|  |
| --- |
| **Instructions:**Children who reach the age of majority (per CA Law, i.e., age 18, married, joined the armed forces, legal emancipation) during study participation must be re-consented as adults. If the adult subject is incapable of providing consent, surrogate consent from a legally authorized representative must be obtained per CA law. 1. This template may be used to obtain informed consent from adult subjects who are able to consent.
2. If an adult subject is unable to consent, obtain re-consent from the subject’s legally authorized representative (LAR) on the research study consent/permission/assent form.
3. If the research requires a written HIPAA research authorization, obtain a new HIPAA authorization that signed by the adult subject or LAR.
4. The areas highlighted in yellow are the areas of the template that need to be completed.
5. Reading Level: This form should be written at no higher than an 8th grade reading level.
6. Remove the yellow highlighting before submission to the IRB.
7. Remove this instructions box before submission to the IRB.
 |

Children’s Hospital Los Angeles

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Addendum to Consent Form for**

[Insert study title]

[If study title is technical, add lay language title]

[If the study involves using different forms for different populations, identify the population group as a subtitle]

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

You are currently enrolled in a research study at Children’s Hospital Los Angeles. When you began the study, your [parent/guardian or legally authorized representative] provided permission for you to be in this study. Now that you are an adult, you have the legal right to consent for your own continued participation. You will receive a signed and dated copy of this form for your records.

The original consent form for the study is attached. A member of the research team will discuss the remaining study activities with you.

Continued participation in this study is completely voluntary. If you choose not to take part in the 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 by the study team, or if you are unclear about any information in this form or the original consent form.

If after receiving this information you agree to continue taking part in this research study, please sign below.

[Add the following signature section for documentation of consent from adults who are capable of providing consent:]
**SIGNATURE OF RESEARCH SUBJECT**

(*For adults who are capable of providing consent*)

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 to your participation in this research study; and
* You will be given a signed copy of this form.

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Print Name of Subject

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

Signature of Subject Date

**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 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 and/or the subject’s voluntarily signed the consent/assent form in your presence.

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

Print Name of Witness

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

Signature of Witness Date