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| **CHLA CONSENT FORM STANDARDS AND SAMPLE LANGUAGE**  **This guidance document provides:**   1. **General Instructions** about how to prepare and format the consent form. 2. **Detailed Instructions** about how to complete each section of the **CHLA Consent Form Template**. 3. **Sample Language** for each section of the consent form template. 4. **CHLA Required Language** for all CHLA consent forms.   Version Date: 02-25-2020 |

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# GENERAL INSTRUCTIONS

Use these Consent Form Standards to customize template consent forms or to create consent forms for research studies. Follow these general instructions to help facilitate better informed decision-making by participants:

**Recommended Formatting**

Use **reader-friendly formatting** so the consent form ***looks*** easy to read.

* Leave a 1-inch margin around the entire document.
* Leave ample white space between headings and paragraphs, but do not double space within paragraphs*.*
* Use subheadings, bullet lists and/or tables when appropriate.
* Use black Times, Arial or similar font, preferably 12-point size, or larger when appropriate for the study population.

**Reading Level**

Write the consent form so it is understandable to a lay audience, e.g., 8th grade reading level; *USA Today* newspaper. The reading level of a document is more difficult if it contains long complex sentences. Whenever possible use words with three syllables or less, non-scientific/non-medical words, simple sentences and break up the text into short straightforward sections. The [**PRISM Readability Tool Kit**](https://www.nhlbi.nih.gov/files/docs/ghchs_readability_toolkit.pdf) is a good resource for writing consent forms that can be understood by most people.

**Version Control**

* For recordkeeping purposes, update the consent version date in the footer each time the document is revised.

**Parental Permission/Assent Forms**

* **Children ages 7- 13:** Create two documents, one for parental permission and a separate simplified assent form for children. In some circumstances children may not be able to sign the assent form, but investigators are required to document on the parental permission form whether assent is obtained.
* **Adolescents ages 14-17:** Create a single parental permission/assent document with signature lines for both parental permission and child assent.
* **Adults Unable to Consent:** The simplified assent form may also be used for obtaining assent from adults who are unable to consent for themselves. In some circumstances adults may not be able to sign the assent form, but investigators are required to document whether assent is obtained.

**Children who Become Adults**

Children who reach the age of majority (per CA Law, i.e., age 18, married, joined the armed forces, legal emancipation) during study participation must be re-consented as adults. The study team must describe the re-consenting process that will be followed in the protocol or CHLA iStar application. If the adult subject is incapable of providing consent, surrogate consent from a legally authorized representative must be obtained per CA law.

# SECTION BY SECTION INSTRUCTIONS

## MAIN HEADING

The following heading is suggested for all CHLA consent forms [customize to study population(s)]:

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| **CHILDREN’S HOSPITAL LOS ANGELES**  **INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A RESEARCH STUDY** |

## STUDY TITLE

* Include the **study title** on the consent form.
* If the official title is technical and difficult to understand, also **use a lay title** or shorter title that the research staff will use **(optional).**
* If a study has **more than one consent form**, label each form appropriately and use the same references within the IRB application (e.g., Consent for Main Study, Consent for Control Group, etc.)

## KEY INFORMATION

The CHLA IRB requires a key information summary section for all consent forms that are longer than 4 pages. **Do not include a Key Information section if the content of this consent document (not including the signature section) is 4 pages or less in length.** This section must come first and should include a concise summary of information that is relevant to why someone might or might not want to take part in the research. The entirety of this section should be no more than one full page in length. A sample key information summary is provided below.

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| **Complete the following language:**  You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.  **What should I know about this research?**   * Taking part in this research is voluntary. Whether you take part is up to you. * If you don’t want to take part, it won’t be held against you. * You can take part now and later drop out, and it won’t be held against you. * If you don’t understand, ask the research team questions. * Ask all the questions you want before you decide.   **How long will I be in this research?**  Participation will last up to \_\_\_\_. [indicate maximum time of participation, if a subject completes all procedures]  **Why is this research being done?**  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.”]  **What happens to me if I agree to take part in this research?**  Study procedures for this research are: [Briefly in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study. A bulleted list is acceptable. See examples below:]   * Take a study drug every week by injection under your skin. * CT scan(s). If you are not able to lie still during the scan, you will get some medicine to help you sleep. * Complete questionnaires about your view on drug use in teens and young adults. * Have blood drawn by inserting a needle into a vein or by using your port. * Complete a diary every day to record your medication use and any side effects you experience. * Let the research team record information from your medical record related to your condition and the treatment you receive.   **Could being in the research hurt me?**  The most important risks or discomforts that you may expect from taking part in the research are: [Briefly list up to 5 main study risks in lay terms most likely to affect someone’s decision about whether to take part in the research study – pick only the most common risks. A bulleted list is acceptable. See examples below:]   * Trouble breathing * Feeling uncomfortable answering personal questions about yourself * Chemo side effects, such as feeling tired, losing hair, and nausea. * Allergic reactions * Irregular heartbeat   Please see the RISKS AND DISCOMFORTS section below for a complete list of expected risks.  **Will being in this research benefit me?**  The most important benefits that you may expect from taking part in this research are: [Briefly list the reasonably expected benefits to the subject most likely to affect someone’s decision about whether to take part in the research study. Keep it to one sentence. If there are no benefits, state: It is not expected that you will personally benefit from this research.]  **What other choices do I have besides taking part in this research?**  Instead of being in this study, your choices may include: [List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted. Briefly list the alternatives. List two maximum:]   * Continue routine care or treatment for your condition. * Join another clinical research study.   **What else should I know about this research?**  Other information that may be important for you to consider so you can decide whether to take part in this research is: [Describe any additional information that may be important to know for this study, such as study requirements that may burden participants, e.g., an extensive study visit schedule, time away from work, overnight stays, etc. If this does not apply, this section can be omitted.] |

## INTRODUCTION

* Use **an active statement**asking for participation in the research, rather than passive statements like “you have been asked” or “you have been invited” to participate.
* Indicate **who is conducting the research** (name and degrees of the PI).
* Provide **the name of the CHLA department/division** conducting the research.
* Explain to potential participants **why research team is asking them to take part** in the study.

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| **Sample Language:**  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 and other support, when applicable].  You are invited to join this study because [explain succinctly and simply why the prospective subject is eligible to participate, e.g., “you have spina bifida.” or “you have Type1 diabetes that has not responded well to standard treatments.”] Participation in this study is voluntary. 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

* Discuss **the purpose of the study**in lay terms and include a statement that explains why the study is research (e.g., “This study is being done to find out if drug X is as good as drug Y to treat condition Z.”)
* Include a statement that the **study involves research**.
* If the study involves **investigational test articles** (i.e., drugs or devices that are not FDA-approved), state this in the consent, by indicating that the drug or device is “experimental” or “investigational” and explain how it is being used in the study.
* Explain the **study design**to participants. Define complex design terms. Explain all procedures relating to research (e.g., randomization, placebo control) to the participants.
* **Include definitions** for specific research design features (e.g., double-blind, randomization, placebo-controlled, dose escalation) if these will help participants understand the study.

