

Children’s Hospital of Orange County

INSTITUTIONAL REVIEW BOARD

**Informed Consent Agreement**

***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT: REMOVE: THIS SECTION, ALL [RED INSTRUCTIONAL TEXT] AND [GREEN CUSTOMIZABLE PROMPTS].***

***[Insert the study title here – Just as it appears on the Protocol]***

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say “you” in this consent form, we mean you or your child; “we” means the study team and other staff.

You are being asked to take part in a research study. Before you give your consent to be a volunteer, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what you will be asked to do. If you don’t understand something in this consent form, please be sure to ask your study team to explain.

**Investigators and Sponsor**

Principal Investigator: *[Insert P.I. Name Here]*

Co-Investigator(s): *[Insert Co-Investigator Name(s) Here]*

Sponsor: *[Insert Sponsor Name Here]*

**Human Research Participant’s Bill of Rights**

(For Medical Experiments)

**The rights listed below are the right of every individual asked to participate in a research study.**

**You have the right:**

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

**QUICK SUMMARY OF RESEARCH STUDY** *[This section is recommended for all studies and REQUIRED for all Federally-funded (including federal-flow through) research projects. The consent form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. In this first section put a concise summary of key information a reasonable person would want to know to make an informed decision.*

*Just put the KEY POINTS! More detail can be outlined in the body of the consent form.]*

* The purpose of this study is to *test [investigational drug], [investigational device], or an investigational dose of a drug or to compare [something] to [something else] or to gather information about [topic].*
* You do not have to be in this study. Some other things you may be able to do are: *[list alternatives briefly]*.
* If you join, you will be in this study up to *[X days, months, years]*.
* *Very briefly explain the key procedures. More detail can be contained in the main body of the consent. Include placebo statement if applicable:* You will *[take a study drug or use a study device X times over X days, months, years or until your condition gets worse or you have bad side effects]*. If applicable: *[You may get placebo (a pill that looks like a drug but has no drug in it)*. Study procedures include: *[physical exams, blood and urine collection, heart tests, x-rays, CT scans, MRIs, biopsies, pregnancy tests, drug/alcohol tests, HIV tests, and questionnaires.]*
* *Benefits: Include one of the following statements. These can also be repeated in more detail in the main body of the consent form. Option 1 - If study has potential for benefit:* You may benefit from this research, but there is no guarantee that being in this study will help you. *Option 2 - If study has no benefit to participant:* Being in this study will not help you. Information from this study might help others in the future
* *Risks: Put in the KEY risks. Not all of them. Just the ones a reasonable person would want to know. A full risk section is below in the main body of the consent:* The most important risks to know about are: *[list in brief the most important risks]*. This form gives more detail and describes other possible risks later. There may also be risks we do not know about yet.
* If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose to better understand this study and your options.

**WHY IS THIS RESEARCH STUDY BEING DONE?**

The purpose of this research study is to *[Complete this statement in one or two sentences – use lay language] Examples: …*find out which type of blood pressure medication has fewer side effects; …test the safety of an experimental drug. We also want to find out what effects, good and/or bad, it has on you and your [specify condition/other as applicable to 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 will test how an experimental drug works and whether it is safe. For studies involving investigational drugs or devices, the name of* ***investigational drug(s) or device(s)*** *must be noted and named. The name by which the drug or device is referred to in this section should be used consistently throughout the consent form.* **NOTE:** *Refer to an investigational drug or device as "investigational" or "experimental" rather than "new," since "new" can suggest that something is automatically better.]*

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

*[State the enrollment goal of the study and where appropriate discuss study cohorts.]*

Approximately       participants will take part in the research at *[Complete- list study specific location]*. A total of       participants will be asked to participate across all study sites.

**HOW LONG WILL THE STUDY GO ON?**

This study includes [*XX visits*] and takes about *[XX hours]* over a period of *[XX days/weeks]*.

You will take *[specify drugs or interventions]* for *[months, weeks/until a certain event].* After you are finished taking *[drugs or interventions]*, the researchers will ask you to visit the office for follow-up exams for at least *[indicate time frames and requirements of follow-up.] For example, "The researchers would like to keep track of your medical condition for the rest of your life. They would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps them look at the long-term effects of the study.”*

**Inclusion Requirements *[Optional Section – may be removed]***

You can participate in this study if you meet the following inclusion criteria:

* *[Complete this sentence or use a bulleted list of inclusion criteria – use* ***lay******language and include only key points. Consider listing historical inclusion criteria that the research team may not be aware of****] Examples: are at least 18 years of age or older; have been clinically diagnosed with depression, never have had a blood clot.*

**Exclusion Requirements *[Optional Section – may be removed]***

You cannot participate in this study if you meet the following exclusion criteria:

* *[Complete this sentence or use a bulleted list of exclusion criteria - use* ***lay******language and include only key points. Consider listing historical inclusion criteria that the research team may not be aware of****] Example: are taking high blood pressure medications.*

There may be other inclusion or exclusion requirements for this study. You may discuss these with the study team.

