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| TEMPLATE FOR CHILD/ PARTICIPANT ASSENT FORM  Please remove this text box when finalizing the document  **GUIDELINES:**  **Important:** **All new 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.  **Table 1:** Revised guidelines for assent requirements and documentation  *(Applicable to new IRB applications submitted on and after 1 October 2022)*   |  |  |  | | --- | --- | --- | |  | 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)* |   **Table 2:** “Existing” guidelines for assent requirements and documentation  *(Applicable to studies submitted and/or approved before 1 October 2022)*   |  |  | | --- | --- | |  | Child has sufficient understanding and intelligence\* | | 0 to 5 years | Written agreement of the child is not required | | 6 to 12 years | Assent Form | | 13 to 20 years | Consent Form |   \*In all scenarios, consent from the child’s legal representative (LR) is required, unless waived by the IRB.  **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   1. 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 2. 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. |

**CHILD/ PARTICIPANT ASSENT FORM**

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.

**Protocol Title:**

(Full protocol title as used in the CIRB Application)

**Principal Investigator’s Name:** (PI’s Name)

**Phone Number:** (Phone Number)

What is this research study about?

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).*

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| 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. |

About *(insert number)* children will be in this research study.

Why am I asked to be in this research study?

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)*.

What will happen if I take part in this research study?

[Describe the research procedure/ activities in age appropriate terms. Also, include how much time is involved or number of visits.]

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| 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. * 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. |

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.]

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| 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. |

Could the research study help me get better?

[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.]

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| --- |
| Example:  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. |

Do I have to be in this research study?

You can choose if you want to be in this research study or not.

* If you say ‘Yes’ now, you can always say ‘No’ later.
* If you say ‘No’, your doctor will still take good care of you.

Do my parents know about this research study?

[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’.

What if I have questions?

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.

Other information about this research study?

If you want to understand more about this research study, please tell your doctor.

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.

ASSENT

This research study has been explained to me and I agree to be in this study.

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Child/ Participant Name for Assent1 Date

Note:

1An 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.

IMPARTIAL WITNESS INFORMATION

*(To be completed by impartial witness, where applicable)*

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Name of Impartial Witness Signature Date of signing

DECLARATION BY PERSON CONDUCTING ASSENT DISCUSSION

*(To be completed by person conducting assent discussion)*

Check which applies:

* The child/ participant is able to read and understand the assent form and has agreed to take part in this study.
* The child/ participant is not able to read the assent form, however, the information was explained verbally to the best of the child’s/ participant’s abilities to understand.

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Name of Person Conducting Signature Date of signing

Assent Discussion