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| --- |
| **Instructions:**  1. Children ages 7- 13:    * Use this simplified assent form to obtain assent from children ages 7 to 13 years old. 2. Adolescents ages 14-17:    * Use a single parental permission/assent document with signature lines for both parental permission and child assent. 3. Adults Unable to Consent:    * Use this simplified assent form for obtaining assent from adults who are unable to consent for themselves. 4. In some circumstances children and adults may not be able to sign the assent form, but investigators are required to document on the parental permission form whether assent is obtained. 5. Reading Level: Write the assent at a reading level that is appropriate for the children and/or adults involved in the study:    * Write the assent form at a 2nd or 3rd grade reading level for children ages 7 and 8.    * Do not write the assent form any higher than an 8th grade reading level. 6. The areas highlighted in yellow are the areas of the template that need to be completed. 7. Remove the yellow highlighting before submission to the IRB. 8. Remove this instructions box before submission to the IRB. |

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| microscope_guy | Children’s Hospital Los Angeles  **ASSENT TO PARTICIPATE IN A RESEARCH STUDY**  [insert a simple or lay title] |

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| --- | --- | --- | --- |
| **Subject’s Name:** |  | **Birth Date:** |  |
| **CHLA MRN#** [remove if N/A] |  |  |  |

1. Dr. [insert name of PI] is doing a research study about [describe the disease, condition, etc. being studied].
2. We are asking you to take part in this research because we want to learn more about [insert a brief description of the purpose of the research].
3. If you agree to be in this study, you will be asked to: [Briefly describe in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study. A bulleted list is acceptable. Consider including the duration of some procedures if they are lengthy.]

[If pregnancy testing will be performed in children, list this as a procedure and add the following:] Your pregnancy test results will not be shared with your parent(s) unless you tell us we can.

[If HIV/STI testing will be performed in children, list this as a procedure and add the following:] If the test says you have HIV or another kind of Sexually Transmitted Infection (STI) and you are at least 12 years of age, we will not share the results with your parent(s) unless you tell us we can. If the test says you have HIV or another kind of STI and you are under the age of 12, the results will be shared with your parent(s).

**When you are in a research study, sometimes good things and bad things can happen:**

1. Things that happen to people in research studies that make them feel bad are called “risks.” The risk(s) for this research study are: [Describe any risks to the subject that may result from participation in the research–use bullets and keep descriptions simple]. These things may or may not happen to you. Some things might happen that the doctors don’t know about yet.
2. Things that happen to people in research studies that are good are called “benefits.” The benefit(s) for this research study are: [Describe any benefits to the subject that may result from participation in the research–use bullets and keep descriptions simple].
3. We will do everything possible to keep your information private.
4. [Indicate if the subject directly receives any payment for being in the research. If there is no payment for participation or payment is not given to the subject directly, this item can be deleted]
5. You do not have to be in this study if you don’t want to. You may stop being in this study at any time [If applicable, modify to indicate that sometimes it is not possible to stop the study all at once and why]. Remember, being in this study is up to you.
6. Please talk with your parent(s) or caregiver before you decide to be in this study. We will also ask your parent(s) or caregiver to give their permission for you to take part in this study. But even if they say “yes,” **you** can still decide not to do this. [If the subject’s doctor is conducting the research:] Your doctor will still take care of you if you decide not to be in this study.
7. You can ask any questions that you have about the study. If you have other questions later, you can call me or ask me next time you see me.



[insert phone number of study office]

* No, I do not want to be in this study.
* Yes, I do want to be in this study.

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### Signature of Subject (if able to sign) Date