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| **Sample Language for Investigational Drugs and Devices, Procedures, and Off-Label Use:**  XX is an experimental drug that has not been approved by the Food and Drug Administration (FDA). XX is the “study drug" being tested in this study.  XX is a drug that is approved by the Food and Drug Administration (FDA) for the treatment of YY. It is not approved for the treatment of ZZ, therefore it’s use in this research study is considered experimental.  XX is a Food and Drug Administration (FDA) approved drug, but its use in this study is experimental because [complete this sentence].  XX is an experimental procedure that is being compared to the standard procedure YY. The researchers are interested in learning which procedure is more useful in treating your condition.  **Sample Language for Study Design:**  **For Phase I Drug Studies**   * The purpose of this research study is to test the safety and possible harms of drug XX when it is given to humans at different dose levels. The researchers want to find out what effects (good and bad) drug XX has on patients with your condition.   **For Phase II Drug Studies**   * The purpose of this research study is to see if drug XX has any benefits at dose levels thought to be acceptable in earlier studies. The researchers want to find out what effects (good and bad) drug XX has on patients with your condition.   **For Phase III Drug Studies**   * The purpose of this research study is to see if drug XX is safe and effective for the treatment of your condition. The researchers want to confirm the right dose levels of drug XX and find out what effects (good and bad) drug XX has on patients with your condition.   **Randomized Studies**   * Randomization is a procedure used to assign research participants by chance to a study group in a clinical trial. In this study, you have a X in Y chance of being assigned to one group or another. * 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.   **Open Label Studies**   * This research study is an open-label study. This means that you, the study doctor, study staff and the Sponsor will know the drug and the dose(s) that you are given.   **Blinded Studies**   * Neither you nor the study doctor will know which of the study drugs you are receiving. However, in the case of an emergency, the research team can quickly find out to what study group you are assigned. Whether you receive [XX, YY, or placebo] will be determined by chance. The chance that you will get any one of the treatments is X in Y. You will not have a choice as to which group you are assigned. * Double-blind means that neither you nor the study doctor conducting the study will know which group you are assigned to. * Single-blind means that you will not know which treatment you are receiving.   **Placebo-Controlled Studies**   * Placebo-controlled means that the one group will get a placebo. This study includes the use of placebo [specify: pills/injections/etc.] A placebo looks like the study drug, but it includes no active drug. * If you are in the group that receives placebo, your condition will go without active treatment for XX weeks.   **Dose Escalation Studies**   * Dose escalation means that participants enrolling early in the study will be given relatively low doses of the study drug and that if the low doses appear to be safe, participants enrolling later will receive higher doses. * The purpose of this research is to find the best dose of the study drug and how much of it can be given safely. The study starts by giving a very low dose of XX, and then the dose is slowly increased as other people enter the trial. [If appropriate, indicate whether dose escalation is by cohorts or if individuals will receive escalating doses.] * In this study, several different doses of study drug will be explored. The dose you will receive will depend on when you enter the study. Since this study is designed to test the safety of study drug, the dose you receive has not yet been determined to be a safe dose for humans. When the study drug is given at a dose level that subjects can no longer take without serious side effects, the study will stop giving subjects higher doses of the drug.   **Dose Titration Studies**   * The purpose of this research is to find the best way to give an experimental drug and how much of it can be given safely. In this study, the experimental drug will be given at a very low dose, and then it will be slowly increased to determine an effective dose of XX. The dose can be increased by giving more at one time or by giving the same dose more often. |

## NUMBER OF PARTICIPANTS

* State the **accrual goal** of the study and where appropriate discuss study cohorts.
* For multi-center studies, indicate accrual numbers for the entire study and for enrollment at CHLA; be consistent with the protocol.

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| **Sample Language:**   * XX people will be asked to take part in this study at CHLA. YY people will be asked to participate nationwide. |

## LENGTH OF PARTICIPATION

* Explain **the duration of the study**or how long the study will last. This will help participants decide if they have the time to participate.
* When appropriate, state that the study involves **long-term follow-up**by specifying the timeframes and requirements for long-term participation.

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| **Sample Language:**  Short-term, simple studies:   * You will be in this study for XX days. * Your participation in this study will last \_\_\_. * Participation in this study will require about XX hours of your time. * This study will require approximately XX hours of your time for each study visit. There will be a total of XX study visits over six months. * You will be in the [insert clinic/center name] for a total of XX days.   Long-term, complex studies:   * If you agree to participate in this study you will [describe the research intervention, e.g., you will take drug XX for XX months/weeks/until a certain event occurs]. After you complete [drug XX, procedure YY] the researchers will ask you to visit the office for follow-up exams every XX months for XX years. |

## PROCEDURES

**Guidelines for all consents:**

* If **screening procedures** are involved, note these first and identify them as tests that will determine whether the person can participate in the study.
* Include **a description of the procedures** involved in the study.
  + Procedures do not necessarily need to include specific names of standard lab tests (e.g., CBC, CMP, lipid panel, UA), but participants should know the type of specimen required for testing and the general purpose of the testing (e.g., “A blood sample will be taken from your arm to perform standard lab testing to make sure you do not have a low red blood cell count.”)
  + Procedures do not necessarily need to include specific names of common standardized behavioral or psychological tests, but participants should know the general purpose of the testing and how long the testing will take (e.g., “A standard test will be used to measure how you are feeling and your current level of depression. The test should take about 30 minutes to complete.”)
* The **use of subheadings** may help to organize this section and increase readability for complex studies.
* **Describe all procedures required for the research** and use appendices or a schedule of assessments to explain which procedures are performed at each study visit.
* **Avoid repeating procedures for each study visit**, as this makes the consent form longer.
* Include how long each visit will take and/or **how many visits are required**, as applicable.
* Explain **how participation in the study differs from routine care/standard treatment***,* as applicable.
* **Describe randomization** to study groups as a study procedure. Explain the probability of assignment to a given group or condition if not described under “Purpose of the Study”. See sample statement below.
* **Define terms** which might not be familiar to a lay person or young adult the first time they are mentioned or replace them with a lay term.
* Specify the **amounts of blood or tissue** to be taken for study purposes using lay equivalents. Include volume of blood in teaspoons or tablespoons, rather than mL, cc, or oz. For reference:
  + 5 mL = 1 teaspoon
  + 15 mL = 1 Tablespoon
  + 250 mL = 1 cup
* Include **review and/or** **collection of information** **from medical records** as a study procedure when protected health information is created, accessed or disclosed for the study.
* For device studies, you may wish to **include simple diagrams**or pictures in the consent.
* If parents of participants complete any procedures, please add the following sub-headers to this section “**FOR YOU**” AND “**FOR YOUR PARENT**” and clarify which procedures will be completed by the participant and by the parent.
* Include **any pregnancy testing done for research purposes**.
* **If pregnancy testing in children:** Indicate that pregnancy test results will not be shared with a subject's parent(s) or legal guardian(s).
* Include **any HIV/Sexually Transmitted Infection (STI) testing done for research purposes**.
* **If HIV/Sexually Transmitted Infection (STI) testing in children:** Indicate that test results will not be shared with a subject's parent(s) or legal guardian(s) for children 12 years and older.
* Include **any birth control requirements of research participation.**
* **Describe any optional procedures** and include a place for subjects and their parent(s)/legal guardian(s) to decide whether to participate (e.g., yes/no boxes). Decisions to participate in optional procedures should be at the end of the consent form before the signature lines. Optional procedures may also be covered in a separate addendum consent form.
* Indicate whether any**research tests will be shared with subjects and their physician(s) for clinical purposes**.

