UNIVERSITY OF CALIFORNIA, DAVIS
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Investigator's Name: Marjorie Solomon, Ph.D.
Department: Psychiatry and Behavioral Sciences

STUDY TITLE:
Specifying and Treating the Anxiety Phenotype in Autism Spectrum Disorder (STAAR)

INTRODUCTION

This is a research study conducted by Marjorie Solomon, Ph.D. from the Department of Psychiatry and Behavioral Sciences. Research studies only include subjects who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is to make you better informed so that you may give or withhold your consent to participate in this research study.

You are being asked to take part in this study as part of a clinical trial of anxiety treatments in autism spectrum disorder (ASD). We hope to learn more about anxiety as it uniquely manifests in ASD and determine how best to alleviate anxiety in children with autism. In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

Forty to eighty percent of children and preadolescents with autism spectrum disorder exhibit clinically significant anxiety symptoms, which are associated with increased social deficits, depression, irritability, and stereotyped and self-injurious behaviors. While it is clear that anxiety symptoms represent a substantial problem for those with ASD, important issues that could inform treatment remain unresolved. The investigators seek to better characterize anxiety in autism and determine whether therapy or medication can better alleviate symptoms of anxiety and/or autism.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 132 people will take part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you decide to participate in this study, you will be asked to do the following:

A study coordinator will explain your child's Bill of Rights as research participants and will thoroughly inform you about the study. Once you have agreed to participate in the study with your child you will sign this consent form. You and your child will meet with MIND Institute clinicians for the screening and baseline study assessments. This may include cognitive, anxiety, and safety testing, as well as an MRI and eye tracking to determine your child's eligibility for the study. The safety testing will consist of a medical history, review of systems, vitals, blood and/or urine sampling, and for some children an electrocardiogram (ECG). You and your child will also be asked to fill out a set of questionnaires about your child and will be asked to provide some demographic information about your child and his/her family. If your child meets study criteria they will be randomly assigned to either the therapy, medication, or placebo study groups and asked to return for additional study visits.

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Behavioral testing
If they have not yet been assessed by our team, your child will first undergo standardized neuropsychological assessments to determine their diagnosis, and to examine their cognitive abilities, and autism and anxiety symptoms. Testing will take approximately 2-3 hours. Additionally, you will be requested to participate in a parent interview about your child's development and anxiety symptoms (2-3 hours). Assessments and interview will be recorded for scoring and reliability purposes to ensure consistency in data collection. If you agree to be recorded, you reserve the right to review/edit the tapes. Your child also will be asked to do an eye tracking task. For this, your child will be seated at a table and look at a series of images while a computer tracks your child's eye movement. This task will take approximately 10 minutes.

MRI
For the MRI, the study team will work closely with you and your child to determine the best way to get your child comfortable with the procedure. Your child will first get to practice with a mock MRI scanner. This scanner simulates the environment of the real MRI, but allows your child to practice and get comfortable with the setting. Your child will also play computer games to practice the type of test they will do during the scan. Your child may take breaks and get snacks as needed. Once your child is comfortable, the team will transition to the real scanner.

In the real scanner, your child will be asked to lay in the scanner and perform a task while looking at a screen with pictures of different faces. Gift cards, snacks, and other incentives may be used to help motivate your child to complete the task. The study team will consult with you to determine what incentives will motive your child best. The scan and task will last a total of approximately 40 minutes, although the full procedure may take longer to accommodate your child's needs. Only participants located within a reasonable distance to the MIND Institute will be asked to complete the MRI portion of the study.

Eye Tracking
Eye tracking measures eye position (gaze) and movement. It measures the ability to look at pictures of faces and designs. Some people with ASD have difficulty looking others in the eye, and in this test your child will sit in a chair and watch faces and images on a screen, a camera will measure how much time your child spends looking at the pictures. Only participants coming to the MIND Institute for an in person visit will be asked to complete this portion of the study.

