**PERMISSION FORM (TEMPLATE VERSION: 10/16/18)**

\*\*Note - only add the CTSI language if the study has been accepted by the CTSI.

Note: Form should be formatted in at least 12 point font (times new roman) or equivalent.

**[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]**

**[*all sections should remain in the application*, unless the conditions for removing a particular section or verbiage is met]**

Guidelines:

1. Use simple language – 6th to 8th grade reading level.
2. Be concise.
3. Use pronouns such as “you” and “your” consistently throughout (except for the “Signature of Research Subject” on the last page) as the person of address is the subject.

Children’s Hospital Los Angeles

**PERMISSION TO PARTICIPATE IN A RESEARCH STUDY**

[Insert title of study]

[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: |  |
|  Subject’s CHLA medical record #[if applicable]: |  | Subject’s Birth Date: |  |
|  |  |

**KEY INFORMATION [**this section must come first and should include the highlights necessary for a lay person who doesn’t read beyond this section to make a reasonable decision about participation in the research. The entirety of this section should fit on the first page of this form.]

1. The information in this form is being used to seek your consent for your child to be in a research study. The decision to allow your child to be in the study is up to you.
2. This research is being done to find out [keep to a single sentence, such as “… the best way to treat people with Cystic Fibrosis.” or “…how teens think about drug use in their social group.”]. Participation will last up to [indicate max time of participation, if a subject completes all procedures]. Study procedures for this research are: [briefly list all types of procedures in the research, but not the details on frequency or timing]
* [procedure: keep it general such as “Your child will take a study medicine every week by injection under the skin.”]
* [procedure: keep it general such as “CT scan(s). If your child is not able to lie still during the scan, they will get some medicine to help them sleep.”]
* [procedure: keep it general such as “Your child will complete questionnaires about their views on drug use in teens.”]
* [procedure: keep it general such as “Your child will have blood drawn by inserting a needle into a vein or by using their port.”]
* [procedure: keep it general such as “Your child will complete a diary every day to record their medication use and any side effects they experience.”]
* [procedure: keep it general such as “Let the research team record information from your child’s medical record related to their condition and the treatment they receive.”]
1. The most likely risks to your child of the research are: [briefly list up to 5 study risks in lay terms – pick only the most common risks]
* [risk: keep it general such as “Trouble breathing”]
* [risk: keep it general such as “Feeling uncomfortable answering personal questions about themselves”]
* [risk: keep it general such as “Chemo side effects, such as feeling tired, losing hair, and nausea.”]
* [risk: keep it general such as “Allergic reactions”]
* [risk : keep it general such as “Irregular heart beat”]
* Please see the **POTENTIAL RISKS AND DISCOMFORTS** section for a complete list of expected risks.
1. The most likely benefits to your child of the research are: [briefly list the potential benefits to the subject, if any. Keep it to 1 sentence.]
* [If there are no direct benefits to subjects, state “You should not expect benefits to your child as a result of being in this research study.”]
1. If you decide to not allow your child to be in the research, your choices are: [briefly list the alternatives: 2 max]
* [keep it general such as “Your child will continue the regular treatment for their condition.”]
* [keep it general such as “As this is not a treatment study, the alternative is for your child to not participate.”]

**INTRODUCTION**

Your child is invited to join a research study led by [insert name and degrees of Principal Investigator] from the [insert department/division affiliation] at Children’s Hospital Los Angeles (CHLA) [insert other institutions as appropriate]. This research is paid for by [Insert name of sponsor, when applicable] and supported in part by the Clinical Translational Science Institute grant awarded to CHLA [if applicable]. Your child is invited to join this study because [explain succinctly and simply why the prospective subject is eligible to participate such as “they have spina bifida.” or “they have Type1 diabetes that has not responded well to standard treatments.”]. Up to \_\_\_ people will be invited to join the study at CHLA [add if multi-site:] and up to \_\_\_\_ people will be in the study at all participating sites [remove entire sentence if accrual is open-ended, such as for a repository.]. Please read the information below and ask questions about anything you do not understand before deciding whether or not to allow your child to be in the study.

**PURPOSE OF THE STUDY**

[This section should provide a clear and accurate statement of the scientific purpose, the objectives of the research, and the reasons why the study is being conducted. This section should be brief and simple. However, enough detail should be presented so that parents understand why the study is being performed. An example is “This study is being done to find out if drug X is as good as drug Y to treat condition W, without the need for daily injections.”]