**Guidance for Studies that Involve Routine Care/Treatment or Medical Procedures:**

Make it clear in the consent form whether procedures are being done for clinical reasons or for research purposes, including whether the procedures are being done **more often** because of the study. Use the following guidelines to determine the extent to which routine care/treatment or procedures and their associated risks need to be described in consent forms:

* If the standard procedure is not explicitly required by the study protocol, the consent form need not describe that procedure or its risks.
* If the routine care/treatment procedure is required for the research for the study, the consent form must include a full description of the procedure and its risks.

**Guidance for Genomic Research and Studies Involving Genetic Testing:**

* [Genome.gov](http://www.genome.gov/27026588) is an excellent resource for creating genomic research consent forms.
* It is recommended that an **Information about Genetic Testing** sub-section be added to the Procedures section.
* Sample Language that Complies with NIH GWAS Requirements is available on the CHLA HSPP website under Other Consent Resources.

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| **Sample Language for Randomization:**  Randomization means that you are assigned to a group by chance (like a flip of a coin). A computer program will place you in one of the groups. Neither you nor the researchers can choose the group you will be in. You will have an [specify: equal/one in three/etc.] chance of being placed in any group. You will be randomized to one of the study groups described below.   * + If you are in Group 1…[Explain what will happen for this group.]   + If you are in Group 2…[Explain what will happen for this group.]   + [For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]   **Sample Language for Contraception to Prevent Pregnancy (Subject):**  Subjects in this study should not become pregnant while participating in this study and while taking/receiving [names of medications or treatment]. The study drugs and/or procedures 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]. The study doctor will discuss these methods with you and how long you should continue using them after you stop taking the study drug/complete study procedures. If you wish to discuss birth control options without your parent(s) present, please let us know so that we can arrange to speak with you about pregnancy and contraception in private. [Add if the study includes pregnancy testing of minors] Your pregnancy test results will not be shared with your parent(s).  **Sample Language for Contraception to Prevent Pregnancy (Subject/Partner):**  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]. The study doctor will discuss these methods with you and how long you should continue using them after you stop taking the study drug. If you wish to discuss birth control options without your parents present, please let us know so that we can arrange to speak with you about pregnancy and contraception in private. [Add if the study includes pregnancy testing of minors] Your pregnancy test results will not be shared with your parent(s).  **Sample Language for HIV/STI Testing in Children Ages 12 and Older:**  If your HIV/Sexually Transmitted Infection (STI) test is positive and you are at least 12 years of age, we will not share the results with your parent(s) unless you tell us we can. If your HIV/Sexually Transmitted Infection (STI) test is positive and you are under the age of 12, the results will be shared with your parent(s).  **Sample Language for Studies that Include Clinical Tests Performed for Research:**  **Results of Tests Performed for the Study**  [Explain whether clinically relevant research results will be disclosed to subjects, and if so, under what conditions (e.g. only validated test results will be shared). Include one of the following statements in the consent form if any research testing is performed. Examples:]   * No clinically relevant research results, including individual research results, will be shared with you or your health care doctor. * Clinically relevant research results will be shared with you and your health care doctor. |

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| **Sample Language for Genomic Studies:**  **Describing DNA and Information about Genetic Testing:**  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 many genes. Genes direct specific things like hair color or height.  [Add if the study involves a drug:] Genes also tell your body how to react to certain drugs. For this reason, looking at DNA can sometimes help explain why people with a disease respond differently to the same drug. For example, some people taking the study drug in this research may respond well while others may have little to no response and/or have side effects. Researchers may study your DNA to learn how the study drug works for you. Information about your DNA may be used to create or improve tests to measure these genetic factors.  [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.  [Add this information, as applicable:]  The plans for this research include genetic analysis of your [specify: blood, saliva, tumor tissue, etc.] [Select one or more 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. This research will examine a select set of your genes [adjust for the study] and/or the genes of your tumor. 4. Samples collected as part of this this study will be put in a repository, and it is possible that researchers who use the repository samples for future research may do whole genome/exome testing. |

## POSSIBLE RISKS AND DISCOMFORTS

* **Risks and discomforts include** physical, psychological, social and economic harm.
* **Explain the risks**and/or possible side effects and discomforts **of procedures** relating solely to research.
* 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.
* **Explain the risks of the tests** required in the study protocol, especially for tests that carry significant risk of morbidity/mortality themselves.
* **Explain the risks associated with each drug separately**; however, for a given drug list the associated risks **once** and not multiple times by treatment arm. Explain any risks associated with combination drug regimens.
* **Organize and describe risks**according to their probability or severity of occurrence (e.g., likely, less likely, and rare but serious.) The definitions listed below may be used for describing the frequency of occurrence of risks. Similar types of categories are also acceptable. 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.

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| **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) |

* **Provide the consequences of risks;**that is, whenever possible, describe how the risks and side effects will make the participant feel. For example, explain "anemia" as follows: "Low red blood count (anemia) can cause tiredness, weakness and shortness of breath."
* **Describe the precautions to prevent risks from occurring**when appropriate. Also describe what will be done if they occur.
* **Pregnancy/Nursing risks:** Discuss known or unknown pregnancy/nursing risks. If participants are advised to use birth control to avoid pregnancy before, during, or after the study, describe these precautions. As appropriate, identify any required or acceptable methods of birth control. When describing requirements for birth control, consider whether the study may include **gender neutral or gender non-conforming subjects**. Consent forms may be tailored by the study team, but this is not required for all research studies.
* **Oncology Studies:** Sample language for side effects of common oncology drugs and drug regimens is available on the CHLA HSPP website under Other Consent Resources.

**Guidelines for Explaining Certain Risks Associated with Procedures Performed for Research:**

* **Blood draw risks:** Standard wording notes temporary discomfort from the needle stick, bruising and, rarely, infection and fainting.
* **Radiation risks:** The IRB recognizes that the risk from small amounts of radiation exposure is difficult to describe in terms that are meaningful to the average layperson. While comparisons to chest x-rays are often used, most lay people have no way of estimating the risks of exposure from chest X-rays either, even though they are probably familiar with the procedure itself. Use a simple statement that alerts participants to the risk of the radiation exposure and advises him/her to speak with the researcher if there are further concerns about this exposure.
* **CT scan risks:** Describe radiation risks from CT scans in the same way as those from x-rays. As with MRI, note the possibility of claustrophobia or discomfort from being in the CT scanner. In addition, include risks and discomforts of contrast agents and sedation, when used.
* **MRI risks:** Warn subjects that because the MRI machine acts like a large magnet, they must not have any metal on or in their bodies. This precaution is needed to prevent any resulting injury. Also note that subjects will be in a tight confined space and may be bothered by feelings of claustrophobia. They may also be bothered by the loud clanging noise during the MRI scan.
* **Unknown risks:** For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, tell subjects that there may be risks associated with the drug/treatment that are as yet unknown, but that the researcher will advise them if any new information becomes available that might affect their desire to participate in the study.

