# **Instructions:**

1. This template may be used to reconsent/reassent already enrolled research subjects who were unable to consent/assent to their own participation in the study at the initial consent/assent conference due to being cognitively impaired, and the subject’s parent/guardian or legally authorized representative consented to the subject’s participation in the study at that time.
2. If the subject is a minor, the parent/legal guardian already provided permission for their child to be in this study at the initial parental consent conference. There is no parental signature section in this document for this reason. The parent/legal guardian can always withdraw their permission for their child to continue being in this study, but they do not have to give their written permission twice.
3. The areas highlighted in yellow are the areas of the template that need to be completed.
4. Reading Level: This form may be appropriate for subjects of all ages if it is written at a reading level that is appropriate for children and/or adults involved in the study (no higher than an 8th grade reading level).
5. Remove the yellow highlighting before submission to the IRB.
6. Remove this instructions box before submission to the IRB.

Children’s Hospital Los Angeles

**CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

[Insert study title]

**Addendum to Consent/Assent Form for Subjects Who Regain the Capacity to Consent/Assent During the Study**

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

You are currently enrolled in a research study at Children’s Hospital Los Angeles. When you first joined this research study, your parent/legal guardian or legally authorized representative gave their permission for you to be in this study because your medical condition and ability to understand things prevented you from being able to decide for yourself whether you could be in the study. However, now that your medical condition is improving and you can understand information more clearly, you can decide for yourself whether you want to continue your participation in this research study. A member of the research team will discuss this addendum consent/assent form with you.

The original consent/assent form for the study is attached for you to read over. The original consent/assent form provides an explanation of the research study and what participation in the study involves. A member of the research team will discuss any questions you have about the information contained within the original consent/assent form as well as discuss the remaining study activities with you. Continued participation in this study is completely voluntary. If you choose not to continue participating in this study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study, you should let the Principal Investigator know.

You should not sign this form if you have any questions that have not been answered, or if you are unclear about any information in this form or the original consent/assent form.

If after receiving this information you agree to continue taking part in this research study, please sign below. You will receive a signed and dated copy of this form for your records.

[Add the following signature section for documentation of consent from adults who are capable of providing consent, and/or documentation of assent from children ages 14 to 17 years old:]

**SIGNATURE OF RESEARCH SUBJECT**

(*For adults who are capable of providing consent; children ages 14 to 17 years old who are capable of providing assent*)

Your signature below indicates:

* You have read this document and understand its meaning;
* You have had a chance to ask questions and have had these questions answered to your satisfaction;
* You consent/assent to your participation in this research study; and
* You will be given a signed copy of this form.

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

Print Name of Subject

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

Signature of Subject Date

[Add the following signature section for documentation of obtaining consent/assent:]

**SIGNATURE OF INDIVIDUAL OBTAINING CONSENT**

I have explained the research to the subject and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/assent to participate.

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

Print Name of Individual Obtaining Consent

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

Signature of Individual Obtaining Consent Date

[Add the following signature section for documentation of a witness signature:]

**SIGNATURE OF WITNESS (if applicable)**

Your signature below indicates:

* You were present for the entire consent conference;
* The information in the consent document and any other written information was accurately explained to the subject;
* The subject had an opportunity to ask questions and those questions were answered; and
* The subject voluntarily signed the consent/assent form addendum in your presence.

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

Print Name of Witness

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

Signature of Witness Date