If applicable:

This study includes the use of placebo [specify:] pills/injections/etc. Placebos look the same, but have no active study medicine in them. Placebos are used to help researchers understand if the effect seen in studies is from the study medicine or your child’s body’s natural response to their condition.

**PROCEDURES**

If you allow your child to be in this study, we will ask your child to do the following things:

Guidelines:

1. Describe the research procedures using simple lay language, short sentences and short paragraphs. The use of subheadings may help to organize this section and increase readability for complicated studies.
2. Only describe research procedures (things that are only being done or being done at increased frequency or changed timing because of study participation)
* If the sponsor ***insists*** that standard of care procedures be included in the consent, you must put them in an appendix after the signature section and add the following direction, “Procedures that are part of your child’s regular care are described at the end of this form, in appendix \_\_\_\_”
1. ***Avoid repeating procedures***: describe all of the types of research procedures, Then add “Please see appendix \_\_\_\_\_\_ for the list of procedures at each research visit.”
2. DON’T list all procedures for each study visit
3. Include how long each visit will take and how many visits are required.
4. It is more important to tell parents exactly what will happen from participation in the study, than it is to provide an exhaustive and sophisticated scientific justification for the study.
5. Define and explain medical and scientific terms in ordinary language (for example, describing the amount of blood to be drawn in terms of teaspoons or tablespoons).
6. For research involving randomization of subjects into different arms of studies, specify the randomization procedures in lay terms, such as “A computer program will determine which group your child is put in. Your child has a 50/50 chance of being assigned to either group, like with a flip of a coin. Your doctor does NOT get to decide which group your child is put in.”

Suggested language if ***subject pregnancy*** is prohibited (this text must be gender neutral in order to respect the participation of and protect the health of gender non-conforming subjects):

Subjects in the study should not become pregnant while on this study and taking [names of medications or treatment]. This study and the medicines used in the study may hurt an unborn child. It is a condition of this study that adequate birth control methods or abstinence be used by all participants and/or their sexual partners with whom they could make a baby while enrolled in the study. Examples of these methods include [indicate methods]. Dr. \_\_\_\_\_\_\_\_ will discuss these methods with your child and how long they should continue using them after they stop taking the study drug. If your child wishes to discuss birth control options without you present, we will make arrangements to speak to them in private.

Suggested language if pregnancy of ***subject* *or partner of subject*** is prohibited (this text must be gender neutral in order to respect the participation of and protect the health of gender non-conforming subjects):

Subjects in the study should not become pregnant or get their partner pregnant while on this study and taking [names of medications or treatment]. This study and the medicines used in the study may hurt an unborn child. It is a condition of this study that adequate birth control methods or abstinence be used by all participants and/or their sexual partners with whom they could make a baby while enrolled in the study. Examples of these methods include [indicate methods]. Dr. \_\_\_\_\_\_\_\_ will discuss these methods with your child and how long they should continue using them after they stop taking the study drug. If your child wishes to discuss birth control options without you present, we will make arrangements to speak to them in private.

**Optional procedure(s)**

**(Omit if there are no optional procedures)**

[describe in lay language, such as “When your child has a bone marrow biopsy planned as part of their usual care, we would like to take extra bone marrow (up to 5ml at each biopsy) to be used for biology studies. Biology studies are laboratory tests to learn more about the disease process in your child’s body. We will take this extra bone marrow up to 3 times.”]

We will ask you about your decision about this optional procedure(s) at the end of this form.

**RESULTS OF RESEARCH TESTS**

[Keep this section only if the study includes research tests (such as scans, blood tests, urinalysis, etc...]

The results of the following research tests will be shared with you and your child’s doctor (put in your child’s medical records) (also specify if there are specific circumstances under which they will be shared):

* (list all tests the results of which will be shared)

The results of the following research tests will NOT be shared with you and your child’s doctor:

* (list all tests the results of which will not be shared)

**INFORMATION ABOUT DATA AND/OR SPECIMENS**

If data/specimens will be ***de-identified*** and then used for future research:

The data [adjust for the study:] and/or specimens ([specify type(s):] blood, urine, etc…) collected as part of this study will be “de-identified.” “De-identified” means that the data [adjust for the study:] and/or specimens may still have your child’s study ID recorded with them, but the link connecting the study ID to your child’s name will be destroyed.

Once your child’s data [adjust for the study:] and/or specimens have been de-identified, they may be used by the researcher conducting this study or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. This future research may be done without consulting you or your child or obtaining consent (permission) for this additional use.

