**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**RADY CHILDREN’S HOSPITAL-SAN DIEGO**

**Consent to Participate in Research**

[Include the below note when the study will involve children or adults unable to consent for themselves. Otherwise delete.]

***Note:*** In this consent the word “you” refers to the person being considered for enrollment in the study described. This may be you as the reader of this document, a person for whom you are serving as the Legally Authorized Representative (LAR) or surrogate, or your child.

1. **Study Title and Number**

Title: [Insert title of study]

Study # [Insert study number from Kuali]

**2. Principal Investigator**

[Insert PI name, title, and department/institute/center]

**3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number**

[Insert PI phone number, research team phone number, and emergency contact number, if different]

**4. Study Sponsor**

[Insert name of study sponsor or remove if not applicable], the study sponsor, is paying UC San Diego [or name of institution conducting the research when UCSD serves as the IRB of record] to conduct this research study.

**5. Study Overview**

This research study is being conducted to [briefly describe in lay terminology the reason why the study is being conducted].

We are inviting you to participate in a research study because [briefly summarize the condition or circumstance that makes an individual eligible for the research. *Do not provide a list of inclusion/exclusion criteria*].

This form explains the research so that you may make an informed decision about participating.

* Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
* You can say yes, but change your mind later.
* If you say no, we will not hold your decision against you.
* You can say no even if the person inviting you is part of your healthcare team.
* Your decision will not affect your health care or other benefits you may be entitled to.
* Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
* You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
* You will be given a copy of this consent form and the Participant’s Bill of Rights.

The purpose of this research study is to [complete with brief statement, no more than 3 sentences. Secondary/exploratory objectives need not be included.].

*[Provide a brief summary of what participation involves. Include the* ***participant’s expected time commitment*,** e.g., “You will first undergo several procedures to determine if you are eligible for the study. If you are eligible, you will be assigned to receive the study drug or placebo (an inactive substance) over a period of about 6 months. During that time, you will visit our clinic weekly for physical examinations, blood tests and other procedures designed to monitor your safety and measure the effect of the study drug or placebo. Each visit will last up to 2 hours.”]

The most common risks or discomforts of this study are [finish sentence with 2 or 3 foreseeable risks/discomforts].

The most serious risks include [finish sentence with 2-3 serious risks and briefly characterize how rare or common these risks may be].

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

*[Insert either option A or B option]*

*[Option A. Use if there is possible direct benefit to participants - please note that compensation or reimbursement is not a benefit of participation. If you need to discuss benefits in additional detail, include an additional section later in the consent document.]* We cannot promise any benefit to you or to others from you participating in this research. However, possible benefits include [first describe all potential direct benefits to the participant, then describe any benefits to others or to society as a whole].

*[Option B. Use if there is no possible direct benefit to the participants]* There are no benefits to you from participating in this research. However, possible benefits to others include [describe any benefits to others or to society as a whole].

Other options instead of participation in this study are [finish sentence with all the alternatives to participation in the research (e.g., standard therapies, other research studies, observation or supportive care). This is the only section where alternatives will be listed. If the only alternative is to not participate, delete this sentence and state: The alternative to being in this study is not to participate.].

***More detailed information about this research study is provided below.***

**6. Whom can I talk to if I have questions?**

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

* UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

**7. How many people will take part?**

We plan to study [insert enrollment number for this site] people here. The research will include [insert enrollment across all sites, or delete this sentence if study is only taking place at UCSD] people across all locations.

**8. What happens if I take part in the research?**

Here is what will happen to you if you agree to be in this study:

*[Include these sentences for studies with an intervention:]* Throughout this form the words, “drug” and “treatment” are used, often these terms refer to experimental drugs and treatments. *[If the project involves an experimental product 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.* ***NOTE:*** *throughout this document the term “study drug” should be used to refer to the active compound being tested, not the placebo. Similarly, the term “study device” should only be used to refer to the device(s) being tested.]*

*Examples– [remove/revise as applicable]:*

*[Insert name here]* is an investigational drug that has not yet been approved by the Food and Drug Administration (FDA). The safety of *[Insert name here]* is being tested at different dose levels.

