and relationship to the subject was indicated. |  |  |  |  |
| **7** | Assent obtained if applicable. |  |  |  |  |
| 8 | ICF was signed and dated by IRB-approved research personnel (listed as study staff to obtain consent) |  |  |  |  |
| 9 | Did the subject, parent/LAR, and study staff enter the same date on the ICF? |  |  |  |  |
| 10 | ICF free of strikeouts or changes. |  |  |  |  |
| 11 | Subject consented with valid, IRB-01 approved version of the ICF. |  |  |  |  |
| 12 | Consent was obtained before initiation of study procedures or collection of data (demographic info, questionnaires, testing, and etc. ) |  |  |  |  |
| 13 | Original signed ICF on file |  |  |  |  |
| 14 | Copy of signed ICF given to subject/family. |  |  |  |  |

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_