**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?**

Before you can participate in the main part of the study...

You may need to have “screening” exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include*:*

*[as applicable – if no screening then remove this section].*

* *[Complete this sentence or use a bulleted list - use* ***lay******language****].*

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done as listed below *[as applicable – if no screening then remove this paragraph and keep the text below].*

**The main study tests and procedures include…**

1. *[Explain the research procedures in chronological order – screening procedures, main study procedures, and follow-up procedures. Include the expected duration of each procedure, or each visit and the procedures to be completed at the visit. It is* ***strongly recommended*** *that you provide a table of visits, tests and procedures. Tables may be easier for the subject to understand and may help to shorten long repeated paragraphs throughout the consent document.*
2. *Use lay language.*
3. *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.”)*
4. *Procedures do not necessarily need to include specific names of common psychological tests (e.g., BDI-II, MMSE, MCMI-III, MACI, QOLI), 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.”)*
5. *Specify the amounts of blood or tissue to be taken for study purposes using a lay equivalent (e.g., tablespoon, teaspoon).*
6. *Include medical record review as a study procedure when protected health information is created, accessed or disclosed for the study.*
7. ***For studies that involve routine (standard of care) medical procedures:***

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

* 1. *If the standard procedure is not explicitly required by the study protocol, the consent form need not describe that procedure or its risks.*
  2. *If the standard procedure is a main focus of the study (e.g., one or more arms of a randomized study is standard) or is explicitly required by the study protocol, the consent form must include a full description of the procedure and its risks.]*

1. *Include as necessary the following terms as applicable to the research procedures:*
   1. R*andomization: You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. <as applicable> A computer program will place you in one of the groups. Neither you nor your study team can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group.*
   2. *Washout period: During this study the medication you normally use for your condition will/may be stopped for up to [XX days/weeks/months].*
   3. *Placebo: During this study there is a XX chance that you will receive a placebo.*
   4. *HIV Testing: Research procedures include testing for HIV.*
2. *For studies that involve* ***Whole Genome Sequencing (WGS):*** *Make clear in the consent form that WGS will be included as a research procedure.*
   1. *Include a description of WGS such as; WGS is the sequencing of a human germline or somatic biospecimen with the intent to generate the complete DNA sequence of that biospecimen.*

After you complete the main part of the study...

*[Explain the follow-up tests, procedures, exams, etc. required, including the timing of each and how they relate to standard care (e.g., they are different from standard care; or they are part of standard care but are being performed more often than usual or being tested for the study. Define the length of follow-up. [If not applicable, please remove.]*

**RETURN OF RESULTS** *[Required if the study will produce clinically relevant research results. If not applicable, please remove.]*

*[Explain the possibility that subjects may or may not receive research results. This section is meant to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.]* Example: *You [will / will not] be provided any clinically relevant information that may pertain to your health.*

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

*[When applicable, include a sub-heading to indicate risks associated with the investigational drug, device or procedure, and then provide another sub-heading to indicate risks related to other procedures involved with the study.]*

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking *[drugs/interventions].* In some cases, side effects can be serious, long lasting, or may never go away. *[The next sentence should be included if appropriate:]* There is also a risk of death*.*

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the *[procedures, drugs, interventions, devices]* include those which are:

*[RISKS: If information is available, list by regimen the physical and nonphysical risks and side effects of participating in the study in three categories: 1. "likely"; 2. "less likely"; 3. "rare but serious" and include the probability of the risk associated with those categories.*

*There is no standard definition of "likely" and "less likely." As a guideline, "likely" can be viewed as occurring in greater than 20% of patients and "less likely" in less than or equal to 20% of patients. However, this categorization should be adapted to specific study agents by the principal investigator (or lead researcher).*

*In the "likely" and "less likely" categories, identify those side effects that may be "serious." "Serious" is defined as side effects that may require hospitalization or may be irreversible, long-term, life threatening or fatal.*

*Side effects that occur in less than 2-3% of patients do not have to be listed unless they are serious, and should then appear in the "rare but serious” category.*