Your child’s de-identified specimens may be used for commercial research. There are no plans for you or your child to share in any profit generated as a result of the use of your child’s specimens. (or modify to indicate what profit sharing plans are in place)

If data/specimens will be ***coded*** used for future research:

The data [adjust for the study:] and/or specimens ([specify type(s):] blood, urine, etc…) collected as part of this study will be “coded.” This means that the link connecting your child’s identity to your child’s study ID will be kept by the research team at CHLA.

Your child’s data [adjust for the study:] and/or specimens may be used by the researcher conducting this study or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. The people conducting the future research will not be given the link connecting your child’s identity to their study ID, so they will only know your child by Study ID. This future research may be done without consulting you or your child or obtaining consent (permission) for this additional use.

[add the following statement if specimens may be used for commercial research (that which may result in a product that could someday have commercial value) – keep in for all industry-funded studies]

Your child’s coded specimens may be used for commercial research. There are no plans for you or your child to share in any profit generated as a result of the use of your specimens. (or modify to indicate what profit sharing plans are in place)

If data/specimens will NOT be used for future research:

The data [adjust for the study:] and/or specimens ([specify type(s):] blood, urine, etc…) collected as part of this study will ***not*** be used for future research, either by the investigator conducting this study or other researchers.

**INFORMATION ABOUT GENETIC TESTING**

[keep this section only if the research includes genetic testing]

[keep this text for all studies:]

Inside each cell in the human body, there are long and complex molecules called DNA. DNA stores the information that directs all cells in the body how to work. DNA is made up of a large number of genes. Genes direct specific things like hair color or height.

[add if the study will ***or*** may include whole genome/exome testing]

When scientists look at the whole length of all your DNA molecules, this is called “whole genome” or “whole exome” testing.

“Whole genome” or “whole exome” tests result in a unique set of genetic blueprints that can be used to identify your child (like a fingerprint) and possibly your child’s near blood relations. In addition, whole genome/exome sequencing can shed light on not only your child’s risks of disease, but also the risks of disease of your child’s close blood relations.

[add if a specific gene or panel of genes will be tested]

Sometimes researchers just look at specific genes that they think might be related to either your child’s condition or how your child will respond to specific medicines.

[keep this text for all studies and modify as needed:]

The plans for this research include genetic analysis of your child’s [specify:] blood, spit, tumor tissue, etc… [Select one of the following sentences:]

1. This includes whole genome/exome tests.
2. This research will only examine a select set of your child’s genes [adjust for the study:] and/or the genes of your tumor.
3. [use this option only if the main study does not plan to do whole exome/genome testing, but will be submitting samples to a repository] This research will examine a select set of your child’s genes [adjust for the study:] and/or the genes of your child’s tumor. However, the samples collected as part of this this study will be put in a repository, and it’s possible that researchers who use the repository samples for future research may do whole genome/exome testing.

**POTENTIAL RISKS AND DISCOMFORTS**

Guidelines:

The definitions listed below may be used for describing the frequency of occurrence of risks. Similar types of categories are also acceptable.

|  |  |
| --- | --- |
| **Descriptor** | **Frequency** |
| Frequent | >25% (occur in 25 or more people in 100) |
| Common | 10% - 25% (occur in 10 - 25 people in 100) |
| Uncommon | 1% - 10% (occur in 1 - 10 people in 100) |
| Rare | <1% (occur in less than 1 person in 100) |

The frequencies should be listed at least the first time that the descriptor is used in the consent form. Commonly this is done in parentheses next to the term.

1. Identify each intervention with a subheading and then describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. In general list side effects or complications from most to least severe.
2. In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research.
3. If there are significant physical or psychological risks to participation that might cause the researcher to terminate the study, please describe them.

[if applicable, a statement similar to the following should be included]

There is a possibility that the study drug/procedure [as applicable] may harm a growing fetus.

[if the research includes whole exome/genome sequencing AND the results will be shared with the subject]

There is a possibility that the results of the genetic testing could reveal both your child’s risk of certain genetic disorders, and also suggest the risk of disease of close family members because certain conditions/traits are hereditary (run in families). There is also a possibility that genetic testing could reveal things about your child’s family that you and/or your child might not know about, such as whether or not your child is related by blood to family members.

[for all studies, except those cohorts with a completely anonymous data collection method involving no identifiers and no links, the following should be included]

There is the potential of accidental release of confidential information.

