**CONSENT 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

**CONSENT 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: |  |
|  CHLA medical record #[if applicable]: |  | 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 consent document.]

1. The information in this form is being used to seek your consent for a research study. Being 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 “Take a study medicine every week by injection under your skin.”]
* [procedure: keep it general such as “CT scan(s). If you are not able to lie still during the scan, you will get some medicine to help you sleep.”]
* [procedure: keep it general such as “Complete questionnaires about your view on drug use in young adults.”]
* [procedure: keep it general such as “Have blood drawn by inserting a needle into a vein or by using your port.”]
* [procedure: keep it general such as “Complete a diary every day to record your medication use and any side effects you experience.”]
* [procedure: keep it general such as “Let the research team record information from your medical record related to your condition and the treatment you receive.”]
1. The most likely risks to you 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 yourself”]
* [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 you 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 as a result of being in this research study.”]
1. If you decide to not be in the research, your choices are: [briefly list the alternatives: 2 max]
* [keep it general such as “Continue the regular treatment for your condition.”]
* [keep it general such as “As this is not a treatment study, the alternative is to not participate.”]

**INTRODUCTION**

You are 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]. You are invited to join this study because [explain succinctly and simply why the prospective subject is eligible to participate such as “you have spina bifida.” or “you 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 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 the subject understands 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 body’s natural response to your condition.

**PROCEDURES**

If you volunteer to be in this study, we will ask you 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 are 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 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 adult subjects 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 you are put in. You have 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 you are 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 you and how long you should continue using them after you stop taking the study drug.

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 you and how long you should continue using them after you stop taking the study drug.

**Optional procedure(s)**

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

[describe in lay language, such as “When you have a bone marrow biopsy planned as part of your 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 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 doctor (put in your 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 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 study ID recorded with them, but the link connecting the study ID to your name will be destroyed.

Once your 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 obtaining consent (permission) for this additional use.

Your de-identified specimens may be used for commercial research. There are no plans for you 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 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 identity to your study ID will be kept by the research team at CHLA.

Your 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 identity to your study ID, so they will only know you by Study ID. This future research may be done without consulting you 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 coded specimens may be used for commercial research. There are no plans for you 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 you (like a fingerprint) and possibly your near blood relations. In addition, whole genome/exome sequencing can shed light on not only your risks of disease, but also the risks of disease of your 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 condition or how you 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 [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 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 genes [adjust for the study:] and/or the genes of your 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 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 family that you might not know about, such as whether or not you are related by blood to your 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 hip while you 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 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 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 you.

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:]

* You may have fewer or less severe symptoms of your disease such as [list symptoms that may be improved with experimental treatment].
* You may have fewer or less severe side effects than you 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 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].
* You may need to take fewer [“pills”, “shots”, etc.] to receive the same [add (as applicable), “or better”] treatment of your condition or control of your symptoms.
* More intense monitoring of your condition than you would normally experience under standard treatment. This extra monitoring may help the doctors to learn earlier if your condition is getting worse.

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

This study includes the use of a placebo. If you are assigned to receive placebo, we do not expect you to have any improvement in your 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 you. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

[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 you. Of course, because everyone responds differently, no one can know in advance if it will help you in your training.

[SUGGESTED TEXT FOR noN-treatment studIES:]

You should not expect any direct benefit 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 you 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 condition.”]

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

[suggested text for treatment studies:]

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

[If applicable, add:]

You may also qualify for other clinical treatment research studies.

 [for all treatment studies, add:]

Please ask questions about all of your 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 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 you for your time participating in this research, the study team would like to offer you 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 you could receive $600 or more for your 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 you would have received as payment. You can be reimbursed for parking, transportation, and meals for both you and your parent/caregiver accompanying you 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 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 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 insurance company will be billed for your participation in this research.