*Physical and non-physical risks and side effects should include such things as the inability to work. Whenever possible, describe side effects by how they make a patient feel, for example, "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath.”*

*Consider all types of risks – psychological, social, economic, legal and physical. Also include risks such as a breach of confidentiality and those risks related to the use of placebo.]*

*For some investigational drugs/ interventions/ devices there may be side effects that have been noted during treatment, but not enough data is available to determine if the side effect is related to the drug/ intervention/ device. Inclusion of this information in the informed consent document is not mandatory, but it may be prudent to mention the most serious effects. If included, these side effects should be listed under a separate category titled "Side effects reported by patients, but not proven to be caused by [drug/ intervention/ device]." Side effects in this category do not have to be labeled as "likely," "less likely," or "rare but serious" and should not be repeated here if they appear in a previous category. Similar to the other categories, these side effects should be listed in a bulleted format.]*

Likely (occurring in greater than *[20]% of patients)*

Less Likely (occurring in *[4% to 20]% of patients)*

Rare but serious (occurring in less than *[4]% of patients)*

*[If appropriate to the study, include the following risk statement(s) and elaborate if needed. If not applicable, remove.]*

**Randomization:** You will be assigned to a treatment program by chance, and the treatment you receive may not work as well or have more side effects than the other study treatment(s) or other available treatments.

**Washout period**: 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 *[XX]*.

**Placebo:** During this study you could receive 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 *[XX]*. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.

**Blood draw:** Removing blood by a needle may cause temporary pain, bruising, bleeding, swelling, dizziness, and on rare instances fainting or infection.

**Exercise testing**: The exercise test 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.

**Psychological discomforts:** Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

**HIV testing:** Being tested for HIV may make you feel nervous or anxious about the test results. A positive test indicates that you have been infected with the HIV virus, but no one knows for certain when, if ever, you will become sick with AIDS or a related condition. Receiving positive results may make you very upset. If other people learn about your positive test results, you may 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.

**MRI:** The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips and pacemakers. Tell the doctor if you have any metal items within your body.

MRI scanning is painless but you might experience discomfort in the machine. You may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. In addition, loud noises occur during the study when the scanner is collecting measurements. These noises are beeping and hammering sounds and may bother you. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs.

[Insert if Gadolinium contrast used during MRI scans] Gadolinium contrast “dye” will be injected into your vein. This increases the ability of the MRI scan to show certain tissues in the brain or elsewhere in the body. Side effects include a mild headache, nausea, or burning at the injection site. Some people are allergic to gadolinium, experiencing hives and itchy eyes, or very rarely, a bee-sting type of severe allergic reaction (anaphylactic shock). Use of gadolinium may be linked to a rare but sometimes fatal condition (nephrogenic systemic fibrosis or NSF) in people with severe chronic kidney disease or acute kidney problems. Therefore, before you are given this dye your risk factors for kidney disease will be reviewed.

**Radiation Risks:** During this study you will have scan(s)donesolely for the purpose of this research. You would not have these scan(s) if you decide not to participate in this research study. These scans use radiation to create pictures of the structures inside the body. The total radiation dose that you will receive from the scan(s) is measured in a unit called a millirem (mrem). Typically, persons in the U.S. receive a radiation dose of about 310 millirem per year from natural sources of radiation, including from the sun, air, water and soils.

There are no known health effects associated with radiation exposure from scans equaling less than 1 rem (1000 mrem). The primary risk from radiation exposure at this level is the potential for a very small increased risk of future cancer. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form. For X-Ray, CT, and DXA scans, no radiation remains in the body after the scan.  For nuclear medicine scans, a small amount of radioactive material will be injected into the body.  This radioactive material will go away over a short period of time.  Your researcher will discuss any special precautions that may be required during this time before you consent to this research study.

