

## SUMMARY OF UPDATES TO THE NHG DSRB ASSENT FORM TEMPLATE (01 Aug 2025)

The latest update to the NHG DSRB Assent Form Template (Version 03, dated 01 Aug 2025) has been updated to align with the SingHealth CIRB Assent Form Template to streamline the IRB submission process for this frequently used document in cross-cluster studies and provide additional useful information to the child/participant.

Please refer to the table below for more details.

Page on ICF Template	Section of ICF Template	Section Title	Change From	Change To	Explanation												
Page 1	Nil	Nil	Nil	<div><p><b>Table 1: Guidelines for assent requirements and documentation</b></p><table><tr><td></td><td>Child has sufficient understanding and intelligence*</td><td>Child does not have sufficient understanding and intelligence*</td></tr><tr><td>0 to 5 years</td><td>Written agreement of the child is not required</td><td>Written agreement of the child is not required</td></tr><tr><td>6 to 11 years</td><td>Assent Form</td><td>Assent Form (unless waived by the IRB)</td></tr><tr><td>12 to 20 years</td><td>Consent Form</td><td>Assent Form (unless waived by the IRB)</td></tr></table><p>*In all scenarios, consent from the child's legal representative (LR) is required, unless waived by the IRB.</p><p><b>Definition:</b></p><p><b>Assent</b> means a child's affirmative agreement to participate in research. Mere failure to object and absent affirmative agreement should not be construed as assent.</p><p><b>Minor</b> refers to a person who is below 21 years of age and who has never been married. The term "Minor" and "Child" are used interchangeably.</p><p><b>Legal Representative (LR)</b> refers to a person having capacity who is</p><p>a) a deputy appointed under the Mental Capacity Act in relation to the giving or refusing of consent on behalf of the minor to being a participant; or</p><p>b) an adult parent (if there is no deputy), or a guardian of the minor (if there is no adult parent to act as a Legal Representative of the minor).</p><p><i>You may delete the above paragraphs in the final document.</i></p></div>		Child has sufficient understanding and intelligence*	Child does not have sufficient understanding and intelligence*	0 to 5 years	Written agreement of the child is not required	Written agreement of the child is not required	6 to 11 years	Assent Form	Assent Form (unless waived by the IRB)	12 to 20 years	Consent Form	Assent Form (unless waived by the IRB)	To provide guidance on the assent requirements and definitions of terms used in the Assent Form
	Child has sufficient understanding and intelligence*	Child does not have sufficient understanding and intelligence*															
0 to 5 years	Written agreement of the child is not required	Written agreement of the child is not required															
6 to 11 years	Assent Form	Assent Form (unless waived by the IRB)															
12 to 20 years	Consent Form	Assent Form (unless waived by the IRB)															

Page 2-3	Nil	Nil	<p>You are being asked to be in a research study. This is because you have [disease or condition]. This study will look at a new (experimental) [drug, device]. We want to see how well it works and if it is safe that is why you have been asked to participate.</p> <p>If you say yes, you will have to do certain things, like: [Insert the procedure/ requirement of the child/ participant]</p> <p>The study [medicine, device, etc.] may not help ... you feel better ... or ... your [disease or symptoms].</p> <p>You can choose if you want to be in this study or not. If you decide not to be in the study, no one will be mad at you. Your doctor will still take care of you.</p>	<div> <div> <b>What is this research study about?</b> <p>You are being asked to be in a research study. This is because you have [disease or condition]. This study will look at a new (experimental) [drug, device].</p> </div> <div> <b>Why am I asked to be in this research study?</b> <p>We want to see how well it works and if it is safe that is why you have been asked to participate.</p> </div> <div> <b>What will happen if I take part in this research study?</b> <p>If you say yes, you will have to do certain things, like: [Insert the procedure/ requirement of the child/ participant]</p> </div> <div> <b>Will I feel any pain or discomfort if I take part?</b> <p>[Describe risks or discomforts using simple terms a child would know and understand; take into account a child's fears.]</p> </div> <div> <b>Could the research study help me get better?</b> <p>The study [medicine, device, etc.] may not help ... you feel better ... or ... your [disease or symptoms].</p> </div> <div> <b>Do I have to be in this research study?</b> <p>You can choose if you want to be in this study or not.</p> <ul style="list-style-type: none"> <li>If you say 'Yes' now, you can always say 'No' later.</li> <li>If you decide not to be in the study, no one will be mad at you. Your doctor will still take care of you.</li> </ul> </div> <div> <b>What if I have questions?</b> <p>You can ask any questions you have, now or later. If you think of a question later, you can ask your parents or have them call the study doctor.</p> </div> <div> <b>Other information about this research study?</b> <p>If you want to understand more about this research study, please tell your doctor.</p> <p>You will be given a Participant Information Sheet and Consent Form. It is the same paper that we give to your parents when we tell them about this research study.</p> </div> </div>	<ol style="list-style-type: none"> <li>Added section headers in a question-and-answer format to improve the readability</li> <li>Added a new section "Will I feel any pain or discomfort if I take part?" to let the child/participant know if there would be any pain or discomfort</li> <li>Under the section "Do I have to be in this research study?", expanded the sentence to "If you say 'Yes' now, you can always say 'No' later." to let the child/participant know that he/she can change his/her mind</li> <li>Added a new section "What if I have questions?" to let the child/participant know that he/she can ask his/her parents or the study doctor if he/she has questions at anytime</li> <li>Added a new section "Other information about this research study?" to let the child/participant know that the/she can request for more information about the study</li> </ol>
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Reference: [DSRB Templates for Study Documentation \(https://ethics.gri.nhg.com.sg/dsrbtemplates/\)](https://ethics.gri.nhg.com.sg/dsrbtemplates/) > Child/Participant Assent Form > 207-008: Assent Form Template