

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

Signature: _____

Date: _____