*[Insert name here]* is an investigational device that has not yet been approved by the Food and Drug Administration (FDA). The safety and effectiveness of the device is being tested

*[Insert Drug X name here]* is an investigational drug that has not yet been approved by the Food and Drug Administration (FDA). It is being compared to a standard drug, *[Insert Drug Y name here]* that has already been approved by the FDA. The researchers are interested in learning which drug is more helpful in treating your condition or disorder.

*[Always include:]* As you read this form, ask questions if something is not clear.

*[Using simple terms and from the participant’s perspective, explain what the participant will do in the study. Address the following points as appropriate. Include charts or timelines if helpful.]*

* visit schedule, duration and location
* describe each procedure and its frequency
* for blood draws, describe how, how often, and how much blood will be collected for the study overall and at each visit
* what information they will be asked to provide
* any tasks to be done between visits (e.g., participant diaries)
* any long-term follow-up procedures
* if any procedures are experimental or unproven and what is experimental about the study (e.g. taking the study drug/placebo, performing procedures in a new order, receiving instruction in a different manner, etc.)
* the difference between procedures that would take place anyway for medical reasons and the procedures that are being done just for research
* if the research will dictate whether or how a drug/device/biologic product will be administered]

*[For randomized studies, include the following paragraphs, otherwise delete]*

You will be “randomized” into one of [insert number of arms] study groups described below.

*[Be sure to insert description of each group.]*

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a [insert probability] chance of being placed in a specific group.

*[Include the following if the study is double-blinded]*

Neither you nor the researchers will know which group you are in.

*[Include the following if the study involves a placebo arm]*

In this study you might receive a placebo. A placebo is a *[pill, solution, cream, liquid, etc.]* that looks like the study drug but has no real medicine in it. A placebo is often used in research studies so that the doctor and you do not know your study group. The study is done this way because knowing whether you are getting the study drug or placebo can change the results of the study. In case of an emergency, we can find out if you are getting the placebo or the medication.

*[Include the following if the study involves a washout period]*

During this study the medication you normally use for your condition [will/may] be stopped for up to *[insert timeframe (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 *[insert information about symptoms the subject may experience (i.e. for schizophrenia: agitation, hallucinations; for hypertension: high blood pressure, nausea, lightheadedness, etc.)]*.

*[Include the following if the study involves a MRI]*

MRI machines use a strong magnet to make pictures of the inside of your body. During the scanning, you will lie on a long narrow couch for *[insert amount of time]* while the machine gathers data. You will not feel anything while the data is being collected. You will also hear tapping noises that are from the MRI scanner.

Since the MRI scanner is a magnet, metal objects will be attracted to the scanner. It is very important that you tell the researcher about any metal objects, devices or implants that are in or on your body before you enter the scanner room. All metal objects must be removed before entering the magnet room. In some cases, having those devices may mean that you should not have an MRI scan.

*[Include the following if the study requires Birth Control to be used. This may apply to subjects able to cause a pregnancy as well as those able to become pregnant. Depending on the age of minors to be enrolled, this information may also be added to the assent form. There are studies where hormonal methods are not appropriate because of the potential interaction with the study drug or decreased effectiveness when used in conjunction with the study drug. In this case, the consent form should clearly state that hormonal methods are not considered an acceptable method of birth control while on the study. Likewise, if one or more of the methods listed are not appropriate for a particular protocol, the section below should be amended appropriately. The following section may be used as is or amended as appropriate]*

The drugs in this study may affect a baby, before or after the baby is born. As a result, those able to become pregnant should not be in this study if they are:

* pregnant,
* breast-feeding, or
* trying to become pregnant.

If you are able to become pregnant, you should use birth control for the entire time you are in the study and for *[insert duration]* months afterwards. *[Review the contraceptive methods against the protocol to make sure that they are consistent. Include only allowable contraceptive methods:]* Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

If you are able to cause a pregnancy, you should not have unprotected sex with someone who is able to become pregnant while on this study. If your partner(s) is/are able to become pregnant, you and your partner(s) should use birth control for the entire time you are in the study and for *[insert duration]* months afterwards. *[Review the contraceptive methods against the protocol to make sure that they are consistent. Include only allowable contraceptive methods:]* Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

If you become pregnant or think you might be pregnant during study treatment or within *[include the timeframe]* after completing study treatment, you must inform the Study Doctor immediately. *[Include if appropriate and add details about the type of follow-up:]* Your Study Doctor will want to follow the pregnancy and collect information about the outcome of the pregnancy.