*[Revise the chart to include the scan(s) involved* ***solely*** *for research purposes and complete the chart accordingly]*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Scan** | **Brief Description** | **Body Part** | **# of Scans** |
| X-Ray | An X-ray is a test that produces images of the structures inside your body particularly your bones. X-ray beams pass through your body, and they are absorbed in different amounts depending on the density of the material they pass through. | *[insert name of body part(s) to be imaged] [or revise accordingly if this will vary depending on study requirements]* | [*insert total number of scans across the entire study]* |
| CT Scan | A computerized tomography (CT) scan uses a series of X-ray images taken from different angles and uses computer processing to create images of the bones, blood vessels and soft tissues inside your body. CT scan images provide more detailed information than plain X-rays do. | *[insert name of body part(s) to be imaged] [or revise accordingly if this will vary depending on study requirements]* | [*insert total number of scans across the entire study]* |
| DXA | This test uses special X-ray devices to measure how many grams of calcium and other bone minerals are packed into a segment of bone. | *[insert name of body part(s) to be imaged] [or revise accordingly if this will vary depending on study requirements]* | [*insert total number of scans across the entire study]* |
| Nuclear Medicine Scans | Nuclear medicine scans use a special camera (gamma) to take pictures of tissues and organs in the body after a radioactive tracer (radionuclide or radioisotope) is absorbed by the tissues and organs. The radioactive tracer shows the activity and function of the tissues or organs. | *[insert name of body part(s) to be imaged] [or revise accordingly if this will vary depending on study requirements]* | [*insert total number of scans across the entire study]* |

**Incidental finding**: There may be a risk of an unexpected finding from the study evaluations performed. If we find results that may affect your health, we will refer you to your primary care physician specialist.

**Unknown risks [*this statement is mandatory and should not be removed]*:** There may be risks related to the research that we don't know about yet. Any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks will be reported to you.

**Confidentiality risk [*this statement is mandatory for all studies that collect Protected Health Information (PHI) and should not be removed]*:** With any study that collects personal health information, there is a risk of loss of confidentiality of your health information. Persons conducting the study are required to comply with applicable laws and policies to protect your health information.

**Reproductive Risks:** The effects of *[specify: experimental procedure, investigational treatment, experimental drug]* on fertility or a fetus are not known. For this reason, you should not become pregnant or father a baby while on this study. Women should not breastfeed a baby while on this study. A *[specify: blood or urine]* pregnancy test will be performed prior to the start of research procedures. Performing this test does not mean that we think you are pregnant. It is just a precaution required by the study.

It is important to understand that you need to use birth control while on this study. Check with the researchers about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.If you become pregnant [during the study, you must immediately contact the researchers. You will be withdrawn from the study and followed through the outcome of your pregnancy.

**Pregnant Partner Risks (for males participating in research involving an investigational drug where the effect on the fetus is unknown):**

*[Use language as appropriate per study protocol and site.]*

*[Example: Should your partner become pregnant while you are participating in this trial or within 6 months following the last dose of the study drug, you should contact the researchers immediately.  This study involves an investigational drug and we don’t know the risks to your unborn child.**The study sponsor may want to collect information about your partner's pregnancy.]*

**Pregnancy Testing in Minors**

If you are a female and have had your menses (your period) you will have some of your *[specify: blood and / or urine]* collected at different times in the study for the purposes of pregnancy testing.

*[If pregnancy testing in minors]*

Per California Law, pregnancy test results may only be provided to a parent or guardian only with your permission.

The study team will not discuss the results of your pregnancy test with your parent or guardian unless you say it is ok.

**Whole Genome Sequencing (WGS):** *[Required if WGS will be included as a research procedure.]*

*Example: WGS generates an extremely large amount of information about people, including factors that will contribute to their future medical conditions. It can provide insight into the health of individuals and their biological family. It is possible that WGS data gathered for one purpose could reveal important information, perhaps unanticipated and unplanned for, years later.*

**ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY? *[If this information is sufficiently covered in the Quick Summary it does not need to be repeated and this section can be removed. If more detail is needed use this section.]***

**Participant Benefits**

*[If possible benefit to the subject is anticipated]*

Taking part in this study may or may not make your health better. While researchers hope *[specify: procedures/ drugs/ interventions/ devices]* will be *[specify: more effective/have fewer side effects]* than the standard (usual) treatment, there is no proof of this yet.

*[If subject is randomized:]* If you are in the group that receives *[specify: procedures/ drugs/ interventions/ devices]* and it proves to treat your condition *[specify: more effectively/with fewer side effects than standard therapy/placebo]*, you may benefit from participating in the study, but this cannot be guaranteed

*[If no direct benefit to the subject is anticipated]* You will not directly benefit from participation in this study.

**Benefits to Others or Society**

*[Insert a statement about possible benefits to science or society here] Example: a decrease in the number of children injured in car accidents.*

This study will help researchers learn more about *[specify: procedures/ drugs/ interventions/ devices]*, and hope that this information will help treat future patients with *[specify:. . . conditions like yours]*.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

**Compensation**

If subjects will be paid choose appropriate text

You will be paid for taking part in this research study.