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| **SAMPLE RISK STATEMENTS FOR COMMON PROCEDURES**  **Blood Draw/Venipuncture:**  Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.  **Blood Transfusion:**  Blood products come from voluntary donors who are carefully selected and tested. There are still some risks to blood transfusion. These risks are uncommon and are usually mild, but may be severe or life threatening.   * Occasional risks include: fever and allergic reactions due to the formation of antibodies (formed by the body to fight infections). * Less common risks include: infections with viruses, such as hepatitis and fluid overload * Very rare but serious reactions include: reactions due to a mismatch between the donor's blood and the recipient's and serious infections including HIV (the virus that causes AIDS)   [Include this statement if applicable] The alternative to volunteer donor blood is directed donor blood donated by a family member or friend, if appropriate for your disease.  **Bone Marrow Aspirate:**  This test may be painful. The pain normally lessens within minutes to hours. Local anesthetic medications will be used to decrease the pain. [Include the former, only if applicable] There is also a small risk of infection or bleeding.  **Breach/Loss of Confidentiality:**  This study involves the use of your identifiable, personal information. There is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see “CONFIDENTIALITY” section below for details).  **Echocardiogram:**  Echocardiograms are generally safe. The gel may feel cold when it is first placed. Some people with sensitive skin can develop a rash from the gel.  **Electrocardiogram (EKG or ECG):**  There is a small risk that redness or swelling could develop from the ECG electrodes (pads) that will be placed on the chest.  **Exercise testing risks:**  The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.  **Eye Examination:**  There is very little risk of harm from an eye examination. [Add this statement if applicable] Eye drops will be needed to make the pupils larger. This may make your vision temporarily blurry and very sensitive to light. You will be given dark glasses to wear. [Include this statement if applicable] Some types of glaucoma may be made worse by dilating drops. If you have high blood pressure or a history of heart disease, in rare instances, dilating drops may make irregular heartbeats or high blood pressure worse. All of these side effects can be treated, when necessary.  **HIV Testing Risks**:  Being tested for HIV can make you feel nervous or anxious about the test results. A positive test indicates that you are infected with the HIV virus, but no one knows for certain when, if ever, you will get AIDS or a related condition. Receiving positive results may make you very upset. If other people learn about your positive test results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining insurance or employment. To the extent permitted by law, the researchers will keep your test results confidential and will not release them to anyone without your written permission. If you test positive, California law requires health care providers and clinical laboratories to report the HIV test results with your personal identifying information to the local health department.  **Insertion of an Intravenous Catheter (IV):**  Placing an IV may cause some pain, and bleeding or bruising at the spot where the needle enters your body. Rarely, it may cause fainting. The longer an IV catheter is left in place, the more common it is for redness or infection to develop.  **Placebo Risks:**  During this study there is a chance that you will receive a placebo. This could lengthen the amount of time before you receive a treatment that may be effective. During this time you may experience worsening of your condition, including increased symptoms such as [ describe]. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.  **Questionnaires and Surveys:**  There are no physical risks but you might feel embarrassed or uncomfortable. You do not have to answer any questions that make you feel too uncomfortable. [Add a statement, if applicable, to discuss any counseling that may be available as a result of concerns that are raised.]  **Randomization Risks:**  You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition.  **Reproductive Risks:**  The effects of the [specify: study drug/radiation/etc.] on a developing embryo or fetus are unknown and may be harmful. [Explain the potential harms, if known of the study drug, radiation, etc. on the fetus.] It is important that females who take part in this study do not become pregnant during the study. Tell the study doctor right away if you become pregnant or think you are pregnant.  **Reproductive Risks (Known):**  You should not become pregnant or father a baby while on this study because the drugs used in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. Therefore, you need to use effective birth control while on this study.  **Reproductive Risks (Unknown):**  The effects of [name of drug(s)] on an unborn baby are not known. For this reason, if you believe that you are pregnant or have a chance of becoming pregnant you should not participate in this study. A [blood / urine] pregnancy test will be performed before the start of study procedures. If you are pregnant, you will not be allowed to participate in the study.If you do participate in this study, you must use a medically effective form of birth control before entering the study, while participating in the study, and for at least [XX days/months] after stopping the study. If you become pregnant during the study, tell the researchers right away.  **Side Effects:**  The researchers will observe you carefully for any harmful side effects. Although the experimental [drug/device/procedure] has been well- tested in laboratory and animal studies, the side effects in people are not completely known at this time. You will be followed closely by the study doctor for the entire time you are a part of this study. If you experience any side effects from the study, the researchers will provide you with the treatment that has the best chance of taking care of the side effects. If you experience any side effects related to the study [drug/device/procedure] that continue at the end of study, we will continue to follow-up with you until these effects stabilize or resolve.  **Unknown Risks of an Investigational Drug/Device:**  The use of [name of drug/device] in this study may have side effects that no one knows about yet. The study doctor will let you know about any new information that might make you change your mind about participating in the study.  **Upper GI Endoscopy:**  Possible risks and discomforts associated with the endoscopy procedure include gagging, nausea, vomiting, sore throat and possible reaction to the numbing medicine used during the procedure. There are other less common risks of endoscopy. [if GI endoscopy will be done by someone who isn't an investigator, add this statement] The doctor performing the endoscopy will explain these risks to you in more detail before you have the endoscopy procedure.  **Withdrawal from Current Medication (Washout Period**):  During this study, the medication you normally use for your condition [will/may] be stopped for up to [XX days/weeks/months]. You [will/may] receive no medication, or medication at a dose which may not help your condition. As a result, you [will/may] have an increase in symptoms including [describe]. |

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| **SAMPLE RISK LANGUAGE FOR GENETIC RESEARCH**  **Genetic Testing/Analysis:**  The risks related to genetic analyses can be to individuals or groups. These harms include stigmatization and insurability. [if applicable add] To reduce this risk, your samples will be stored and labeled with a code number. [if applicable add] If the results are used for future research, the researchers will not be able to identify you. Information about this study will not be recorded in your medical record.  There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law may protect you in the following ways:   * Health insurance companies and group health plans may not request your genetic information that we get from this research. * Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. * Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.   This Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.  There may be other risks that are not known at this time. Tell the study investigator or study staff right away if you have any problems.  [If applicable, add:]  New information about parentage may be discovered by this research. This could include unknown adoption and paternity (fatherhood). These types of findings will not be shared with you unless there are medical concerns. We will not reveal this information to any third party, including other family members. |