*[Include as appropriate:]* You should not donate sperm/eggs during study treatment or within *[include the timeframe]* after completing study treatment.

*[For research involving biospecimens that will or might be used for whole genome sequencing, provide a lay explanation of genome sequencing and DNA.]*

This research [will/could] involve studying your biology and the likelihood that a particular biological feature (including genes) may increase the chance of developing a disease. Genes are pieces of DNA, or deoxyribonucleic acid that give instructions for building the proteins that make our bodies work. These instructions are stored in the form of a code. You inherit this code from your parents. We [will/might] use your specimens for whole genome testing. This means making a list of the entire order, or sequence, of your DNA.

**9. What are the risks and possible discomforts?**

Participation in this study may involve risks or discomforts. [Describe all risks and discomforts, using simple terms and from the participant’s perspective, associated with participation:]

* Consider the risks of each procedure
* Consider physical, psychological, privacy, legal, social and economic risks
* Indicate the likelihood and severity of potential risks
* Include only the risks of the research procedures. Do NOT include risks of procedures (except those that produce radiation) that would be done (and done the same way) even without the research.
* If the research increases (either in severity or likelihood) an already present risk to the subject that they would encounter without the research, explain how this risk is changed by the research

*[Include these sentences for studies with an intervention:]* We will closely monitor you during the study and will treat any discomforts or side effects that you have the best we can. If your side effects are severe we may [finish sentence e.g., lower your dose or stop giving you the study drug or placebo].

*[If Applicable:]* ***Risks of Radiation Exposure:***

During your participation in this research study, you will be exposed to radiation from scheduled imaging scans. The total exposure resulting from these imaging studies is calculated to be approximately [fill in with appropriate amount of exposure] millisieverts (mSv). This amount is [more/less/equal—choose one] than you would receive from one year of natural exposure in the San Diego area, which is approximately 1.6 mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future.

The principal investigator for this research study has determined and verified that [all/most/some/none—choose one] of the imaging scans prescribed for this study would typically be performed as part of the standard medical care required to adequately monitor your current illness. [Investigator may be specific here by listing the scans that are considered standard of care if applicable or deemed to be useful information for the research participant. In addition, non-radiation producing imaging alternatives would be included here if described in the Research Plan.] If you are especially concerned about radiation exposure, or you have had many x-rays and/or imaging scans already, you should discuss this with the study doctor or your regular doctor.

*[If Applicable:]* ***Risks of Genetic Testing:*** Federal and State laws generally protect your genetic information in the following ways: a) Health insurance companies and group health plans may not request your genetic information from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

We will minimize the possibility of results from this research being linked to you, but there is always the remote possibility that information from the research may be disclosed. If your genetic risk for certain diseases is accidently divulged to the wrong source, you might be discriminated against in obtaining life or health insurance, or employment.

*[If Applicable:]* ***Risks of Genetic Testing with Family Members:*** Because we are testing family members we may detect instances of nonpaternity or adoption. If you wish, you may let us know in confidence if this is a possibility. In all cases, this information will be kept in the strictest confidence and will not be told to anyone.

*[If Applicable:]* ***Risks of Magnetic Resonance Imaging (MRI) Studies:*** The magnetic resonance imaging (MRI) machine is a powerful magnet. This magnet may cause any metal in your body to move. If you know of any metal in your body, you will need to tell the researcher right away. Otherwise, there are no known risks of MRI. Some people with claustrophobia (fear of closed spaces) may find the MRI scanner too confining. In that case, you can ask to be removed from the scanner and this will be done immediately. The MRI scanner makes a loud beeping sound. We may ask you to wear protective earplugs during scanning.