You will be paid $ [specify: type of payment and amount/value] at certain time points during the study. There are [specify: # of study sessions] visits. The total compensation for participation in the entire study is $ [specify: enter total compensation for completion of the study]. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

[If subjects will be compensated for one session] You will receive [specify: type of payment and amount/value] for taking part in this research study.

*[This statement is required for studies that provide any form/amount of compensation]* The law requires that CHOC submit an IRS 1099 form for individuals to whom it provides compensation exceeding $600 per calendar year. Compensation provided by this research study will count toward the annual total for this purpose.

*[If subjects will not be paid]* You will not be paid for taking part in this research study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

[Option 1: If all costs will be the responsibility of the research subject, use the following language:]

You or your insurance company will be responsible for all costs related to participation in this study. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, talk to your study team or contact your insurance company. [*When the costs to a subject for an experimental procedure are expected to be high, an estimate of those costs should be given and insurance pre-authorization is highly recommended.]*

[Option 2: When some costs are part of regular treatment (standard of care) and will be billed to the research subject and some are for research purposes only and will be billed to the research study, use the following language:]

Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs.

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment.

*[Option 3: If there are no costs to the subject to participate in the study, use the following language*:]

There will be no cost to you or your insurance company to participate in this study.

*[Use this statement if applicable; elaborate if any resources are avialble to assist with these costs and any related process.]* There may be out-of- pocket expenses such as parking and transportation fees.

**WHAT OTHER CHOICES DO YOU HAVE IF YOU DON’T WANT TO PARTICIPATE? *[If this information is sufficiently covered in the Quick Summary it does not need to be repeated and this section can be removed. If more detail is needed use this section.]***

If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

* Getting no treatment
* Getting standard treatment for your condition without being in a study
* Getting a different experimental treatment/taking part in another study

*[Additional bullets should include, when appropriate, alternative specific procedures or treatments.]*

*[If no alternatives]* There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

**WHAT HAPPENS IF YOU WANT TO STOP TAKING PART IN THIS STUDY?**

*[Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject’s withdrawal from the study]*

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the study team immediately**. The study team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The study team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to *[complete this sentence].*

*[Include as Applicable to Inform Subjects of Their Rights Related to Data Retention. If not applicable, please remove.]*

*[When research is subject to the FDA (regardless of whether or not HIPAA applies]:*

If you choose to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

*[When research is subject to the HIPAA Privacy rule (AND not subject to FDA regulations]:*

If you choose to withdraw or are withdrawn from this research study, you may choose to end the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

*[When research is not subject to the FDA or HIPAA regulations]:*

If you choose to withdraw or are withdrawn from this research study, the researchers will discuss with you what they plan to do with your study data. Researchers may choose to include your study data already collected or they may choose to remove your data from the study data and destroy it, as per your request.

*[When private identifiable information or biospecimens are maintained for future research]* You are free to withdraw your consent to use your *[identifiable private information and/or biospecimen]* for future research at any time, but there are some limitations. If you withdraw your consent, the researchers will not use your *[identifiable private information and/or biospecimen]* in future research studies. Any of your information or biospecimens already being used in a research study before your request to withdraw will continue to be used for that study. Also, if *[identifiable private information and/or biospecimens]* have already been given to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

WHAT HAPPENS IF YOU ARE INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

**Emergency, Side Effects, Illness, or Questions About the Study**

If you need medical treatment, get treatment and inform the person treating you that you are in this research study, and then let your study team know. If you have any questions about the study, or need to talk to the study team, you may call:

Monday – Friday 8:00am – 4:30pm ***[Insert Department name and phone number]****.* You may leave a message with the secretary and the doctor will call you back.

Evenings, Weekends, & Holidays **CHOC Hospital 714-997-3000 or 800-992-2462 (CA only)**. Ask for the on-call physician for ***[Insert Department Name]***. You may be asked to leave a message with the page operator, and the physician on-call will return your call as soon as possible.

If you are injured as a result of being in this study, CHOC will provide necessary medical treatment. The costs of the treatment may be covered by CHOC or the study sponsor, [insert sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. CHOC and the study sponsor do not normally provide any other form of compensation for injury, such as loss wages, disability, or discomfort. For more information about this, you may call the Office of Research Compliance at (714) 509-8869 or by email at [ORC@choc.org](mailto:ORC@choc.org).

**HOW WILL INFORMATION ABOUT YOU AND YOUR PARTICIPATION BE KEPT?**

**Subject Identifiable Data**

*[Keep all statements that apply to this study and remove/revise as applicable]*

No identifiable information will be collected about you.