[for all studies, it is recommended that the following be included]

There may be additional risks of being in this study that we do not know about and therefore cannot describe.

**Risks of optional procedures**

**(omit if no optional procedures)**

[describe the risks of the optional portions of the research such as “Taking additional bone marrow for biology studies may involve inserting a second needle into your child’s hip while they are asleep. This may result in additional bruising or risk of infection at the extra needle site.”]

**ANTICIPATED BENEFITS TO SUBJECTS**

General Guidelines:

1. Do not include financial rewards for participation in this section.
2. Do not include benefits to science or society.

[suggested text for treatment studies:]

[Suggested text if study is a phase 1 drug/biologic trial:]

The main purpose of phase one clinical trials (like this study) is to test the safety of the treatment. In these types of studies, researchers collect information on side effects that happen in patients as the intensity of treatment is increased.

The likelihood of your child receiving direct benefit from being in this study is small.

[Suggested text if study is a phase 2 or 3 trial:]

Based on experience with this [add: “drug,” “procedure,” “device,” etc.] in [add: “animals,” “patients with similar disorders,” etc.], researchers believe it may help people with your child’s condition [add (as applicable): “or, it may be as good as standard therapy but with fewer side effects”]. Of course, because people respond differently to treatment, no one can know ahead of time if it will help your child.

The potential benefits of the study include: [the following are just examples – please do not use if they do not apply to your research and please create new ones if the benefits of your study are not listed below:]

* Your child may have fewer or less severe symptoms of their disease such as [list symptoms that may be improved with experimental treatment].
* Your child may have fewer or less severe side effects than they might have with standard treatment. The side effects we expect to be reduced are [list potentially reduced side effects].
* The length of time of your child’s treatment may be reduced. Usually, the treatment for this condition takes \_\_\_\_ [amount of time]. With this research, we expect treatment to take \_\_\_\_ [amount of time].
* Your child may need to take fewer [“pills”, “shots”, etc.] to receive the same [add (as applicable), “or better”] treatment of their condition or control of their symptoms.
* More intense monitoring of your child’s condition than they would normally experience under standard treatment. This extra monitoring may help the doctors to learn earlier if your child’s condition is getting worse.

[Suggested text to add if study includes the use of placebo:]

This study includes the use of a placebo. If your child is assigned to receive placebo, we do not expect your child to have any improvement in their condition.

[Suggested text if study involves a social/behavioral intervention:]

Based on experience with this type of intervention program, researchers believe it may be of benefit to people like your child. Of course, because everyone responds differently, no one can know ahead of time if it will help your child.

[Suggested text if study involves an educational intervention:]

Based on experience with this type of intervention program, researchers believe it may improve [“knowledge,” “skill level,” etc…] in [residents, nurse trainees, fellows, etc.] like your child. Of course, because everyone responds differently, no one can know in advance if it will help your child’s education.

[SUGGESTED TEXT FOR noN-treatment studIES:]

You should not expect any direct benefit to your child as a result of participating in this research.

**Direct benefits of optional procedures**

**(omit if no optional procedures)**

[describe the direct benefits to the subject of the optional portions of the research such as “There is no benefit to your child from allowing us to take additional bone marrow for future research.”]

**ANTICIPATED BENEFITS TO SOCIETY**

[State the anticipated benefits, if any, to science or society expected from the research. An example is “Researchers hope to learn more about how drug X works in people with condition Y.” or “Information from this study will help doctors to better treat people with condition Y in the future.”]

**Societal benefits of optional procedures**

**(omit if no optional studies)**

[describe the benefits to society of the optional portions of the research such as “The information gained from the bone marrow biology studies may help advance understanding of your child’s condition.”]

**YOUR OPTIONS IF YOU DON’T WANT YOUR CHILD TO BE IN THIS STUDY**

[suggested text for treatment studies:]

The alternative to being in this research study is for your child to get the standard treatment for their condition. The standard treatment(s) for your child’s condition is/are [describe all standard treatments, if any].

[If applicable, add:]

Your child may also qualify for other clinical treatment research studies.

 [for all treatment studies, add:]

Please ask questions about all of your child’s treatment options before deciding whether or not to join this research.

[SUGGESTED TEXT FOR noN-treatment studIES:]

As this is not a treatment study, your other option is to not have your child be in the study.