*[If contrast is used include:]* The dye that is injected *[location of dye injected]* for the scan may make you feel dizzy, queasy or get a headache with it or notice a cold feeling near the injection site. There is a rare chance of having an allergic reaction to the dye that very rarely can be serious and life threatening.

*[If Applicable:]* ***Risks of Loss of Confidential Information:*** There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will *[describe steps being taken to protect subjects’ confidentiality e.g.* “use a code on any specimens and/or information we collect and we will keep a link between the code and your identity in a different location.”*]*

*[If Applicable:]* ***Risks Associated with Reproduction, Pregnancy:***  Procedures involved in this research might be dangerous for pregnant individuals and/or fetuses. [describe the dangers]. You should not become pregnant or cause a pregnancy while in this research. Methods of birth control [allowed/required] for this study are described in Section 8 above. If you are breastfeeding, you should not breastfeed a baby while taking part in the study as the [e.g., study drug] could harm the baby.

*[Add the following two paragraphs if pregnancy testing will be performed on minors enrolled in this research:]* After your child has been enrolled in this study and during the research, pregnancy testing will be performed. The results of minor pregnancy tests are confidential according to California Minor Consent Laws. Results will be given to your child by one of the study nurses or doctors in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Our policy is that we would not tell parent(s) or guardian(s) without your child's permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your child's life or someone else's life is at risk or if abuse is suspected, it may be necessary to inform you as parent(s) or guardian(s) of a positive pregnancy test. If we believe it's necessary to tell a parent or guardian of a positive pregnancy test without your child's permission, we will meet with your child first in private to discuss our concerns before divulging any information regarding pregnancy.

During research, if your child has a positive pregnancy test, we may withdraw your child from the study. This means that even if we do not reveal the results, you may suspect that your child is pregnant despite our best efforts to maintain confidentiality. If your child becomes pregnant or if there is any chance that your child is pregnant (late menstrual period), please contact the study personnel immediately so that we may provide medical assistance and counseling.

*[If Applicable:]* ***Risks of Collection of Sensitive Information:*** Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study

*[If Applicable:]* ***Risks of Interviews/Questionnaires/Quality of Life Assessments that Discuss Sensitive Issues:*** Some of these questions may seem very personal or embarrassing. They may upset you. You may skip any question that you do not want to answer. If the questions make you very upset, we will help you to find a counselor, refer you to an appropriate clinic for follow up, or you can contact [insert contact information for service appropriate to the study subject matter].

*[If Applicable:]* ***Risks of Incidental Findings:*** Although the testing you will have in this study is being undertaken for research purposes only and should not be considered a substitute for normal medical care, it is possible that the doctors may notice something that may be serious or could affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

***Possible Unknown Risks:*** In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any new findings that might affect your health or welfare, or might affect your willingness to continue in the research.

**10. How will information about me be protected?**

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

* Members of the research team and other staff or representatives of UCSD or Rady Children’s Hospital-San Diego (Rady Children’s) whose work is related to the research or to protecting your rights and safety.
* Representatives of the study sponsor or product manufacturer
* Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected. [If applicable, The Food and Drug Administration (FDA) may inspect research records and learn your identity.].

*[Insert any additional methods that will be used to protect the confidentiality of the study data. Example:* Study information will be labeled with a code instead of your name or other information that can easily identify you. The record linking your identifying information (name, address, etc.) and the code will be kept separate from the rest of the study information.*]*

*[If the study involves pharmacy, laboratory or medical procedures insert either option A (for studies without collection of sensitive information) or option B (for studies with sensitive information). Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]*

*[Option A:* This consent form, the separate authorization form described below, and some details of your study participation will be noted in your UC San Diego Health or Rady Children’s Hospital San Diego (Rady Children’s) record. If you do not currently have a UC San Diego Health or Rady Children’s record, one will be developed for you. People involved with your medical care and insurance at UC San Diego, Rady Children’s, or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health or Rady Children’s record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.*]*

*[Option B if the study involves sensitive information:* This consent form, the separate authorization form described below, and some details of your study participation will be noted in your UC San Diego Health or Rady Children’s Hospital-San Diego (Rady Children’s) record. If you do not currently have a UC San Diego Health or Rady Children’s record, one will be developed for you. People involved with your medical care and insurance may become aware of these details. UC San Diego and Rady Children’s also participate in Health Information Exchange (HIE) with multiple other health systems. Sharing your electronic Health Record (EHR) with other health systems is only allowed when they are involved in your medical care. Study details included in your EHR would also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their EHR. During this study, you may not be able to access certain information related to this study in your UC San Diego Health or Rady Children’s record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.*]*

*[Always Include:]* The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study will be completed in \_\_\_\_\_ [weeks/months/years]. This is only an estimate and the actual time to complete the study may be longer or shorter depending on a number of factors.

