**GENERAL ADDENDUM FORM (TEMPLATE VERSION: 10/4/16)**

**[all instructions (in RED) and text not applicable to the research should be deleted when the form is modified for use on a particular study]**

Children’s Hospital Los Angeles

**CONSENT/PERMISSION/ASSENT[[1]](#footnote-1) TO PARTICIPATE IN A RESEARCH STUDY**

[Insert study title]

**Addendum: New Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Subject’s Name: |  | | |
| CHLA#[if applicable]: |  | Birth Date: |  |
|  |  |

You were previously informed that if there was significant 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.

Suggested text for new information:

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

Suggested text for change to research plan:

The research plan for the study in which you are currently participating at Children’s Hospital Los Angeles has changed.

[Describe the new information or change to the research plan 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. This form may be appropriate for subjects of all ages if written in developmentally appropriate language.]

You have the right to withdraw from this research study at any time and discontinue participation without penalty. Your choice about whether or not to continue participating will have no effect on your care, services or benefits at Children’s Hospital Los Angeles.

The original consent form for the study is attached. A member of the research team will discuss the new information with you. Continued participation in this study is completely voluntary. Please read the information provided and ask questions about anything you do not understand, before deciding whether or not to continue participating in the research.

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

|  |
| --- |
| **SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)** |

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

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

Signature of Subject Date

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| **SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)** |

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;
* [if applicable – keep in if the parent completes any questionnaires or participates in other research activities] 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

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

Signature of Parent/Legal Guardian Date

|  |
| --- |
| **SIGNATURE OF INDIVIDUAL OBTAINING CONSENT** |

I have explained the research to the subject and/or the subject’s parent(s)/legal guardian(s) 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.

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

Print Name of Individual Obtaining Consent

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

Signature of Individual Obtaining Consent Date

|  |
| --- |
| **SIGNATURE OF WITNESS (if applicable)** |

Your signature below indicates:

* I was 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);
* The subject and/or the subject’s parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
* The subject and/or the subject’s parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

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

Print Name of Witness

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

Signature of Witness Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

|  |
| --- |
| Please check appropriate box and sign below.  The undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby certifies that verbal assent was obtained from the subject.  Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information.)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_  Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Routing of signed copies of the form:

1. Give to the subject (copy)
2. Give to the parent/legal guardianif subject is a minor (copy)
3. Place in the CHLA Medical Record (copy) [if applicable]

4) Place in the Principal Investigator's research file (original)

1. This form also serves as the permission form for the parent(s) to read and sign. In this case, “You” refers to your child. [↑](#footnote-ref-1)