**PAYMENT FOR PARTICIPATION**

 **(Note: If your research will not offer payment, please omit this entry and delete the heading.)**

To thank your child for their time participating in this research, the study team would like to offer your child payment. The payments for participation are as follows:

*[describe the payment amounts, prorated and total]*

* payment amount (per visit and total for completing all study visits)
* how payment will be made (ClinCard, cash, check, gift card, toys, iPads, backpacks, other objects, etc.)
* when payment is scheduled (i.e. “at the end of each visit”).

[if you will be using ***ClinCard*** for subject payments, add the following]

Please see appendix \_\_\_ at the end of this form for information on how ClinCard works for subject payment.

[if the payment is expected to reach $600 or more in a calendar year, please include the following:]

If the payments are greater than $150 per visit or if there is a possibility that your child could receive $600 or more for your child’s participation in any Children’s Hospital Los Angeles studies, you will need to provide the name, address, date of birth, and social security number (or taxpayer ID number) of the person (family or friend) you’d like to receive the payments. If payments (for all research and/or clinical programs) in a calendar year equal $600 or more, the income will be reported to the IRS and a 1099 form will be issued. The person you designate to receive the payments can use this form with their income tax return, if appropriate.

If you don’t have a family member or friend available to receive payments, you may instead ask for reimbursement for expenses up to the amount your child would have received as payment. You can be reimbursed for parking, transportation, and meals for both your child and their caregiver accompanying them for the research visit. To receive reimbursements, you will need to provide a name and date of birth. For each expense, you will also need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

If you don’t wish to receive payment or reimbursement, you have two other choices. You can decline payment or you can choose to donate your child’s payments to Children’s Hospital Los Angeles (a non-profit hospital), to be used in the area of greatest need or for a specific program you can designate.

Please let the research team know how you would like to manage the funds set aside for your child’s participation.

**COSTS TO YOU FOR BEING IN THIS STUDY [add, if applicable:] & REIMBURSEMENT FOR YOUR EXPENSES**

Guidelines:

1. If it is possible that procedures or tests the subjects will undergo will not be covered by their insurance, health benefits plan, or other third party payers, this should be made clear.
2. Itemize and estimate the charges that subjects participating in the research will be expected to pay if the charges are not paid by their insurance or other third payer.

Suggested text:

This research study is funded by [name of agency/company**]** and supported in part by the Clinical Translational Science Institute (CTSI) grant awarded to CHLA [if applicable]. Participants and their families are not responsible for any of the costs involved in this study. Neither you nor your child’s insurance company will be billed for your child’s participation in this research.

(if applicable add) This study includes procedures that are also a part of the standard treatment of your child’s condition. The cost of these procedures will be billed to your child’s insurance or other third-party payer. You may be responsible for any co-pays or deductibles.

(if applicable add) It is possible that your child’s insurance will not pay for all of the treatments and tests that your child will receive if your child participates in the research. That is because many insurance companies, HMOs, and health benefits plans often do not cover experimental treatments. If that happens, the charges your family will have to pay will be as follows: [Provide an itemized list.]

(if the study is a cancer clinical trial add:)

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s Web site at <https://www.cancer.gov/about-cancer/treatment/clinical-trials/paying/insurance>

(add If the study DOES include reimbursements for travel or other expenses:)

In consideration of the expenses you may have related to your child’s participation in the research, you or a family member or friend you designate will receive up to $\_\_\_\_\_ *[indicate the per-visit reimbursement allowance]* in expense reimbursement per visit for your child’s participation in the study. You can be reimbursed for parking, transportation, and meals for both your child and their caregiver accompanying them for the research visit.

In order for a specific person to receive the reimbursement, you would need to provide their name and date of birth. For each expense, you will need to submit receipts or submit a mileage reimbursement form. Reimbursements are not reported to the IRS.

Reimbursement will be provided through the use of [name mechanism, such as “ClinCard’].

[if you will be using ***ClinCard*** for reimbursements, add the following]

Please see the end of this form for information on how ClinCard works for reimbursement.

[if you will be using ***another mechanism, such as a sponsor 3rd party program*** for reimbursements, add the following AND modify Appendix 1 to provide the details on that program]

Please see appendix \_\_\_\_ at the end of this form for information on how [name of sponsor reimbursement program] works for reimbursement.

[add If the study DOES NOT include reimbursements for travel or other expenses:]

Your family is responsible for other costs which may result from your child’s participation in the study, such as time off of work, car fare, baby sitter fees, food purchased while at the hospital, etc.