*[Insert if the study will access, use, or disclose Protected Health Information. Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]*

You will be asked to sign separate Rady Children’s Hospital-San Diego and University of California San Diego Permission to Use Protected Health Information for Research form to use and disclose (share) your health information that identifies you for the purposes of this research study and [insert additional uses of information] (see the separate authorization form for more information). Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

*[Insert if the study receives any funding from the NIH, CDC or if the PI secures a CoC]*

*[Your specimens and]* Information about you *[is/are]* protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release *[your specimens or]* information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use *[your specimens and]* information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect *[specimens and]* information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

* You or your family voluntarily release information about yourselves.
* You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
* *[If research is federally funded:]* A federal agency audits or evaluates research that it funds.
* [Researchers [intend/are required] to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases*.]*
* *[If research is FDA regulated:]* The Food & Drug Administration requires information as part of overseeing drugs, devices or other products.

*[If possible legal issues will limit confidentiality, describe what information will be disclosed and to whom. For example, if the research team is likely to uncover child (those under 18 years old) abuse, elder abuse (those 60 years old or older), or infectious diseases that are reportable under local laws. Remove the below language and insert site-specific language when this document is adapted for sites outside California.]*

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. In addition, if researchers are made aware that a subject has certain communicable diseases including sexually transmitted diseases/infections (STDs/STIs), hepatitis, and HIV, this must be reported. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

*[If the study includes investigator(s) who is not/are not a “mandated reporter” of child (less than 18 years old) or elder (60 years old or greater) abuse, please use the following:]*

We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities.

*[If the study involves taking photographs of the subjects, include the following:]*

As a part of this study, photographs will be taken of your face and/or parts of your body. These photographs will be subject to the same confidentiality conditions described above. Even so, someone who knows you well, may be able to identify you from the photos and know you are participating in this study. To minimize this risk, we will take the following precautions: *[include any steps that will be taken to minimize a subject’s identity becoming known (e.g. photos will not be used in publications, eyes will be blurred in face photos, unique markings/tattoos will be covered/removed, photos will only be of small sections of interest, etc.)****PLEASE NOTE: When photographs will be taken for research purposes RCHSD policy CPM 11-79 also requires that the “Authorization for Use, Disclosure or Publication of Photographs” be obtained by the researcher and signed by the parent or legal guardian before photos are taken.****]*.

**11. Will I need to pay to participate in the research?**

*[If the study does not involve billable events, please use this paragraph. Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]* There will be no cost to you for participating in this study. *[However, if there are costs associated to participation, these should be stated (i.e., parking, meals, as well as costs associated with drug/device/procedure) and that the participant or the participant’s insurer will be responsible for the cost, as appropriate.].* You and/or your health plan/insurance company will need to pay for all costs of [As appropriate, add: “caring for” Or “preventing” Or “treating”] your condition while in this study.

*[If this study involves billable events, please use the following two paragraphs. Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]*

The [study drug or placebo/device/procedure] will be supplied at no cost while you take part in this study. The cost of getting the [study drug or placebo/device/procedure] ready and giving it to you [As appropriate, add: “…is also provided at no cost.” Or “…is not paid by the study sponsor so you or your health plan/insurance company may have to pay for this.”]It is possible that the [study drug/device/procedure] may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of [As appropriate, add: “caring for” Or “preventing” Or “treating”] your condition while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance company to find out exactly what they will pay for. Examples of procedures and drugs that may be billed include the following: [provide a list, as appropriate, and include costly approved drugs that will not be provided by the sponsor].

