Summary of Changes to the CIRB Child/ Participant Assent Form Template (version 3 to 4) - 10 Aug 2022

<table>
<tr><th>No.</th><th>Section</th><th>Change From</th><th>Change To</th><th>Explanation</th></tr>
<tr>
<td>1.</td>
<td>Cover Page - Instructions to Researchers</td>
<td>
<u>Instructions for Child/ Participant Assent Form</u>

Assent means a child's affirmative agreement to participate in research. Mere failure to object and absent affirmative agreement should not be construed as assent.

Minor 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.

In general the CIRB recommends that assent of a minor be sought when the child is 6 years of age or older, unless the child's decision-making capacity is impaired.

For children below 6 years of age, written agreement of the child is not required.

For children 6 to 12 years of age, Child/ Participant Assent Form[1] should be provided to document their agreement regarding participation.

<u>NOTE (1):</u>
If an investigator deems that the children age 6 to 12 years, has sufficient understanding and intelligence, Participant Information Sheet and Consent Form[2] may be used instead. Their agreement regarding participation should be documented together with informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian).

<u>NOTE (2):</u>
Information provided must be in a language understandable to children age 13 years. <u>ALL</u> consent documents should be written in simple language, at Primary 6 reading level or lower, which means short sentences, paragraphs and simple terms. Avoid medical/ scientific/ technical language or if they must be used, to include in brackets simple definitions or explanations for such terms.

For children 13 to 20 years of age, Participant Information Sheet and Consent Form[2] should be provided to document their agreement regarding participation, together with the informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian).

<u>Completing the template:</u>
• Language should be at a level appropriate to the child's age and development.

• Please note that parts in italics and/or yellow highlights should be modified for your specific research. Other parts may need to be modified as well depending on your research study.

• Please delete this page before submitting to CIRB.
</td>
<td>
TEMPLATE FOR CHILD/ PARTICIPANT ASSENT FORM
Please remove this text box when finalizing the document

<u>GUIDELINES:</u>
Important: All <u>new</u> IRB applications (for research involving children) submitted on and after 1 October 2022, are required to implement the revised assent requirements and documentation outlined in Table 1. The term "submitted" refers to the date when the IRB application reaches CIRB via iSHaRe, upon completion of the institution endorsement process.

Studies submitted and/or approved before 1 October 2022 may continue with the "existing" assent requirements and documentation, outlined in Table 2 till study completion, unless the researchers make voluntary determination to implement the changes.
For example, (1) Ongoing research study approved on 24 February 2020; or (2) IRB application submitted on 26 September 2022 and later approved by CIRB on 11 October 2022 will continue with the "existing" guidelines. However, if the researchers decide to implement the revised guidelines for their studies, the determination should be clearly documented on Section M4 of CIRB amendment form, and submitted for CIRB review and approval.

<u>Table 1:</u> <u>Revised guidelines for assent requirements and documentation</u>
(Applicable to <u>new</u> IRB applications submitted on and after 1 October 2022)
<table>
<tr><th></th><th>Child has sufficient understanding and intelligence*</th><th>Child does <u>not</u> have sufficient understanding and intelligence*</th></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>
<u>Table 2:</u> <u>"Existing" guidelines for assent requirements and documentation</u>
(Applicable to studies submitted and/or approved before 1 October 2022)
<table>
<tr><th></th><th>Child has sufficient understanding and intelligence*</th></tr>
<tr><td>0 to 5 years</td><td>Written agreement of the child is not required</td></tr>
<tr><td>6 to 12 years</td><td>Assent Form</td></tr>
<tr><td>13 to 20 years</td><td>Consent Form</td></tr>
</table>
*In <u>all</u> scenarios, consent from the child's legal representative (LR) is required, unless waived by the IRB.
</td>
<td><u>Important</u>

- Describe changes to the guidelines for assent requirements and documentation, and the implementation.</td>
</tr>
</table>

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No.	Section	Change From	Change To	Explanation
2.	**Cover Page - Instructions to Researchers**	**Instructions for Child/ Participant Assent Form** **Assent** means a child's affirmative agreement to participate in research. Mere failure to object and absent affirmative agreement should not be construed as assent. **Minor** 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. In general the CIRB recommends that **assent** of a **minor** be sought when the child is 6 years of age or older, unless the child's decision-making capacity is impaired. For **children below 6 years** of age, written agreement of the child is not required. For **children 6 to 12 years** of age, Child/ Participant Assent Form[1] should be provided to document their agreement regarding participation. NOTE (1): If an investigator deems that the children age 6 to 12 years, has sufficient understanding and intelligence, Participant Information Sheet and Consent Form[2] may be used instead. Their agreement regarding participation should be documented together with informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian). NOTE (2): Information provided must be in a language understandable to children age 13 years. **ALL** consent documents should be written in simple language, at Primary 6 reading level or lower, which means short sentences, paragraphs and simple terms. Avoid medical/ scientific/ technical language or if they must be used, to include in brackets simple definitions or explanations for such terms. For **children 13 to 20 years** of age, Participant Information Sheet and Consent Form[2] should be provided to document their agreement regarding participation, together with the informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian). **Completing the template:** • Language should be at a level appropriate to the child's age and development. • Please note that parts in italics and/or yellow highlights should be modified for your specific research. Other parts may need to be modified as well depending on your research study. • Please delete this page before submitting to CIRB.	**Definition:** **Assent** means a child's affirmative agreement to participate in research. Mere failure to object and absent affirmative agreement should not be construed as assent. **Minor** 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. **Legal Representative (LR)** refers to a person having capacity who is 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 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). **In this template:** • [Square brackets in blue text] indicate instructions to researchers only and should not be included in the assent form. • (Brackets in yellow highlight) indicate where specific information is to be inserted. • Yellow-highlighted text without brackets indicates words or phrases that should be looked at carefully whether to retain it, modify it or delete it as relevant to your study. **Completing the template:** • Write at reading level appropriate to the child's/ participant's age and development. • Remove text in red, text in blue, yellow highlight. • Change *text in italics* to standard lettering. • Delete this "TEMPLATE FOR CHILD/ PARTICIPANT ASSENT FORM" text box when finalizing the document.	Administrative change - Add definition for Legal Representative (LR). - Update instruction for completing the template.
3.	**Introductory paragraph**	You are being asked to take part in a research study. This paper tells you about a research study we are doing. You can ask questions any time.	You are being invited to take part in a research study. This paper tells you what the research study is about. Please read it carefully. You can ask questions at any time.	Administrative change - Relocate for better flow. - Rephrase for clarity.