**EMERGENCY CARE AND COMPENSATION FOR INJURY**

**(delete this section and header for minimal risk research)**

[Suggested text if study is industry sponsored:]

It is important that you tell the study doctor right away if you or your child feels that they have been injured because of taking part in this study.  You can tell the study doctor in person, or call them at [Principal Investigator’s phone number].  If your child is injured or becomes ill as a direct result of being in this study, CHLA will provide necessary medical treatment.  The costs of treatment may be billed to you or your child’s insurer like other medical costs, or may be covered by the study sponsor, depending on a number of factors.  CHLA has no program to provide you or your child with any additional compensation as a result of any injuries. You do not waive any liability rights for personal injury by signing this form.

[Suggested text if study is NOT industry sponsored:]

It is important that you tell the study doctor right away if you or your child feels that they have been injured because of taking part in this study.  You can tell the study doctor in person, or call them at [Principal Investigator’s phone number].  If your child is injured or becomes ill as a direct result of being in this study, CHLA will provide necessary medical treatment.  The costs of treatment will be billed to you or your child’s insurer like other medical costs.  CHLA has no program to provide you or your child with any additional compensation as a result of any injuries. You do not waive any liability rights for personal injury by signing this form.

**PRIVACY AND CONFIDENTIALITY**

Guidelines:

1. Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel.
2. If any other uses are contemplated, explain how specific consent will be solicited.
3. If applicable, state if and when individual responses to survey questionnaires will be destroyed, following analyses of the data.

[Suggested text if you WILL NOT obtain a Certificate of Confidentiality]

[add the following if the study and/or repository will record coded data:]

The data and/or specimens (specify type(s): blood, urine etc.) collected as part of this study will be “coded”. Coded means that the data and/or specimens will have your child’s study ID recorded with them, and the link connecting the study ID to your child’s name will be kept separately in a secure location by a member of the research team. Only the members of the study team will be able to see the link or the information that can identify your child.

People on the research team and, if appropriate, your child’s doctors and nurses will know that your child is a research subject. All results will be kept confidential but may be made available to you and/or your child’s doctor if you wish.[ [add the following sentence if data/specimens from the study will be sent outside of CHLA:]

The data and/or specimens (specify type(s): blood, urine etc.) collected as part of this study will be sent to (indicate institution(s)). No information about your child or provided by you or your child during the research will be disclosed to others without your written permission, except:

- if necessary to protect your child’s rights or welfare (for example, if your child is injured and needs emergency care); or

- if required by law (for example, if we learn of child or elder abuse, harm to self or others, or if your child has certain infectious diseases).

When the results of the research are published or shared with other scientists, no information will be included that would reveal your child’s identity.

[if the study includes photographs, videos, or audio recordings, add one of the following statements:]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will be used for educational purposes. When they are, your child’s identity will be protected or disguised. [Describe how personal identities will be shielded, disguised, etc.] [Describe the subject’s right to review/edit the tapes]

[OR]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will be used for educational purposes without being modified, so people who [modify per the study:] see/hear them may be able to identify your child. Before any of these will be shared outside of the research team, we will ask you for your permission to use them on a separate release form. You may decline to allow your child’s [modify per the study:] photographs, videos, and/ or audio recordings to be used without being modified and your child can still be a part of this study. [Describe the subject’s right to review/edit the tapes]

[OR]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will not be shared outside of the research team. They will be destroyed by the end of the research.

Authorized representatives of the Food and Drug Administration (FDA) (keep if the study includes an FDA-regulated test object or is funded by the FDA), the Department of Health and Human Services (keep if study is funded by the NIH or other DHHS agency), the manufacturer of the drug [or device] being tested [insert name of company or delete item if no drug/device manufacturer is relevant to this research] (keep if there is a commercial sponsor or funder), the Clinical Translational Science Institute (CTSI) (keep if you plan to apply to CTSI for support of this research), and the CHLA Institutional Review Board (IRB) (keep this for ***all*** studies) may need to review records of individual subjects. As a result, they may see your child’s name; but they are bound by rules of confidentiality not to reveal your child’s identity to others.

[Add if study includes treatment or medical procedures]

Because this study involves [select appropriate] the treatment of a medical condition and/or medical procedures, a copy of this consent form will be placed in your child’s medical record. This will allow the doctors that are caring for your child to obtain information about what [select appropriate] medications and/or procedures they are receiving in the study and treat them appropriately.