**12. What if I agree to participate, but change my mind later?**

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health or Rady Children’s or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.

*[Include the following if you will ask participants to undergo any termination procedures, otherwise delete.]* If you stop early, please contact us immediately. We will ask you to [describe procedures/schedule and the reason].

*[If the research is a clinical trial, include the following.]* If you stop participating, we may not be able to remove the information we have already collected about you or specimens we have already collected from you.

*[Include the following if you plan to continue collecting new data about participants after they withdraw, for example by accessing their health records even after they withdraw from the interventional portion of a clinical trial.]* If you stop participating, we will ask you for permission to [describe the data collection methods (e.g., data from your routine medical care)].

*[Include for research where this is a possibility.]* We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

*[If you might terminate a participant’s study participation early, include the following.]* In addition, the study doctor or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This could happen because [give simple examples. e.g., it is in your best medical interest, you do not follow the instructions given you by the study personnel].

*[If subjects can request the destruction of already collected specimens, include the following.]*

If you decide later that you do not want the specimens collected from you to be used for future research, you may tell this to [insert who subjects should contact], who will use their best efforts to stop any additional studies. [Pick most applicable option. Option 1) However, in some cases, such as if your specimens have already been tested, the data from these tests are no longer linked to your identity and cannot be removed from the research database. Option 2) However, in some cases, such as if your specimens are found to be generally useful, it may be impossible to locate and stop such future research once the materials have been widely shared with other researchers.]

**13. What will happen to information and/or biospecimens collected from me?**

The *[choose as appropriate:* data and/or specimens*]* we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your *[choose as appropriate:* data and/or specimens*]* in other research. *[Include if applicable:]* In addition, data that have been de-identified will be uploaded to *[name of repository]* for other researchers to access and use.

*[If biospecimens (even if identifiers are removed) may be collected, use the following Moore clause.]*

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.

*[If the protocol involves genetic information that will be deposited in NIH-supported repositories the following three paragraphs must be included.]*

Information from analyses of your biospecimens and your information will be put into one of the National Institutes of Health (NIH) databases along with information from the other study participants and will be used for future research. While these databases will be accessible by the Internet, only anonymous information from the analyses will be put in a public database. Common identifying information about you, such as your name, address, telephone number, or Social Security number, will not be placed in the public database.

While the public database will not contain information traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic information in these databases back to you. For example, someone could compare information in a database with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic information to you.

While your privacy and confidentiality are very important to us and we will use safety measures to protect it, we cannot guarantee that your identity will never become known.

**14. What are my responsibilities if I take part in this research?**

[Include if this is a clinical trial. Otherwise, delete this section.]

If you take part in this research, you will be responsible for: [Describe any responsibilities of the subject. E.g. taking the study medication every day, coming in for study visits as described above, completing your study diary every day, etc.]

**15. Will I be compensated for participating in the research?**

*[Include if participants will be compensated or reimbursed.]* If you agree to take part in this research, we will provide you [describe compensation and/or reimbursement] for your time and effort. [Explain how payment is established. This amount must be prorated. Be specific. Describe circumstances under which a subject may not receive payment (e.g. not showing up for an appointment)] *[If reimbursement will be provided]* You will be reimbursed for the following expenses that you incur [complete this sentence – *e.g., parking fees, transportation fees, meals.]*

*[If subjects will receive payment/reimbursement by check]* Your name and Social Security number will be collected and released to the UC San Diego Office of Accounting or Rady Children’s to process the [payment/reimbursement] check.

*[If subjects will receive payments in excess of $600 per calendar year. Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]* If you receive compensation in excess of $600 per calendar year, your name and Social Security number will be collected and released to the UC San Diego Office of Accounting or Rady Children’s Hospital Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax-reporting purposes.

*[If subjects will not be compensated or reimbursed]* We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

**16. What else is important for me to know?**

*[Include a statement whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions the results will be provided to participants. This section is meant to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results. If no results will be provided to subjects (aggregate or individual), state so.]* *Example:* You [will/will not] be provided any clinically relevant information that may pertain to your health. You [will/will not] be provided a summary of the research findings. [Describe what results (if any) will be provided to subjects and when].