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No.	Section	Change From	Change To	Explanation
4.	**What is this research study about?**	A research study is a way to learn information about something. We want to find out more about [*Describe the purpose of this research]. Example: This study will look at a new (experimental) [drug, device, etc.]. We want to see how well it works and if it is safe.*	A research study is a way to learn information about something. We are doing this research to find out more about (*describe the purpose of this research).* Example: A research study is a way to learn information about something. This research will look at a study pill. We want to see how well it works and if it is safe.	Administrative change - Rephrase for clarity.
5.	**Why am I asked to be in this research study?**	You are being asked to take part in this research study. This is because you have [*Indicate name of disease or condition/ other reason(s) for inclusion].*	You are being invited to take part in this research study. This is because you have *(indicate name of disease or condition being studied and/or other reason(s) for inclusion).*	Administrative change - Rephrase for clarity.
6.	**What will happen if I take part in this research study?**	If you say yes to be in this research study, you will be asked to do certain things, like [*Describe the research procedure/ activities. Also include how much time is involved or number of visits*].	[Describe the research procedure/ activities in age appropriate terms. Also, include how much time is involved or number of visits.] Example: If you say yes to be in this research study, we would ask you to do things, like: • Medical records: We would look at your past doctor visits and use information about your care. • Questions: We would ask you to read questions on a piece of paper. Then, you would mark your answers on the paper. • Talking: We would ask you questions. Then, you would tell us your answers.	Administrative change - Expand the guidance note for clarity. - Add examples of language for the description of research procedures.

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No.	Section	Change From	Change To	Explanation
			• Blood draw: We would give you a needle poke to get 1 teaspoon (5mL) of your blood. This will happen every 3 months for one year. If possible, we will try to get blood without a new poke.	
7.	**Will I feel any pain or discomfort if I take part?**	*[Describe risks or discomforts using simple terms a child would know and understand; take into account a child's fears].* *Example: The study pills might make you feel [……]. Be sure and tell your parent if you feel any of these things.*	[Describe risks or discomforts using simple terms a child would know and understand; take into account a child's fears.] Example: The study pill might make you feel *(describe the possible expected side effects)*. Be sure to tell your parent if you feel any of these things. The needle poke to get your blood will hurt, but the pain will go away after a while. We can put a cream on your skin before we take blood, so you will not feel the pain as much. Sometimes the needle can leave a bruise on the skin.	Administrative change - Add examples of language for the description of possible risks and discomforts.
8.	**Could the research study help me get better?**	The research study [*medicine, device, etc.*] may not help … you feel better … or … your [*disease or symptoms*]. *[Describe potential direct benefits to the child].*	[Describe potential direct benefits to the child or contribution to medical knowledge, if there are no benefits. Include the most appropriate statement for your study.] Example:	Administrative change - Expand the guidance note for clarity. - Add examples of language for the description of potential benefits.

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No.	Section	Change From	Change To	Explanation
			The research study may help you *(describe the potential benefits to the child).* **OR** The study pill may not help … you feel better … or your [disease or symptoms]. **OR** This research study will not help you. We do hope to learn something from this research though. And someday we hope it will help other children who have *(state the disease or condition)* like you do.	
9.	**Do my parents know about this research study?**	Your parents know about this research study too. You can talk to your parents about this study before you tell us 'Yes' or 'No'. *NOTE: Delete this section if the research is designed for conditions or for populations, which the parental or guardian permission is not a reasonable requirement to protect the participants (e.g. research involving child abuse or neglect).*	[Delete this section if the research study is designed for conditions or for populations, which permission from legal representative (i.e. adult parent/ guardian/ deputy) is not a reasonable requirement to protect the research participants (e.g. research involving child abuse or neglect).] Your parents know about this research study too. You can talk to your parents about this study before you tell us 'Yes' or 'No'.	Administrative change - Relocate the guidance note for better flow. - Define Legal Representative (LR).

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10.	**ASSENT**	Nil	Note: [1]An impartial witness is required, if the child/ participant is unable to read, and/or write his/her name and/or date on the assent form. For the latter, the child/ participant can affix his/her thumbprint onto the name field (where applicable). The impartial witness will be required to write the child's/ participant's name and date of assent on his/her behalf.	Administrative change - Include guidance note on the requirement for impartial witness.
11.	**IMPARTIAL WITNESS INFORMATION**	Nil	**IMPARTIAL WITNESS INFORMATION** *(To be completed by impartial witness, where applicable)* _____ Name of Impartial Witness _____ Signature _____ Date of signing	Administrative change - Add provision for documentation of impartial witness information, where applicable.
12.	**DECLARATION BY PERSON CONDUCTING ASSENT DISCUSSION**	Nil	**DECLARATION BY PERSON CONDUCTING ASSENT DISCUSSION** *(To be completed by person conducting assent discussion)*	Administrative change - Add heading to the section.