|  |
| --- |
| **Instructions:**1. This template may be used to provide new or additional information to parents/guardians/legally authorized representatives, and enrolled research subjects.
2. The areas highlighted in yellow are the areas of the template that need to be completed.
3. Reading Level: This form may be appropriate for subjects of all ages if it is written at a reading level that is appropriate for both parents/guardians/legally authorized representatives, and children and/or adults involved in the study (no higher than an 8th grade reading level).
4. Remove the yellow highlighting before submission to the IRB.
5. Remove this instructions box before submission to the IRB.
 |

Children’s Hospital Los Angeles

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

[Insert study title]

**Addendum: New Information**

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

New information has been learned about the research study that you are currently participating at Children’s Hospital Los Angeles.

If you are reading this consent form as a [parent/legal guardian or legally authorized representative] “you” also refers to [“your child” (the research participant)/the research participant].

You were previously informed that if there was new information found during the course of the study or the research plan was changed in a way that might affect your decision to continue participating in the study, you would be informed and your consent to continue participating in the study could be requested.

This form has more information about the research study. It may add or change the information in the consent form you signed at the beginning of the study. You will receive a signed and dated copy of this form for your records.

[Describe the new information or change in research using simple language. Include a lay language description of any new procedures, risks, benefits, findings, etc., and explain how the information affects currently enrolled subjects.]

The original consent form for the study is attached. A member of the research team will discuss this addendum consent from 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 or if you are unclear about any new information in this 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, 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.

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Print Name of Subject

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Signature of Subject Date

[Add the following signature section for documentation of parental permission from the parent(s) or legal guardian(s) of children:]

**SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)**

(*For all subjects under the age of 18*)

Your signature(s) 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 agree to your child’s participation in this research study;
* [Include the following statement if the parent completes any questionnaires or participates in other research activities related to the child:] You agree to your own participation in this research study; and
* You will be given a signed copy of this form.

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Print Name(s) of Parent(s)/Legal Guardian(s)

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

Signature of Parent/Legal Guardian Date

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Signature of Parent/Legal Guardian Date

[Add the following signature section for documentation of consent from a legally authorized representative for adults lacking the capacity to consent:]

**SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE**

(*For adult subjects who are not 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 allow the subject to participate in this research study; and
* You will be given a signed copy of this form.

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

Print Name of Legally Authorized Representative

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Signature of Legally Authorized Representative Date

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

**SIGNATURE OF INDIVIDUAL OBTAINING CONSENT**

I have explained the research to the subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

[Add this information when children and/or adults lacking the capacity to consent are subjects:]

**Assent Instructions:** All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.

* I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.

OR

* The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

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Print Name of Individual Obtaining Consent

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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 and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable];
* The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] had an opportunity to ask questions and those questions were answered; and
* The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] voluntarily signed the consent/permission/assent form in your presence.

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Print Name of Witness

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Signature of Witness Date