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| **SAMPLE RISK STATEMENTS FOR RADIOLOGY PROCEDURES**  **General Statement for Ionizing Radiation:**  This study involves exposure to radiation from a [name of procedure]. You will receive a radiation dose. This dose is not necessary for your medical care. You will get the radiation only because you are taking part in this study. Radiation can increase the risk of cancer after many years but at a dose much higher than you will get. Because of the low dose of radiation, it is very likely that you will see no ill effects.  **Contrast Agent** [add when applicable]  You will receive a contrast agent as part of your [name of procedure]. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching, hives, and can also be serious or life-threatening emergency from difficulties breathing. If this occurs, it is treatable.  **DXA and pQCT Scans:**  This research study involves exposure to a small dose of radiation from a [name of procedure]. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is unlikely that you will see any effects at all.  **Magnetic Resonance Imaging (MRI):**  There are no known risks of physical harm associated with MRI. However, MRI machines produce loud banging noises, which cause some people to become stressed or upset. You may also feel uncomfortable inside the magnet if you do not like to be inside small places or have difficulty lying still.  The MRI magnet is always on and attracts certain metal objects. Any metal objects on or inside of your body may heat up, move, and/or not function properly within the scanning room. Metal objects in the room can fly through the air toward the magnet and hit those nearby. There are many safety measures in place to reduce these risks. The staff will screen all persons and materials entering the scanning room for metal. When the study begins, the door to the room will be closed to minimize the risk of someone accidentally bringing a metal object into the scanner room.  **Contrast Agent** [add when applicable]**:**  You will receive a contrast agent as part of your MRI. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives and can be as serious life-threatening emergency from difficulties breathing. If this occurs, it is treatable. |

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| **RISK STATEMENTS FOR GENERAL ANESTHESIA AND SEDATION**  **General Anesthesia:**  You [may] will need general anesthesia in order to have a [name of procedure]. There are very rare but serious side effects associated with general anesthesia including: irregular heartbeat, increases or decreases in blood pressure, rare reactions to medications used in the anesthesia, and blockage of breathing passages. Other rare complications include nerve injury, lung injury, heart attack and brain damage. An extremely rare but serious complication is rapid increase in body temperature. All of these complications are treatable but might lead to coma or even death. You will have an opportunity to discuss these risks with the anesthesiologist.  **Sedation:**  Sedative medicines may make you sleep for several hours and sometimes can have prolonged effect. Uncommon but serious complications include: irregular heartbeat, increases or decreases in blood pressure, rare reactions to medications used, and blockage of breathing passages. All of these complications are treatable but rarely, may lead to coma or even death. Emergency personnel and equipment will be available in the event of a serious adverse reaction to sedation. You will have an opportunity to discuss these risks and the specific drugs that will be used with the nurse or doctor who will supervise the sedation.  **Transport under General Anesthesia:**  During transport to and from [Location #1] to [Location #2] there is a small risk that the breathing tube or an intravenous catheter may come out. If either problem happens, it could result in serious breathing or bleeding problems. To minimize the likelihood of any harm, your child's anesthetic care will be directed by experienced anesthesiologists with assistance from nurses and respiratory therapists during the scheduled procedure and transport. You will have an opportunity to discuss these risks with the anesthesiologist. |

## POSSIBLE BENEFITS TO SUBJECTS

* Clearly **describe all expected benefits**. Do not overstate the benefits. Payments and/or the provision of free drugs or medical procedures should not be described as benefits.
* Only direct benefits to the participants should be described in this section. Do not include general or societal benefits here.
* **If there is no anticipated direct benefit** to the participant from the study, state this.

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| **Sample Language:**   * You will not directly benefit from participation in this study. * You may benefit from this study if you are assigned to the study group that receives [XXX] and [XXX] proves to be beneficial. * The study will test whether [XXX] improves your condition. However, you may not benefit personally from taking part in this study. * Taking part in this study may or may not improve your health. While doctors hope [procedure/ drug/ intervention/ device] will be [more effective/have fewer side effects] than standard (usual) treatments, there is no proof of this yet. * Participation in this study is purely for research purposes and will not improve your health or treat any medical problem or condition you may have.   **Phase 1 Drug 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.  **Phase 2 or 3 Trial:**  Based on experience with this [procedure/ drug/ intervention/ device] in [animals/patients with similar disorders], 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. |

## POSSIBLE BENEFITS TO SOCIETY

* Describe the anticipated benefits to science or society expected from the research.
* Only general or societal benefits should be described in this section. Do not include direct benefits to the participants here.

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| **Sample Language:**  This study will help the researchers learn more about [procedure/drug/ intervention/ device]. Hopefully this information will help in the treatment of future patients with [disease/condition]. |

## YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY

* Describe the **alternatives to participation** in the study.
  + Inform participants of the range of options available to them, especially for studies that involve medical interventions.
  + For studies that do not involve medical interventions and/or do not offer a potential direct benefit to participants, it is acceptable to say that the alternative is not to participate in the study.
* Include applicable information on alternative procedures or courses of treatment that may be advantageous to the participant if he/she refuses to participate or withdraws from the study (e.g., treatment without being in a research study; participating in another study; getting no treatment.)

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| **Sample Language:**  **Example #1:**  If you decide not to participate in this study, your other choices include:   * Receiving standard treatment, such as \_\_\_\_\_ for your condition. * Taking part in another study. * Receiving no treatment at this time.   Please ask questions about all of your treatment options before deciding whether or not to join this research.  **Example #2:** [For studies involving end-stage diseases, add the following paragraph as an additional bullet.]   * Receiving comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by your disease. It does not treat the disease directly, but instead tries to improve how you feel.  Comfort care tries to keep you as active and comfortable as possible.   **Example #3:**   * There are no alternative treatments or procedures available. The only alternative is not to participate in this study.   **Example #4:**   * This research is not a treatment study. Your alternative is not to participate in this study. |

## COSTS TO YOU FOR BEING IN THIS STUDY

* Inform participants about **any additional costs** that may result from participation in the study.

**Note:** Do **not** provide an actual dollar amount for the costs.

**Do** identify which study procedures will result in additional costs.

* If there are **no additional** costs for participation, state this in the consent form.
* As appropriate, inform the participants of any **additional costs** they will incur such as parking fees or transportation that **will not** be reimbursed.
* **Do not discuss research related injury costs in this section.** See the section below, “RESEARCH INJURY” for CHLA required language for treatment and compensation for research-related injury.
* **Sponsor covered items and services:** The costs section may be specific about items and services that will be covered by a Sponsor, e.g., the study drug. **Note:** Sponsor-initiated clinical trials are to be fully funded by the sponsor and such costs should not be billed to third party medical insurance, unless such billing is permissible per State and Federal law. Insurance billing cannot be a condition for Sponsor payment.
* **Insurance coverage and participation in research studies:** Include a statement informing subjects that because they are participating in a research study, insurance providers may not cover all costs.
* **For NCI-funded studies:** Provide participants with the website address and phone number of the National Cancer Institute (NCI) that offers more information on clinical trials and insurance coverage. See <http://www.cancer.gov/clinicaltrials/education/insurance-coverage> for details.