*[If the study involves greater than minimal risk, choose option A or Option B below. Remove the below language and insert site-specific language when this document is adapted for sites outside UCSD/RCHSD.]*

*[Option A: If this is an industry-sponsored study, please use the following:]*

If you are injured as a result of being in this study, UC San Diego or Rady Children’s will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or Rady Children’s or the study sponsor [insert name *– if federally funded, do not mention the name of the sponsor*], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University, Rady Children’s, and the sponsor do not normally provide any other form of compensation for injury. For more information about this, you may contact the UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

If you receive Medicare benefits, the sponsor, [insert Sponsor name] is required by law to report payments made to you for treatment, complications, and injuries that arise from this study. Information will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose. UC San Diego or Rady Children’s will provide the Sponsor with your name, date of event and health identification number (if not available, then Social Security number) only for Medicare beneficiaries that have had a study-related injury for which the sponsor has issued reimbursement to the University.

*[Option B: If this a grant-sponsored or PI-initiated study, please use the following:]*

If you are injured as a direct result of participation in this research, the University of California or Rady Children’s will provide any medical care you need to treat those injuries. The University and Rady Children’s will not provide any other form of compensation to you if you are injured. You may call the Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

*[If applicable, include a statement about Investigator Financial Conflict of Interest as designated by the COI Committee]*

*[If research is a clinical trial/research]* A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

**17. What are my rights when providing electronic consent?**

*[Include the below language when the consent documentation will be conducted electronically (e.g. via DocuSign or an equivalent system). If the consent documentation will not be conducted electronically, delete this section. Remove the below language and insert site-specific language when this document is adapted for sites outside California.]*

California law provides specific rights when you are asked to provide electronic consent:

* You have the right to obtain a copy of the consent document in a non-electronic format.
* You have the right to provide consent in a non-electronic format.
* If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes.  If you wish to withdraw your electronic consent please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

**18. Additional Choices to Consider**

*[If any specific procedures are optional (i.e., participants can still take part in the research even if they do not agree to the optional procedure), add the following to document their choice. Copy and repeat the text below for each separate optional procedure if subjects can choose to participate in some optional procedures without participating in* ***all*** *optional procedures.]*

In Section [X], we described some extra procedures [briefly summarize extra procedures]. These extra procedures are optional, meaning that you can participate in the study even if you refuse the procedures. Please indicate your choice by initialing the appropriate line below:

\_\_\_\_\_\_\_\_\_\_I AGREE to participate in these optional procedures.

\_\_\_\_\_\_\_\_\_\_I DO NOT AGREE to participate in these optional procedures.

*[If you will offer the option to receive general results of the research and/or any relevant individual results, please describe here and provide participants with option to document their choice.]*

We would like to offer the opportunity to receive general results of the research [and relevant individual results]. You may also change your mind about this choice. Please initial your choice below:

\_\_\_\_\_\_\_\_\_\_YES, send me a summary of the research results [and my individual results].

\_\_\_\_\_\_\_\_\_\_NO, do NOT send a summary of the research results [or my individual results].

*[If you would like to use the study population to recruit for future studies, include the following choice:]*

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

\_\_\_\_\_\_\_\_\_\_YES, you may contact me

\_\_\_\_\_\_\_\_\_\_NO, you may NOT contact me

*[Delete if there will be no adults who can consent for themselves]*

**Signature Block for Adults Able to Provide Consent**

|  |
| --- |
| **Participant** |
| *I have received a copy of this consent document and a copy of the “Experimental Participant's Bill of Rights” to keep. I agree to participate in the research described in this form.**[Add the two paragraphs below for research that collects human fetal tissue from elective abortions:]**Informed consent for donation of Human Fetal Tissue was obtained by someone other than the person who obtained the informed consent for my abortion, occurred after the informed consent for my abortion, and will not affect the method of my abortion.**Lastly, no enticements, benefits, or financial incentives were used at any level of the process to incentivize my abortion or the donation of Human Fetal Tissue.*Printed Name of ParticipantSignature of Participant Date |
| **Person Obtaining Consent** |
| *I document that:** *I (or another member of the research team) have fully explained this research to the participant.*
* *I have personally evaluated the participant’s understanding of the research and obtained their voluntary agreement.*

*[Add the below bullet points for research that collects human fetal tissue from elective abortions:]** I was not the individual who obtained informed consent for the participant’s abortion.
* I conducted the informed consent process after the informed consent for the participant’s abortion.
* This informed consent will not affect the method of the participant’s abortion.
* No enticements, benefits, or financial incentives were used at any level of the process to incentivize the participant’s abortion or the donation of Human Fetal Tissue.

