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

**and UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**Assent to Participate in Research (Ages 13-17 years)**

[Please note, the adolescent assent form should be an explanation of the research procedures in a language and length that is appropriate to the child’s age, experience, maturity, and condition. Although the format is similar to the consent form for the parent, this assent form should be further simplified and defined accordingly. It is suggested that the adolescent assent form be written at the sixth-grade reading level.]

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**

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, no more than 1 sentence. *Do not provide a list of inclusion/exclusion criteria*]. The purpose of this research study is to [complete with brief statement, no more than 2 sentences. Secondary/exploratory objectives need not be included.].

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

* Research is voluntary- whether or not you join is your decision. You can discuss your decision with others (such as family, friends or another physician [“physician” can be deleted if not medical study]).
* You can say yes but change your mind later.
* If you say no, we will not hold your decision against you.
* Your decision will not affect your health care [may replace “health care” with “relationship with UC San Diego and Rady Children’s Hospital San Diego” if not relevant to type of research or relationship between subject and UC San Diego or Rady Children’s Hospital San Diego] or any other benefits you may be entitled to.
* You can say no even if the person inviting you is part of your healthcare team [may delete or replace “healthcare team” with other types of relationships (e.g., your course instructor) as warranted by specifics of the study].
* Please ask the principal investigator 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 will be given a copy of this assent form.

*[Provide a brief summary of what participation involves. Include the* ***participant’s expected time commitment*,** e.g., “You will first have some test and exams to determine if you are eligible for the study. If you are eligible, you will be given the study drug or placebo (an inactive substance) over a period of about 6 months. During that time, you will come into the clinic weekly to have tests 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 and 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 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](mailto: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 one institution] people across all locations.

**8. What happens if I take part in the research? [This description should be a *simplified* version of the information given in the Adult/Parent consent.]**

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

*[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 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.

*[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 effects of the study *[treatment/device]* and procedures may have some risks that we can’t predict or don’t yet know about on the reproductive system (sperm, eggs) or to a developing fetus. For this reason, participants in this study should not become pregnant or cause a pregnancy, and we require that all participants agree to either abstain from sexual intercourse or use reliable, effective contraception during *[and for a little while after, if applicable]* study treatment.

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.

After you are enrolled in this study and during the research, pregnancy testing will be performed. The results of the pregnancy test are confidential and will be told to you 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 your parent(s) or guardian(s) without your permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to inform your parent(s) or guardian(s) of a positive pregnancy test. If we believe it's necessary to tell your parent or guardian of a positive pregnancy test without your permission, we would meet with you first in private to discuss our concerns prior to divulging any information regarding pregnancy.

During the research, if you do have a positive pregnancy test, we may withdraw you from the study. This means that even if we do not reveal the results, your parent(s) or guardian(s), may suspect that you are pregnant despite our best efforts to maintain confidentiality. If you become pregnant or if there is any chance that you might be pregnant (late menstrual period, broken condom, missed oral contraceptive pills, etc.) please contact the study personnel immediately so that we may provide medical assistance and counseling. The phone call will be strictly confidential, and we will not notify your parent(s) or guardian(s) without your permission.

*[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 principal investigator 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 Magnetic Resonance Imaging (MRI) Studies:*** The magnetic resonance imaging (MRI) machine is a powerful magnet. This magnet may cause any metal on or in your body, or in the room with you, to move. 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. 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.

*[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].

***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 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.*]*

*[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 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.

*[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 researcher has or is given such information, they may be required to report it 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 researcher has or is given such information, they may have to report it 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.)]*.

**11. Will I have 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.].* Your parents or guardians 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.

**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, Rady Children’s Hospital San Diego, or any services you receive from them. No matter what you decide, there will be no penalty to you.

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

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

*[If you might terminate a participant’s study participation early, include the following.]* In addition, the principal investigator 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].

**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 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.

**15. Will I be paid 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]*

*[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.

1. **Will you receive any results from participating in this study?**

[Provide a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions the results will be provided to subjects]

**17. What if I am injured as a direct result of being in this study?** [Include this section only for greater than minimal risk studies. Otherwise delete.]

If you are injured or become ill as a direct result of this research study, you will be provided with medical care.

**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.]*

[If assent process will be oral or signature waived, this page can be deleted]

###### Your Signature and Assent

You have received a copy of this assent document [insert when the study meets the California definition of a medical experiment: and a copy of the “Experimental Subject's Bill of Rights”] to keep.

You agree to participate.

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

Subject’s signature Date

###### Signature Of Person Obtaining Assent

In my judgment, the participant is voluntarily and knowingly giving assent and possesses the legal capacity to give assent to participate in the study.

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

Signature of person obtaining assent Date

[Include this page only if the study meets the California Definition of a Medical Experiment]

**Experimental Subject'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](mailto:irb@ucsd.edu) or 858-246-4777