[Suggested text if you WILL obtain a Certificate of Confidentiality]

[add the following if the study and/or repository will record coded data:]

The data and/or specimens (specify type(s): blood, urine etc.) collected as part of this study will be “coded”. Coded means that the data and/or specimens will have your child’s study ID recorded with them, and the link connecting the study ID to your child’s name will be kept in a secure location by a member of the research team. Only the study doctors and those working with them on this study will be able to see the link or the information that can identify your child.

People on the research team and, if appropriate, your child’s doctors and nurses will know that your child is a research subject. All results will be kept confidential but may be made available to you and/or your child’s doctor if you wish.[add the following sentence if data/specimens from the study will be sent outside of CHLA:] The data and/or specimens (specify type(s): blood, urine etc.) collected as part of this study will be sent to (indicate institution(s)).

Authorized representatives of the Food and Drug Administration (FDA) (keep if the study includes an FDA-regulated test object or is funded by the FDA), the Department of Health and Human Services (keep if study is funded by the NIH or other DHHS agency), the manufacturer of the drug [or device] being tested [insert name of company or delete item if no drug/device manufacturer is relevant to this research] (keep if there is a commercial sponsor or funder), the Clinical Translational Science Institute (CTSI) (keep if you plan to apply to CTSI for support of this research), and the CHLA Institutional Review Board (IRB) (keep this for ***all*** studies) may need to review records of individual subjects. As a result, they may see your child’s name; but they are bound by rules of confidentiality not to reveal your child’s identity to others.

To help us protect your child’s privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH) [or “FDA,” as applicable]. With this Certificate, the researchers cannot be forced to disclose information that may identify your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify your child, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your child or their involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information about your child, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your permission, information that would identify your child as a participant in the research project under the following circumstances:

* voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health [or “the Food and Drug Administration,” as applicable].

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child’s identity.

[if the study includes photographs, videos, or audio recordings, add one of the following statements:]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will be used for educational purposes. When they are, your child’s identity will be protected or disguised. [Describe how personal identities will be shielded, disguised, etc.] [Describe the subject’s right to review/edit the tapes]

[OR]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will be used for educational purposes without being modified, so people who [modify per the study:] see/hear them may be able to identify your child. Before any of these will be shared outside of the research team, we will ask you for your permission to use them on a separate release form. You may decline to allow your child’s [modify per the study:] photographs, videos, and/ or audio recordings to be used without being modified and your child can still be a part of this study. [Describe the subject’s right to review/edit the tapes]

[OR]

The [modify per the study:] photographs, videos, and/ or audio recordings made of your child during this research will not be shared outside of the research team. They will be destroyed by the end of the research.

[Add if study includes treatment or medical procedures]

Because this study involves [select appropriate] the treatment of a medical condition and/or medical procedures, a copy of this consent form will be placed in your child’s medical record. This will allow the doctors that are caring for your child to obtain information about what [select appropriate] medications and/or procedures they are receiving in the study and treat them appropriately.

**JOINING AND LEAVING THE STUDY**

Your decision about whether or not to let your child join this research is up to you. Your choice about whether or not to let your child participate will have no effect on your child’s care, services or benefits [or employment, academic evaluation, etc. if applicable] at Children’s Hospital Los Angeles. If you agree to allow your child to join the study, but later decide to remove your child from this study, you may do so without affecting your or your child’s rights to health care, services, or other benefits at Children’s Hospital Los Angeles. Please contact the Principal Investigator if you wish to have your child leave the study.

The investigator may remove your child from participating in this research if necessary to protect their health or if other situations arise that make it necessary to do so. If your child does not meet the requirements for the study at screening, experiences certain side effects or becomes ill during the research [or describe other circumstances, if applicable], they may have to leave the study even if you would like them to continue. The investigator, [insert name], will make the decision and let you know if it is not possible for your child to continue. The decision may be made either to protect your child’s health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

Please add one of the following:

[use the following language if the research team plans to keep the data/specimens already collected if the subject chooses to withdraw from the study]

If your child stops being in the study, any [data and/or specimens] collected before they leave will be used to for the research but no more [data and/or specimens] will be collected.

[OR]

[use the following language if the research team plans to not keep the data/specimens already collected if the subject chooses to withdraw from the study]

If your child stops being in the study, any [data and/or specimens] collected before they leave will not be used and no more [data and/or specimens] will be collected.