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| **Sample (Recommended) Language:**  Use this language as it applies to the research.  Taking part in this research study might lead to added costs to you or your insurance company.    (Name of investigational drug/device) will be provided to you at no cost while you take part in the study. [The next sentences should be included as applicable: You and your health plan/insurance company will need to cover the cost of the infusion/injection of the study drug. It is possible that the (name of investigational drug) may not continue to be supplied while you are on the study. If this occurs, the research doctor will talk to you about your options.]    Many of the tests, procedures, and/or drugs provided to you as part of this study are routinely used to treat your illness/condition. You would receive these tests, procedures, and/or drugs even if you were not participating in this study.  You or your health plan/insurance company will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs because you are in a research study.  If your health plan/insurance company will not pay these costs, you will have additional expenses from being in this study, such as the costs associated with treating side effects.  If you have questions about your insurance coverage, or the items you might be required to pay for, please discuss them with the study team.    **Include for cancer clinical trials:** The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay.  This can be found at the website below or can be provided by the study team: [www.cancer.gov](http://www.cancer.gov) or 1-800-4-CANCER (1-800-422-6237) |

## REIMBURSEMENT FOR YOUR EXPENSES

This section should not be included if subjects will not be reimbursed for additional costs incurred as a result of participation, or if there are no additional costs.

* If participants will be reimbursed for costs (e.g., parking, transportation, meals, etc.), describe in detail the plans for reimbursement.
* This section of the consent form should indicate:
  + For what specifically subjects will be reimbursed.
  + How reimbursement will be made (e.g., prepaid debit card, cash, check, etc.).
  + When participants will be reimbursed (e.g., immediately after the interview, approximately six weeks after individual completion of the study). Include a reimbursement schedule, if appropriate.
  + Whether participants need to submit receipts in order to be reimbursed.
  + Whether participants need to provide any personal information (e.g., name, date of birth, address social security number, etc.) to receive reimbursements, if applicable.

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| **Sample Language:**  **No Reimbursement:**  You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.  **Reimbursement for Out-of-Pocket Expenses:**  You will be reimbursed for the following expenses [complete this sentence, e.g., parking and transportation for study visits.] In order to be reimbursed, please be sure and save your receipts so that you can provide these to the research staff. Reimbursement will be provided through the use of [name payment mechanism, e.g., prepaid debit card, ClinCard].  **Identity of Participant Required for Payment:**  Personal information about you, including your name, address, and social security number, will be released to the CHLA Patient Billing Office for the purpose of payment. |

## PAYMENT FOR PARTICIPATION

* If participants will be paid for participation, describe in detail the type of payment, amount, and terms of payment.
* Payment for participation should be commensurate to the participants’ time and the inconvenience of being a research subject.
* This section of the consent form should indicate:
  + The **total dollar amount** that participants will be paid and any relevant information such as pro-rating if a person does not complete the study, or bonus payments at the end of the study.

**Note:** Participants should not be required to complete the entire study in order to be paid, and any bonuses for study completion should be modest.

* + **How payment will be made** (e.g., prepaid debit card, ClinCard, cash, check, gift card, toys, iPads, backpacks, other objects, etc.)
  + **When participants will be paid** (e.g., immediately after the interview, approximately six weeks after completion of the study). Include a payment schedule, if appropriate.
  + **Who will receive the payment** (e.g., child or the parent of the child).
  + Whether participants need to **provide any private information** (e.g. name, date of birth, address social security number, etc.) to receive payment, if applicable.
  + Payments for research participation are considered **taxable income**. If subjects are paid more than $600 total in a calendar year for participation in research studies, CHLA will report this as subject income to the IRS.

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| **Sample Language:**  **No Payment:**  You will not be paid for your participation in this research study.  **Payment:**  For taking part in this research you will paid up to a total of $ [insert dollar amount]. You will be paid as follows:   * Describe the payment schedule in terms of amount. * Describe when and how payments will be made. * Describe the amount of payment if the subject leaves the study early.   **Identity of Participant Required for Payment:**  Personal information about you, including your name, address, and social security number, will be released to the CHLA Patient Billing Office for the purpose of payment.  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. |

## RESEARCH INJURY

This section is not required for minimal risk research. Below is the CHLA standard treatment and compensation injury language.

**Important Notes for Working with Sponsors:**

The CHLA IRB prefers to use the paragraphs below for describing treatment and compensation for research injury. The CHLA IRB **will not approve** language that:

* Attempts to define a research-related injury (for example, by specifically excluding pre-existing conditions and underlying disease)
* Attempts to impose standards of behavior on participants (for example, “Sponsor will pay your costs if you followed the study team directions”)
* Attempts to limit the amount of coverage that will be provided (for example, “Sponsor will pay your reasonable medical costs only,” or “Sponsor will not pay for lost wages”)
* Includes legal or not lay-friendly terminology (for example, “Sponsor will not pay if the investigator was negligent or engaged in willful misconduct”)
* Discusses the Sponsor’s obligations versus the institution’s (for example, “Sponsor will not pay if the study team did not follow the protocol”)
* Appears contractual or is potentially exculpatory (for example, “You agree that Sponsor is not responsible”)

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| **CHLA Required Language:**  [You must use one of CHLA’s standard subject injury language statements for research involving more than minimal risk.]  **Use this language for non-industry sponsored or unfunded studies:**  If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The research doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.  **Use this language for industry sponsored studies:**  If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The research doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. [Name of sponsor/funding source] will pay your costs for reasonable and necessary care if you have been injured because of taking part in this research study. [Include the next sentences, if applicable:] If you receive Medicare/Medicaid and [Name of sponsor/funding source] pays for medical treatment for injury relating to your participation in this research, [Name of sponsor/funding source] will need to collect certain personal information about you, such as your name, date of birth, gender, social security number or Medicare/Medicaid identification number and information related to this research study. By signing this informed consent form, you are giving permission to [Name of sponsor/funding source] to collect your personal and treatment related information and report it to the Centers for Medicare & Medicaid Services (CMS), while participating in the study and for as long as [Name of sponsor/funding source] is required by the government to report this information. The sponsor will not use this information for any other purpose.    **Include with one of the paragraphs above:**  CHLA [and name of sponsor/funding source, as applicable] has/have no plans to pay you or give you other compensation for injury. You do not give up any rights right to pursue a claim through the legal system by signing this form. |

## CONFIDENTIALITY

* Inform participants of the extent to which the researchers intend to maintain confidentiality of records that identify them. Specifically:
  + - * + How data, records, specimens containing private or personal information will be secured to prevent access by unauthorized individuals. Include what methods are in place to code or de-identify data, records, and specimens.
        + Describe who will have access to data, records, specimens, including whether they will be shared with others for future research.
* Indicate what regulatory or other agencies might have access to the research records (e.g., the FDA, sponsoring company, CHLA IRB, authorized CHLA representatives).
* Data security and storage procedures need to be in compliance with the CHLA Information Security requirements.

**Guidance:**

* **Do not guarantee complete confidentiality:** An inherent risk of participating in research is a loss of privacy and the potential for a breach in confidentiality. There is no legal privilege between the researcher and participant as there is between physician and patient or counselor and client. Thus, a guarantee of “complete” or "strictest” confidentiality should not be given or implied.
* **A separate CHLA HIPAA research authorization form is required:** Due to the complexities of HIPAA and California Medical Information Act (CMIA), a separate CHLA Research Authorization form is used to comply with all applicable laws concerning access, use and disclosure of health information for research.