Identifiable information collected about you will be removed at the end of data collection.

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. *[Explain why personal identifiers will be retained.]*

Identifiable information collected about you will be kept with the research data. *[Explain why personal identifiers will be retained.]*

**Data Storage***[Describe the method(s) of data storage. Keep all statements that apply to this study and remove/revise as applicable]*

Research data will be kept in paper format in a secure location at CHOC Children’s. Only authorized individuals will have access to it.

Research data will be stored electronically on a CHOC Children’s approved laptop computer/device in an encrypted (protected) file *[and is password protected]*.

Research data will be stored electronically on a secure CHOC Children’s approved *[computer or network]* in an encrypted (protected) file *[with password protection]*.

The *[audio/video recordings]* that can identify you will also be stored in a secure location; then transcribed and erased as soon as possible.

The *[audio/video recordings]* will also be stored in a secure location; then transcribed and erased at the end of the study.

The *[audio/video recordings]* will also be stored in a secure location and transcribed. The recordings will be kept with the other research data.

**Data Retention***[Explain how long the research data will be maintained. Include only the longest period that applies and remove/revise as applicable]*

The researchers plan to keep the research data until analysis of the information is completed.

The researchers plan to keep the research data until the research is published and/or presented.

The researchers plan to keep the research data for approximately [\_] years.

The researchers plan to keep the research data indefinitely *[Note that HIPAA authorization expires after 50 years; therefore, only de-identified data may be retained after authorization expires]*.

The researchers plan to store your research data *[and/or biospecimens]* in a repository indefinitely. The researchers may continue to use and share your information *[and information obtained from analyses of your biospecimens]* indefinitely. [*Also, the use and sharing of your identifiable biospecimens will continue until the specimens are gone.]*

As this is an FDA regulated study, the researchers plan to keep the research data for 2 years after an approved marketing application. If approval is not received, the research data will be kept for 2 years after the investigation is discontinued and the FDA is notified.

The researchers plan to keep the research data for seven years after all children enrolled in the study reach the age of majority (age 18 in California).

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**

Information gathered about you while in this study will be kept confidential according to applicable laws and regulations by the study team, except that:

* The Sponsor of the study [*insert sponsor’s name*] and their representatives will receive information concerning the study and will have access to your medical records as they relate to this study.
* The Food and Drug Administration and possibly health authorities of other nations may require access to your medical records concerning this study.
* Certain agencies, either Federal or State may require your medical information concerning this study.
* Certain legal actions may require disclosure of your medical information.
* Your medical information may be released to the CHOC Institutional Review Board or its legally authorized representative.

While the study team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

***Future Research*** *[Required if the research involves collection of identifiable private information or identifiable biospecimens, choose one of the following statements and remove the other option.]*

*[Option 1]* Your *[information or biospecimen]* collected as part of this research will not be used or distributed for future research studies.

*[Option 2]* Your information *[and biospecimens]* may be used for future research still to be planned. Possible future research studies may include, for example:

*[Add information here about any applicable possible future research that may be conducted. Examples are provided below.]*

* *Studying the causes and progression of different diseases and conditions*
* *Whole genome sequencing (meaning that your entire personal genetic code will be identified)*
* *Research that creates cell lines by growing cells from your biospecimens in a laboratory – including cells that can be used to create different types of tissue*
* *Research about drug abuse and alcoholism diagnosis and treatment*
* *Research about mental health diagnosis and treatment*
* *Research about developmental disabilities*

You will not be informed about any of the specific research studies that might be conducted with your information *[and biospecimens]*. This means that your information *[and biospecimens]* could be used in research in which you might not have chosen to participate (i.e. without your additional consent). *[Choose one of the following statements and remove the other option.]*

*[When de-identified information or biospecimens will be shared]* Any information *[or biospecimens]* shared for future research will **not** include your name or other personal identifying information.

OR

*[When identifiable information or biospecimens may be shared]* The study team would like your permission to share your information *[or biospecimens]* for future research with your name or other personal identifying information included. Please initial your level of permission below:

\_\_\_\_\_\_ Yes, my private identifiable information *[and/or biospecimens]*, including my name or other identifying information may be used for future research.

If you say ‘yes,’ researchers may use your identifiable information *[or biospecimens]* in many different research studies, over a long period of time, without asking your permission again. The study team may share your identifiable information *[and biospecimens]* with other research, academic, *and [medical institutions]*; also, with other researchers, *[drug and device companies, and biotechnology companies]*.