**SAFETY ISSUES WITH LEAVING THE STUDY EARLY**

(Note: If there are no potential *physical* consequences of withdrawing from the research, please omit this section.)

[Explain the consequences of a subject’s decision to withdraw from the research and state whether withdrawal must be gradual, for reasons of safety. Examples are “If you decide to have your child leave the study, please talk with the study doctor so they can come up with a plan to taper your child off the study medication, so they do not experience withdrawal.” Or “If you decide to have your child leave the study after their bone marrow has been destroyed but before they have received their transplant, your child is at very high risk of infection and death, as their immune system has been wiped out. If you no longer wish for your child to have the transplant planned as part of this research study, please talk with your child’s study doctor to make arrangements for an alternative transplant.”]

**NEW INFORMATION**

**(Note: If subject participation only involves one study visit and the data collection method is completely anonymous with no identifiers and no links, please omit this entry and delete the heading.)**

If there is significant new information found during the course of the study or the research plan is changed in a way that might affect your decision to allow your child to continue participating in the study, you will be informed and your permission to allow your child to continue in the study may be requested.

**HOW TO OBTAIN INFORMATION**

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. [Principal Investigator’s name] at [phone].

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

[If this is an applicable clinical trial including all those with FDA regulated drug(s) and/or medical device(s), the following statements should be added.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

**FINANCIAL INTEREST OF THE INVESTIGATOR**

[Indicate the funding source for the study, if any. If applicable, describe any direct financial incentive to the investigator if the subject agrees to participate in the study. ]

Suggested text for funded study:

Funding for this research study is provided by [Indicate funding sources, including CTSI, if applicable]. The amount of funding is based/not based [choose one] upon the number of research subjects enrolled. If your child’s doctor is an investigator for this study they are interested in both your child’s healthcare and the conduct of this research. You are not under any obligation to have your child participate in a research study conducted by your child’s doctor.

Suggested text for unfunded study:

This study is not funded. If your child’s doctor is an investigator for this study, they are interested in both your child’s healthcare and the conduct of this research. You are not under any obligation to have your child participate in a research study conducted by your child’s doctor.

**RIGHTS OF RESEARCH SUBJECTS**

You may remove your child from this study at any time without penalty. You are not giving up any legal rights if you decide to let your child be in this research study. If you have questions about the rights of research subjects, have complaints or concerns about the research, or just want to talk to someone other than the Investigator, you may call Children’s Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

**Optional procedures**

**(Note: If no research procedures are optional, please remove this section)**

May the researchers [describe optional procedure in simplified fashion]? Please provide your initials beside your decision.

\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No

**Contact for future research**

**(Note: If you are not planning on creating a participant pool, please omit this entry and delete the heading.)**

May someone from CHLA contact you to invite you and your child to participate in future research? Please provide your initials beside your decision.

\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No

[if you are requesting a waiver of documentation of consent, please omit all of the signature sections AND remove the identification box on the first page]

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

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.

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

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’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 permission for their child 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

Routing of signed copies of the consent form:

1. Give to the parent/legal guardian (copy)
2. Place in the CHLA Medical Record (copy) [if applicable]
3. Place in the Principal Investigator's research file (original)

**APPENDIX \_\_\_\_ – Schedule of Study Procedures**

**[omit this appendix if study has single visit]**

[sample table – please create one with the same level of detail – use tools like alternate shading (as in the sample below) to make it easier to follow]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Visit 1**(start of study) | **Visit 2**(1 week after start) | **Visit 3**(1 month after start) | **Visit 4**(6 months after start) |
| Blood draw | X | X | X | X |
| MRI | X |  |  | X |
| Questionnaires | X |  |  | X |
| Bring unused pills/empty pill bottles back |  | X | X | X |
| Physical exam | X | X | X | X |

**APPENDIX \_\_\_\_ – Use of ClinCard for Payments and/or reimbursements**

**[omit this appendix if ClinCard is not being used]**

To receive payments or reimbursements, you will be issued a ClinCard, which is a specially designed debit card for clinical research. When a visit is completed, funds will be approved and loaded onto your card and can be used at your discretion. You will be issued one card for the duration of your child’s participation. If your card is lost or stolen, please ask the research coordinator for a replacement ClinCard. If the ClinCard funds are not used within 6 months, a fee will be deducted. You will be provided details about the use of the ClinCard in a separate form.

All personal information collected for payments or reimbursement is stored in a secure fashion and will be kept completely confidential.