|  |
| --- |
| **Instructions:**  1. Use this simplified assent form template for Single Patient Expanded Access only. Please refer to the Expanded Access and Emergency Use of a Test Article (Drugs, Biologics and Devices) guidance available on the HSPP website at <https://www.chla.org/research/hspp> for information on single patient expanded access.  * Children ages 7- 13:   + Use this simplified assent form to obtain assent from a child ages 7 to 13 years old. * Adolescents ages 14-17:   + Use a single parental permission/assent document with signature lines for both parental permission and child assent. * Adults Unable to Consent:   + Use this simplified assent form for obtaining assent from an adult who is unable to consent for themself. * In some circumstances the patient may not be able to sign the assent form, but the treating physician is required to document on the parental permission form whether assent is obtained.  1. Reading Level: Write the assent form at a reading level that is appropriate for the child or adult who will be treated:    * Write the assent form at a 2nd or 3rd grade reading level for a child age 7 or 8.    * Do not write the assent form any higher than an 8th grade reading level. 2. The areas highlighted in yellow are the areas of the template that need to be completed and/or edited to meet the needs of the treatment. 3. Remove the yellow highlighting and brackets before submission to the IRB and/or use. 4. Remove this instructions box before submission to the IRB and/or use. |

|  |  |
| --- | --- |
| microscope_guy | Children’s Hospital Los Angeles  **ASSENT FORM**  **Single Patient Expanded Access**  Experimental Treatment with [Insert Name of Drug/Biologic or Device] |

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient’s Name:** |  | **Birth Date:** |  |
| **CHLA MRN#** |  |  |  |

1. Your doctor has recommended that you receive treatment with a [drug or device], called [insert name of drug or device], because you have a disease called [insert name of condition].
2. Using [insert name of drug or device] for your type of disease is considered experimental. This means that we do not know for sure if this treatment will help you.
3. If you choose to get the experimental treatment, you will be asked to: [Briefly describe in simple terms the procedures that are most likely to affect someone’s decision about whether to get the treatment. 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 get an experimental treatment, sometimes good things and bad things can happen:**

1. Things that happen to people that make them feel bad are called “risks.” The risk(s) for this treatment are: [Describe any risks that may result from the treatment–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 that are good are called “benefits.” The benefit(s) for this treatment are: [Describe the benefits that may result from the treatment–use bullets and keep descriptions simple].
3. We will do everything possible to keep your information private.
4. You do not have to get the experimental treatment if you don’t want to. You may stop the treatment at any time [If applicable, modify to indicate that sometimes it is not possible to stop the treatment all at once and why]. Remember, getting this treatment is up to you.
5. Please talk with your parent(s) or caregiver before you decide to get the treatment. We will also ask your parent(s) or caregiver to give their permission for you to get the treatment. But even if they say “yes,” **you** can still decide not to do this. Your doctor will still take care of you if you decide not to get the treatment.
6. You can ask any questions that you have about the treatment. If you have other questions later, you can call me or ask me next time you see me.



[insert phone number of doctor’s office]

* No, I do not want to get the experimental treatment.
* Yes, I do want to get the experimental treatment.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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