\_\_\_\_\_\_ No, my information *[and/or biospecimens]* may be used for future research, but my name or other identifying information cannot be included without my explicit permission.

If you say ‘no,’ researchers who want to use your identifiable information *[or biospecimens]* will need to ask your permission on a study by study basis. However, researchers may still use your information *[or biospecimens]*, without your name or other personal identifying information, in many different research studies, over a long period of time, without asking your permission again. The study team may share your information *[and biospecimens]* with other research, academic, and *[medical institutions]*; also, with other researchers, *[drug and device companies, and biotechnology companies]*.

***ClinicalTrials.gov*** [*Per FDA, this language will be required for clinical trials approved by the IRB on or after March 7, 2012. Although the language is optional for new studies approved before that date, sponsor may request the language. This language must be included verbatim.*]ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on 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.

***Certificate of Confidentiality*** *[*[*For NIH funded research that started or is ongoing on or after 12-13-16, if research is biomedical, behavioral, or clinical in nature and collects identifiable, sensitive information (including biospecimens)*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)*. Also, for non-federally funded research, seeking a Certificate of Confidentiality. If not applicable, please remove]*

To help us protect your privacy, *[we have obtained / are in the process of obtaining]* a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[sponsor name]* which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

*[If not applicable, please remove]* The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, *[State here the conditions under which voluntary disclosure would be made (e.g., Examples: child abuse, elder abuse, domestic violence or sexual assault). If no voluntary disclosures will be made, the researchers should so state.].*

*[If not applicable, please remove. Required if the researchers intend to disclose information covered by a Certificate, with the consent of the research participant.]* The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research data in the medical record].*

**ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?** *[To be removed if not applicable]*

*[If the considerations listed below are not applicable, please remove this heading]*

**Use of Biospecimens***[Required if the study involves collection of specimens]*

*[If biospecimens will be discarded]*

Biospecimens (such as blood, tissue, or saliva) collected for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

*[If biospecimens and / or information derived therefrom will be collected from a research subject and used for research and / or development purposes]*

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

**Genetics***[Required if the study involves genetic testing or access to genetic information]*

*[Standard Template]* In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf> or CalGINA: <http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf>

*[Alternative language for research that involves individuals who have a diagnosis and/or are being treated for a genetic disease or disorder]* In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not prohibit discrimination on the basis of an already clear genetic disease or disorder.  This means if you have a diagnosis and/or are being treated for a genetic condition, a health insurer may use the information to determine eligibility or rates.  Also, GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf> or CalGINA: <http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf>

**Investigator Financial Conflict of Interest**

Your physician and others concerned with this study [will/will not] be reimbursed for their time and expense of doing this research.

*[More language may be required if there could be the appearance of a conflict of interest. If not applicable, please remove. If a study team member has a disclosable financial interest the CHOC Conflict of Interest Oversight Committee will develop specific language detailing the disclosable financial interest].*

**Future Contact***[Required if researchers intend to contact participants for future research. If not applicable, please remove.]*

The study team would like your permission to contact you for future research. Please initial your level of permission below:

\_\_\_\_\_\_ Yes, CHOC researchers may contact me in the future to ask me to take part in other research studies.

\_\_\_\_\_\_ No, CHOC researchers may **not** contact me in the future to ask me to take part in other research studies.

**Participant Rights**

You are agreeing to be in this research study by your own choice. You can decide not to be in the study at all or you can decide to stop being in the study even after the study has started. No matter what you decide you will still get your doctor’s care and won’t lose any other benefits you have now. You also won’t be giving up any of your legal rights by signing this consent form.

It is important that you understand the details about this study. If you have any questions that haven’t been answered, please be sure to ask the study team.

If you have any questions about your child’s rights as a participant in a research study, please contact the CHOC Institutional Review Board for the protection of research participants through:

Office of Research Compliance

(714) 509-8869

**This research project has been reviewed by an institutional review board for the protection of the rights of human participants in research projects, in accordance with federal regulations**.**

Children's Hospital of Orange County

INSTITUTIONAL REVIEW BOARD

**PEDIATRIC ASSENT FORM**

**NOTE:****A Pediatric Assent Form is necessary for patients 7-11 years of age.**

**Study Title:**

(Please ensure that this form is edited to be appropriate for the corresponding study and consent. If your study does not involve participants between the ages of 7-11 delete this page from the document.)