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

(if applicable add) It is possible that your insurance will not pay for all of the treatments and tests that you will receive if you participate 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 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 participation in the study. You can be reimbursed for parking, transportation, and meals for both you and your parent/caregiver accompanying you 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 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 feel that you 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 you are injured or become 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 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 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 feel that you 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 you are injured or become 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 insurer like other medical costs.  CHLA has no program to provide you 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 study ID recorded with them, and the link connecting the study ID to your 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 you.

People on the research team and, if appropriate, your doctors and nurses will know that you are a research subject. All results will be kept confidential, but may be made available to you and/or your 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 you or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or

- if required by law (for example, if we learn of child or elder abuse, harm to self or others, or if you have 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 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 you during this research will be used for educational purposes. When they are, your 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 you 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 you. Before any of these will be shared outside of the research team, we will ask you for your permission on a separate release to use them. You may decline to allow your [modify per the study:] photographs, videos, and/ or audio recordings to be used without being modified and 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 you 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 name; but they are bound by rules of confidentiality not to reveal your 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 medical record. This will allow the doctors that are caring for you to obtain information about what [select appropriate] medications and/or procedures you are receiving in the study and treat you 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 study ID recorded with them, and the link connecting the study ID to your 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 you.

People on the research team and, if appropriate, your doctors and nurses will know that you are a research subject. All results will be kept confidential, but may be made available to you and/or your 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 name; but they are bound by rules of confidentiality not to reveal your identity to others.

To help us protect your 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 you, 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 you, 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 yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, 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 consent, information that would identify you 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 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 you during this research will be used for educational purposes. When they are, your 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 you 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 you. Before any of these will be shared outside of the research team, we will ask you for your permission on a separate release form to use them. You may decline to allow your [modify per the study:] photographs, videos, and/ or audio recordings to be used without being modified and 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 you 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 medical record. This will allow the doctors that are caring for you to obtain information about what [select appropriate] medications and/or procedures you are receiving in the study and treat you appropriately.

**JOINING AND LEAVING THE STUDY**

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

The investigator may remove you from participating in this research if necessary to protect your health or if other situations arise that make it necessary to do so. If you don’t meet the requirements for the study at screening, experience certain side effects or become ill during the research [or describe other circumstances, if applicable], you may have to leave the study even if you would like to continue. The investigator, [insert name], will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your 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 you stop being in the study, any [data and/or specimens] collected before you 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 you stop being in the study, any [data and/or specimens] collected before you 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 leave the study, please talk with the study doctor so they can come up with a plan to taper you off the study medication, so you do not experience withdrawal.” Or “If you decide to leave the study after your bone marrow has been destroyed but before you have received your transplant, you are at very high risk of infection and death, as your immune system has been wiped out. If you no longer wish to have the transplant planned as part of this research study, please talk with your 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 continue participating in the study, you will be informed and your consent to continue participating 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 you. 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 doctor is an investigator for this study they are interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your doctor.

Suggested text for unfunded study:

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

**RIGHTS OF RESEARCH SUBJECTS**

You may leave this study at any time without penalty. You are not giving up any legal rights if you decide to 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 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 RESEARCH SUBJECT** |

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.

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

Print Name of Subject

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

Signature of Subject Date

[delete the section below if “adults not competent to consent” are not being enrolled]

|  |
| --- |
| **SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE (if the subject is an incompetent adult)** |

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 ward’s participation in this research study; and
* You will be given a signed copy of this form.

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

Print Name of Legally Authorized Representative

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

Signature of Legally Authorized Representative Date

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

I have explained the research to the subject and have answered all of his/her questions. I believe that he/she understands all of the information described in this document and freely gives consent 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;
* The subject had an opportunity to ask questions and those questions were answered; and
* The subject voluntarily signed the consent form in my presence.

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

Print Name of Witness

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

Signature of Witness Date

Routing of signed copies of the consent form:

1. Give to the subject (copy)
2. Give to the legally authorized representative, if subject is an incompetent adult (copy) [delete this if “adults not competent to consent” are not being enrolled]
3. Place in the CHLA Medical Record (copy) [if applicable]
4. 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 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.