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| --- |
| **Instructions:** 1. Use this consent 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.
2. The areas highlighted in yellow are the areas of the template that need to be completed and/or edited to meet the specific 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.
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**CHILDREN’S HOSPITAL LOS ANGELES**

**INFORMED CONSENT/PARENTAL PERMISSION/ASSENT FORM**

**Single Patient Expanded Access**

Single PatientExpanded Access for [Insert Name of Drug/Biologic or Device] Treatment of [Insert Name of Disease or Condition]

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

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

**INTRODUCTION**

* Your doctor, [insert name and degrees of treating physician], from the [insert department/division affiliation] at Children’s Hospital Los Angeles (CHLA) has recommended that you receive treatment with a [drug or device], called [insert name of drug or device], because you have a serious condition called [insert name of condition].
* [Insert name of drug or device] is not approved by the Food and Drug Administration (FDA) for your condition and therefore this use is investigational, or experimental. It is not known whether this treatment will be beneficial to you. There is no guarantee that your condition will improve.
* This consent form explains how [insert name of drug or device] will be used.
* Please read it carefully and take as much time as you need. Ask your doctor to explain any words or information in this informed consent that you do not understand before deciding whether or not to be treated with the experimental [drug or device].

**PROCEDURES**

If you decide to have this treatment, we will ask you to do the following things:

[Describe what the treatment will entail and how long it will last. Include a description of the tests and procedures that will be necessary, as appropriate.]

**POSSIBLE RISKS AND DISCOMFORTS**

[Describe all reasonably foreseeable risks and discomforts, and their likelihood of occurrence when appropriate.]

**POSSIBLE BENEFITS**

[Describe the expected benefits to the patient resulting from the treatment. Do not overstate the benefits. Provision of free drugs or medical procedures are **not** considered benefits.]

**YOUR OPTIONS IF YOU CHOOSE NOT TO RECEIVE THIS EXPERIMENTAL TREATMENT**

[Describe any alternative treatments available to the patient for their condition.]

**COSTS** **TO YOU FOR THIS EXPERIMENTAL TREATMENT**

[Describe any additional costs that the patient could incur as a result of the treatment, such as parking fees or transportation that will not be reimbursed. If there are no additional costs, state this in the consent form. Use the following language, as applicable:]

Receiving this treatment might lead to added costs to you or your insurance company.

(Insert name of drug/device) will be provided to you at no cost. [The next sentences should be included as applicable:] You and your health plan/insurance company will need to cover the cost of the infusion/injection of the investigational drug.

You or your health plan/insurance company will need to pay for routine procedures such as clinic visits, laboratory tests and scans. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs because you are receiving an experimental treatment. If your health plan/insurance company will not pay these costs, you will have additional expenses, such as the costs associated with treating side effects.

If you have questions about your insurance coverage, or the items you might be required to pay for, please discuss them with the treatment team.

**INJURY**

If you think you have been hurt by taking part in this experimental treatment, tell the doctor in charge of this experimental treatment as soon as possible. The doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this experimental treatment. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.

CHLA [and name of sponsor/funding source, as applicable] has/have no plans to pay you or give you other compensation for injury. You do not give up any rights to pursue a claim through the legal system by signing this form.

**CONFIDENTIALITY**

Your private information, data and medical records will be shared with individuals and organizations that oversee this experimental treatment, including:

* The [drug or device] manufacturer, [insert name of company or delete if none]
* Government agencies, such as the Food and Drug Administration (FDA)
* The CHLA Institutional Review Board (IRB) and authorized representatives of CHLA

Because this treatment involves medical procedures and/or the treatment of a medical condition [adjust as applicable], a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about any medications and/or procedures [adjust as applicable]you are receiving and treat you appropriately.

We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. We will not release information about you to others not listed above, unless required or permitted by law. For instance:

* if we learn of child or elder abuse, harm to self or others, or
* if you have certain infectious diseases; or
* you are injured and need emergency care.

**QUESTIONS ABOUT THE EXPERIMENTAL TREATMENT**

If you have questions, concerns, or complaints about the treatment plan, or think this treatment has hurt you or made you sick, talk to your doctor:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call your doctor, [insert treating physician’s name], at [insert phone number].

Evenings, nights, weekends or holidays you may call the hospital number, (323) 660-2450 and ask for the [insert name of Division or Clinical Service] Service doctor on-call.

[Use this language verbatim:]

This experimental treatment is being overseen by the CHLA Institutional Review Board (“IRB”). An IRB is a group of people who perform ethical review of research studies and experimental treatments. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

* You have questions, concerns, or complaints that are not being answered by your doctor.
* You are not getting answers from your doctor.
* You cannot reach your doctor.
* You want to talk to someone else about the experimental treatment.
* You have questions about your rights as a patient.

**FINANCIAL INTEREST OF THE TREATING PHYSICIAN** [Add the disclosure statement required by the Conflict of Interest in Research Committee here or remove this section if there are no conflicts of interest.]

**YOUR RIGHTS**

You can agree to take part in this experimental treatment and stop your participation at any time. 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.

Your participation in this experimental treatment is entirely voluntary. If you choose not to take part in the experimental treatment or decide to stop your participation at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to stop treatment after agreeing to participate, you should let your doctor know. You are not under any obligation to participate in this experimental treatment.

You will be told about any new information found during the course of the treatment that may affect your health, welfare, or choice to continue with the experimental therapy. If this happens, you might be asked to sign a new consent form.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the medical care you receive from CHLA.
* If you decide not to take part, you can still receive medical care from CHLA.
* You will be given a copy of this signed and dated consent form and the “Experimental Subject’s Bill of Rights” to keep.

[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 PATIENT**

(*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 experimental treatment; and
* You will be given a signed copy of this form.

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Print Name of Patient

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Signature of Patient 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 patients 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 experimental treatment; and
* You will be given a signed copy of this form.

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

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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 patients 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 patient to participate in this experimental treatment; and
* You will be given a signed copy of this form.

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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 experimental treatment to the patient and/or the patient’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 the patient is a child or adult lacking the capacity to consent, as applicable:]

**Assent Instructions:** Patients unable to consent are required to assent, unless the treating physician determines that the capability of the patient is so limited that the patient cannot reasonably be consulted.

Patient ages 7 to 13: If assent is obtained, the patient must be given a simplified assent form.

Patient ages 14 to 17: If assent is obtained, have the patient sign this consent form, unless the treating physician determines that the patient is not capable of signing.

Adult patient who is not capable of providing consent: If assent is obtained, the patient must be given a simplified assent form, or the patient can sign this consent form.

* I have explained the experimental treatment to the extent compatible with the patient’s capability, and the patient has agreed to participate.

OR

* The patient is not able to assent because the capability of the patient is so limited that the patient 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 patient and/or the patient’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable];
* The patient and/or the patient’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] had an opportunity to ask questions and those questions were answered; and
* The patient and/or the patient’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