* I understand that I am being asked to be in this research study because the study team wants to learn more about a new *[medicine/treatment]* for my *[disease/illness]*.
* I understand that I will be given a medicine called *[Insert drug name and route of administration].* Side effects of the medicine might be *[Insert simplified list of side effects the child may experience].*
* I understand that if I have any of these or other side effects I should tell my parent(s) right away so they can tell my doctor.
* I understand that if the medicines make me sick, I may be given other medicines to help me feel better, but they may make me sleepy.
* I understand that I will have a small amount of blood drawn each time I visit the doctor.
* I understand that I will have x-rays taken. This is like having a picture taken.
* I understand that the researcher and his/her helpers will tell me what activities I can participate in during my treatment.
* I understand that I may change my mind about being in this study and that nobody will be angry with me.
* I understand that I can ask questions about what the study team is doing and things will be explained to me in a way that I will understand.
* I understand that the study team includes *[insert name(s) of designated contact(s)]* and I can call him/her/them at (###) ###-#### if I need to ask a question.

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

Signature of 7 to 11 Year Old Participant Date

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

Signature of Person Obtaining Consent Printed Name Date

(Principal or Co-Investigator)

the child is not capable of providing assent in the Investigator's opinion due to

altered mental status or physical incapacity, specifically:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**DO YOU AGREE TO PARTICIPATE IN THIS STUDY?**

**Signature and Consent**

My signature below indicates that I am the parent/legal guardian of this child, and that he/she is not a ward of the state or other agency, that I am the Legally Authorized Representative (LAR) for the participant, or that I am a participant legally able to consent for myself. I have read the above information about the study***, [Insert name of research study****]*. I have had a chance to ask questions to help me understand what will be expected in this study. I agree to be in the study and I have been told that I can change my mind later if I want to. I have been told that by signing this consent form I am not giving up any of my legal rights. I have been informed that I will be given a signed and dated copy of this agreement which includes the Human Research Participant’s Bill of Rights for my records.

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

Name of Participant (printed) Age

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Parent/Legal Guardian/Legally Authorized Representative (LAR) #1 Date

or Participant if 18 Years of Age or Older and able to sign

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Parent/Legal Guardian/ Relationship

Legally Authorized Representative (LAR) #1 if Participant is under 18 Years of Age or unable to sign

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Parent/Legal Guardian #2 Date

*[Required if study is greater than minimal risk with no potential for direct benefit - remove if not applicable]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Parent/Legal Guardian #2 Relationship

*[Required if study is greater than minimal risk with no potential for direct benefit - remove if not applicable]*

If permission is only obtained from one parent/legal guardian, the reason for not obtaining the permission of the other parent is:

the other parent is deceased

the other parent unknown

the other parent does not have decision making capacity

only one parent has legal responsibility for the care and custody of the child

the other parent is not reasonably available, i.e., the other parent is not contactable by phone, mail, email or fax or the other parent’s whereabouts are unknown. State reason and document any attempts to contact if applicable:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**Assent for Participants Ages 12 Through 17**  *[This section may be deleted if your study does not involve participants between the ages of 12-17]*

My signature below means that I have read the above information about the study, ***[Insert name of research study]***. I have had a chance to ask questions to help me understand what will be expected of me in this study. I agree to be in the study and I have been told that I can change my mind later if I want to. I have been told that by signing this consent form I am not giving up any of my legal rights. I have been informed that I will be given a signed and dated copy of this agreement and of the Human Research Participant’s Bill of Rights for my records.

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

Signature of Participant Date

***A witness signature is required only if: (Researchers: check all that apply)***

Consent is obtained from the subject using the Short Form process, as approved by the IRB.

The subject has decision-making capacity, but cannot read, write, talk or is blind.

The subject’s legal guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.

The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive

research procedures).

Note: The witness must be impartial (i.e. **not** a member of the participant’s family, **not** a member of the study team).

**For the witness/interpreter:**

I confirm that the information in this consent form was accurately explained to and apparently understood by the subject or legally authorized representative and that informed consent was given freely.

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

**Signature of Witness/Interpreter Date**

**(Record Interpreter Identification Number if phone/remote interpretation services used)**

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

**Printed Name of Witness/Interpreter**

**(If no witness signature is required, this witness signature section of the consent form may be left blank)**

**Investigator Signature**

My signature below means I have fully explained the research study described by this form. I have answered the participant’s and/or parent’s/guardian’s/Legally Authorized Representative’s questions and will answer any future questions to the best of my ability. I will tell the person(s) taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

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

Signature of Person Obtaining Consent Printed Name Date

(Principal or Co-Investigator)