**Note:** Do not add additional information about the use of protected health information in the consent form. The CHLA HIPAA research authorization form cannot be altered.

* **Protection from forced disclosure of research data and records**: Researchers may wish to obtain a Certificate of Confidentiality (CoC) for studies that involve illegal activities or collect sensitive information, that if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. CoCs allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. For studies where a CoC will not be obtained, participants should be informed about a loss of privacy if records are subpoenaed.
* **Use, storage, access and sharing of data and specimens:** Data statements below may also include information about specimens, as appropriate. In all cases participants need to be informed about the confidentiality provisions in place for the use and sharing of data and specimens.

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| **Sample Language for Confidentiality:**  **Choose One:**   * **Data/Specimens Labeled with a Unique Code:**   The data and specimens [adjust for the study, specify type(s) of specimens, if applicable: blood, urine, tissue, etc.] collected as part of this study will be “coded.” Coded means that the data and specimens [adjust for the study] collected for this study will be assigned a unique code or Study ID. Your research data and specimens [adjust for the study] will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data and specimens. [adjust for the study]   * **Data/Specimens that are De-Identified:**   The data and specimens [adjust for the study, specify type(s) of specimens, if applicable: blood, urine, tissue, etc.] collected as part of this study will be “de-identified” or “anonymized.” This means that there will be no way to link the data and specimens [adjust for the study] back to you.  People on the research team [add if treatment study or involves medical procedures: and your doctors and nurses] will know that you are in this research study. All results will be kept confidential. [Add if data/specimens from the study will be sent outside of CHLA:] The data and specimens [adjust for the study] collected as part of this study will be sent to [specify locations].  You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:   * The research sponsor, [insert name of company or delete if no sponsor]. * People who work with the research sponsor [delete if no sponsor]. * Government agencies, such as the Food and Drug Administration (FDA) [if FDA regulated], and the Department of Health and Human Services [if the study is funded by the NIH or other DHHS agency]. * The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.   **Include for Studies that Include Treatment or Medical Procedures:**  Because this study involves medical procedures and/or the treatment of a medical condition [adjust for the study], a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about any medications and/or procedures [adjust for the study]you are receiving in the study and treat you appropriately.  **Include for Studies that Do Not have a Certificate of Confidentiality:**  We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. All identifiable information about you will be replaced with a unique code or study ID. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information.  We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. We will not release information about you to others not listed above, unless required or permitted by law. For instance:   * if we learn of child or elder abuse, harm to self or others, or * if you have certain infectious diseases; or * you are injured and need emergency care.   The results of the research may be presented or published. We will keep your name and other identifying information confidential.  **Include for Studies Involving Photographs, Videos, or Audio Recording Taken for Research Purposes:**   * The photographs, videos, and/ or audio recordings [adjust for the study] 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. * The photographs, videos, and/ or audio recordings [adjust for the study] made of you during this research may be used for educational purposes. If 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 photos/recordings.] * The photographs, videos, and/ or audio recordings [adjust for the study] made of you during this research may be used for educational purposes without being modified, so people who see/hear [adjust for the study] 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 to use them on a separate release form. You may decline to allow your photographs, videos, and/ or audio recordings [adjust for the study] to be used without being modified and still be a part of this study. [Describe the subject’s right to review/edit the photos/recordings.]   **Studies with a Certificate of Confidentiality - Include one of the following:**  **Example #1:**  This research is covered by a Certificate of Confidentiality from the National Institutes of Health [or “FDA,” as applicable]. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.    There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.    Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.  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].  The results of the research may be presented or published. We will keep your name and other identifying information confidential.  **Example #2:**  To help us protect your privacy, we have obtained a Certificate of Confidentiality from the [National Institutes of Health/Food and Drug Administration]. 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.  **Exceptions:**   * The researchers are required by law to disclose information about incidents such as child abuse or the intent to hurt yourself or others. * The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. * A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you without your consent. In addition, * Under California law, the privilege of confidentiality does not extend to information about sexual or physical abuse of a [child/dependent adult.] If any member of the research team has or is given such information, he or she is required to report it to the authorities. The obligation to report includes alleged or reasonably suspected abuse as well as known abuse. [As appropriate, provide descriptions and examples of the types of information which would be reported.]   **Example #3:**  To help us protect your privacy, we have obtained a Certificate of Confidentiality from the [National Institutes of Health/Food and Drug Administration]. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.  The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.  [Language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others]. |

## FUTURE RESEARCH USE OF DATA AND/OR SPECIMENS

This section is not required unless research involves the collection of identifiable (or coded) data/specimens.

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| **Sample Language:**  **No Use of Data and Specimens for Future Research:**  The data and specimens [adjust for the study] collected as part of this study will not be used for future research, even if all identifiers are removed.  **Alternative Language for Discarding of Samples:** Any specimens (specify: tissue, blood, urine) obtained for routine lab testing will be discarded or destroyed once they have been used for the purposes described in the protocol.  **Use of Data and Specimens for Future Research (De-identified):**  Once this research study is completed, the data and specimens [adjust for the study] collected as part of this study will be “de-identified” or “anonymized.” This means that there will be no way to link the data and specimens [adjust for the study] back to you. Once your data and specimens [adjust for the study] have been de-identified, they may be used by the researcher conducting this study, the study sponsor, 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. Future research [might/will not] include whole genome sequencing.  **Use of Data and Specimens for Commercial Profit (De-identified):**  Your de-identified specimens may be used for commercial profit. There are no plans for you to share in any profit generated as a result of the use of your data and specimens. [Or explain plans for sharing commercial profit.]  **Alternative Language for Commercial Profit:** Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to [the Sponsor of this study (company name optional) or the name of the national group). These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product.  **Use of Data and Specimens for Future Research (Coded):**  Your data and specimens [adjust for the study] collected as part of this study may be used by the researcher conducting this study, the study sponsor or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. The data and specimens [adjust for the study] will be labeled with a unique code or Study ID. The link connecting your identity to your study ID will be kept by the research team at CHLA. This future research may be done without consulting you or obtaining consent (permission) for this additional use. Future research [might/will not] include whole genome sequencing.  **Use of Data and Specimens for Commercial Profit (Coded):**  Your coded specimens may be used for commercial profit. There are no plans for you to share in any profit generated as a result of the use of your data and specimens. [Or explain plans for sharing commercial profit.] |

## STUDY WITHDRAWAL

* Inform participants of **circumstances** under which their participation may be ended by the investigator without their consent, if applicable.
* Inform participants of any procedures for **safe and orderly withdrawal** from the study if they withdraw or are removed from the study.
* Inform participants that the study might also be **stopped by the researchers, the FDA, or the study sponsor*.***

**Withdrawal from FDA-regulated clinical trials:**

* Inform participants if they withdraw from an FDA-regulated clinical trial, that the data collected about them up to the point of withdrawal will remain part of the study database and may not be removed. See [FDA Guidance](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126489.pdf) for more details.
* Participants may withdraw from the interventional portion of a study and consent to allow for continued follow-up and/or further data collections are outlined below:
  + A separate consent document is required for this limited participation activity if such a situation is not described in the original informed consent.
  + The consent form clearly must distinguish between study-related interventions and continued follow-up of associated clinical outcome information (e.g., lab results, review of medical records).
  + If a participant **does not consent to continued follow-up** of associated clinical outcome information, their medical records or other confidential records cannot be accessed to obtain any **new information** about the participant.