Printed Name of Person Obtaining ConsentSignature of Person DateObtaining Consent |
| **Witness (if applicable)** |
| *I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.**[Add the two paragraphs below for research that collects human fetal tissue from elective abortions:]**I document that informed consent for donation of Human Fetal Tissue was obtained by someone other than the person who obtained the informed consent for the abortive procedure, occurred after the informed consent for the abortion, and will not affect the method of the participant’s abortion.**Lastly, no enticements, benefits, or financial incentives were used at any level of the process to incentivize the participant’s abortion or the donation of Human Fetal Tissue.*Printed Name of WitnessSignature of Witness Date |

*[Delete if there will be no adults who are unable to provide consent]*

**Signature Block for Adults Unable to Provide Consent**

|  |
| --- |
| **Participant** |
| *I have received a copy of this consent document and a copy of the “Experimental Participant's Bill of Rights” to keep. I give my permission for the named person below to participate in the research described in this form.*Printed Name of ParticipantPrinted Name of Legally Authorized RepresentativeSignature of Legally Authorized Representative Date |
| **Person Obtaining Consent** |
| *I document that:** *I (or another member of the research team) have fully explained this research to the legally authorized representative of the participant.*
* *I have personally evaluated the legally authorized representative’s understanding of the research and obtained their voluntary agreement.*
* *I have personally evaluated the participant’s understanding of the research and, if capable of providing their assent, obtained their assent to participate in the research as indicated below.*

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

Printed Name of Person Obtaining ConsentSignature of Person Obtaining Consent Date |
| **Witness (if applicable)** |
| *I document that the information in this form (and any other written information) was accurately explained to the legally authorized representative. The legally authorized representative appears to have understood and freely given consent for the participant to join the research.*Printed Name of WitnessSignature of Witness Date |

*[Delete if the study will not involve children]*

**Signature Block for Parent(s)/Guardian(s) of Child Participants**

|  |
| --- |
| **Participant** |
| *I have received a copy of this consent document and a copy of the “Experimental Participant's Bill of Rights” to keep. I give my permission for the named child below to participate in the research described in this form.*Printed Name of ParticipantPrinted Name of Parent/GuardianSignature of Parent/Guardian DateThe person providing the signature above is: (Choose One) * Parent
* Individual legally authorized to consent to the child’s general medical care (See below note)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.Printed Name of Second ParentSignature of Second Parent DateIf signature of second parent not obtained, indicate why: (Choose One)* The IRB determined that the permission of one parent is sufficient *[Delete if the IRB did not make this determination]*
* Second parent is deceased
* Second parent is unknown
* Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |
| **Person Obtaining Consent** |
| *I document that:** *I (or another member of the research team) have fully explained this research to the parent(s)/guardian(s) of the participant.*
* *I have personally evaluated the parent’s/guardian’s understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining ConsentSignature of Person Obtaining Consent Date |
| **Witness (if applicable)** |
| *I document that the information in this form (and any other written information) was accurately explained to the parent(s)/guardian(s). The parent(s)/guardian(s) appears to have understood and freely given consent for the participant to join the research.*Printed Name of WitnessSignature of Witness Date |

**Experimental Participant's Bill of Rights**

**Every individual asked to participate in a research study has the right to be:**

1. Informed about the nature and purpose of the study.
2. Provided an explanation of 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. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.
5. Informed about 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. Told of the types of medical treatment, if any, available if complications should arise.
7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.
9. Provided a copy of the signed and dated written consent form and a copy of this form.
10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

* UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777