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| **Sample Language:**  The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers, the FDA, or the study sponsor might also decide to stop the study at any time.  If you decide to stop being in the study, or are removed from the study, or the study is stopped, the researcher will ask you to… [complete this sentence.For example, return for a final close-out visit or evaluation, return unused study medication, complete an exit telephone interview.]  **Add this for FDA-Regulated Clinical Trials:**  If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study and may not be removed from the study database.  **Add this for studies if the data/specimens will be destroyed if the subject withdraws or is withdrawn from the study (not applicable for FDA-regulated clinical trials):**  If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you will be destroyed. |

## QUESTIONS ABOUT THIS STUDY

The consent form must include these required elements for contacting the CHLA Investigator:

* How to contact the CHLA investigator with any questions, concerns or complaints about the research.
* How to contact the CHLA investigator in the event of a research-related injury.
* For more than minimal risk studies, provide a 24-hour contact number (e.g., CHLA main number) in this section.

The consent form must include these required elements for contacting the CHLA IRB:

* How to contact the CHLA IRB for questions, concerns or complaints about the research, and
* How to contact the CHLA IRB for questions about their rights as a research subject.
* The statements below should be used for all consent documents.

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| **Sample Language CHLA Investigator:**  **Sample Language for Research that is Minimal Risk:**  If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team at (XXX)-XXX-XXXX.  **Sample Language for Research Involving More than Minimal Risk:**  If you have questions, concerns, or complaints about the study, or think this research has hurt you or made you sick, talk to the CHLA research team at (XXX)-XXX-XXXX.  Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, [Principal Investigator’s name], at [phone].  [Add a 24-hour contact number for more than minimal risk research:] 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.  **Applicable Clinical Trials:** If the consent form is for a study that meets the [definition](http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) of an “Applicable Clinical Trial,” that requires [clinical trial registration](https://clinicaltrials.gov/ct2/manage-recs/fdaaa), the statement provided below must be added to the consent. **Note:** This statement cannot be altered, per federal regulation.  *ClinicalTrials.gov* is a Web site that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.  **Required Language for CHLA IRB:**  This research is being overseen by the CHLA Institutional Review Board (“IRB”). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or [hspp@chla.usc.edu](mailto:hspp@chla.usc.edu) if:   1. You have questions, concerns, or complaints that are not being answered by the research team. 2. You are not getting answers from the research team. 3. You cannot reach the research team. 4. You want to talk to someone else about the research. 5. You have questions about your rights as a research subject. |

## FINANCIAL INTEREST OF THE INVESTIGATOR

If a member of the study team has a disclosable financial interest in the outside entity funding the study or other personal financial interests in entities that might reasonably be affected by the research, include a financial interest statement. Add the disclosure statement required by the Conflict of Interest in Research Committee (COIRC) here or remove this section if there are no conflicts of interest.

## RIGHTS OF RESEARCH SUBJECTS

* Inform all participants of the following:
  + **Participation is voluntary.**
  + **Refusal to participate** will involve no penalty or loss of benefits to which the subject is otherwise entitled.
  + The **subject may discontinue participation**at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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| **Sample Language:**  You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.  Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know. [Add the following sentence if medical research:] You are not under any obligation to participate in a research study conducted by your doctor.  You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.   * You have a right to have all of your questions answered before deciding whether to take part. * Your decision will not affect the medical care you receive from CHLA. * If you decide not to take part, you can still receive medical care from CHLA. * You will be given a copy of this signed and dated consent form [and the “Experimental Subject’s Bill of Rights”] to keep. * [You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.] |

## OPTIONAL PROCEDURES

Add this section if there are optional procedures included in the research.

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| **Sample Language:**  May the researchers [describe optional procedure in simple language]? Please provide your initials beside your decision.  \_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No [Subject] [Add if minors 14 years and older are included]  \_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No [Parent/Legal Guardian/Legally Authorized Representative (for children or adults unable to consent)] |

## SIGNATURE OF RESEARCH SUBJECT

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| **Add the following signature section for documentation of consent from adults who are capable of providing consent, and/or documentation of assent from children ages 14 to 17 years old:**  **SIGNATURE OF RESEARCH SUBJECT**  (*For adults who are capable of providing consent; children ages 14 to 17 years old who are capable of providing assent*)  Your signature below indicates:   * You have read this document and understand its meaning; * You have had a chance to ask questions and have had these questions answered to your satisfaction; * You consent/assent to your participation in this research study; and * You will be given a signed copy of this form.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name of Subject  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Subject Date  **Add the following signature section for documentation of parental permission from the parent(s) or legal guardian(s) of children:**  **SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)**  (*For all subjects under the age of 18*)  Your signature(s) below indicates:   * You have read this document and understand its meaning; * You have had a chance to ask questions and have had these questions answered to your satisfaction; * You agree to your child’s participation in this research study; * [Include the following statement if the parent completes any questionnaires or participates in other research activities related to the child:] You agree to your own participation in this research study; and * You will be given a signed copy of this form.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name(s) of Parent(s)/Legal Guardian(s)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Parent/Legal Guardian Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Parent/Legal Guardian Date  **Add the following signature section for documentation of consent from a legally authorized representative for adults lacking the capacity to consent:**  **SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE**  (*For adult subjects who are not capable of providing consent*)  Your signature below indicates:   * You have read this document and understand its meaning; * You have had a chance to ask questions and have had these questions answered to your satisfaction; * You consent to allow the subject to participate in this research study; and * You will be given a signed copy of this form.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name of Legally Authorized Representative  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Legally Authorized Representative Date  **Add the following signature section for documentation of obtaining consent/permission/ assent:**  **SIGNATURE OF INDIVIDUAL OBTAINING CONSENT**  I have explained the research to the subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.  **Add this information when children and/or adults lacking the capacity to consent are subjects:**  **Assent Instructions:** All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.  Subjects ages 7 to 13: If assent is obtained, subjects must be given an assent information sheet.  Subjects ages 14 to 17: If assent is obtained, have the subject sign this consent form, unless the investigator determines that the subject is not capable of signing.  Adults subjects who are not capable of providing consent: If assent is obtained, subjects must be given an assent information sheet, or the subject can sign this consent form.   * I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.   OR   * The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name of Individual Obtaining Consent  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Individual Obtaining Consent Date  **Add the following signature section for documentation of a witness signature:**  **SIGNATURE OF WITNESS (if applicable)**  Your signature below indicates:   * You were present for the entire consent conference; * The information in the consent document and any other written information was accurately explained to the subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable]; * The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] had an opportunity to ask questions and those questions were answered; and * The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] voluntarily signed the consent/permission/assent form in your presence.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name of Witness  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Witness Date |