Safety Testing
Blood samples will be taken for clinical testing and for exploratory measures. The blood will be taken from a vein in your child's arm. The amount of blood taken will be no more than 7 teaspoonfuls each at the initial screening visit and visit 9. The blood collected for clinical testing will be processed through the UC Davis Medical Center, UC Los Angeles Medical Center, or Quest Laboratories and will help the study team determine whether your child can safely participate in the study. A urine sample may also be collected if your child is female and a urine pregnancy test is needed to determine study eligibility. An electrocardiogram (ECG) may also be done at the screening visit to measure your child's heart rhythms by placing several small sticky pads, attached to leads and connected to a machine, on your child's chest, arms, and legs. Vitals measurements, such as weight, height, and blood pressure will also be collected at in person study visits.

Research Blood Collection
At the first blood draw scheduled for your child, some of the blood samples collected will be for exploratory research measures. The samples will be used to get DNA, plasma, and different cell types from your child's blood. The tests done with these samples are experimental and are not like those done for clinical purposes and we do not provide any medical reports to you from these samples. Your child's samples will be stored in the study's private freezers with a numerical code and will be used only for research purposes. Some processed samples may be shared with other researchers or collaborators on the study, but your child's identifying information will not be shared.

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After these testing visits, if eligibility criteria is met your child will be randomly placed into one of three treatment groups. The three groups your child may be put into are:

1) cognitive behavioral therapy (CBT)
2) sertraline medication treatment
3) pill placebo (control treatment)

If your child is randomized to the pill placebo group you will be informed at the follow-up visit 19 and will have the option to participate in Phase 2 of the study, during which you will be given the choice of treatment, either sertraline or CBT.

Therapy

Cognitive-Behavioral Therapy (CBT) is an empirically-supported, problem-solving, goal-directed therapy that examines and treats the relationships between thoughts, feelings, and behaviors that are maintaining the excessive anxiety and preventing adaptive coping. If placed in the CBT group, your child will attend weekly 1 hour therapy sessions conducted remotely or at the MIND Institute for 16 weeks, using the Behavioral Interventions for Anxiety in Children with Autism program, a therapy curriculum which has been specifically adapted and designed for children with ASD.

Medication (Sertraline & Pill Placebo)

Sertraline is an SSRI antidepressant medication that may be used to help with anxiety and/or autism symptoms. A placebo will look the same as the sertraline pill, but will not contain any active medication ingredient. If placed in the medication group, your child will be randomly assigned to take either sertraline or the placebo daily for up to 20 weeks. Your child will be started on a low dose to minimize side effects, and the dose will gradually be increased over the course of the study. The medication should be taken daily, and will be provided through the UC Davis Investigational Drug Services Pharmacy. You will be asked to keep a medication log documenting when you give the daily medication, including any skipped doses. The study team will monitor your child throughout the course of the 20 weeks through a combination of in-person and remote visits.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment your child gets. You will have an equal chance of being given each treatment. Neither you nor the study doctor will know which treatment your child is getting until their study participation is complete for the medication and placebo groups. The investigator will not be able to tell you whether your child received active medication or placebo until their participation has been completed.

Post-treatment

At the end of treatment, your child will repeat some of the set of testing done at the beginning (MRI, eye tracking, and some of the behavioral testing). This will be used to determine how the treatment phase impacted your child.

You will be asked to complete one more visit after the end assessment visit if your child is in the medication or placebo groups. This visit will serve as a check-in to see how your child is doing after ending treatment. After 28 weeks in the study you will be asked to complete a phone call to see how your child is doing and complete a behavioral interview. This will be compared to the tests done at the end of treatment to determine whether the effects are lasting.

Phase 2

If your child was in the placebo group you will be informed at the follow-up visit 19 phone call and asked if you would like to participate in Phase 2 of the study, during which your child will receive the treatment of your preference (sertraline or CBT). If you decide to continue participating, you will have 60 days from completing the follow-up phone call to begin Phase 2.

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WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to make sure your child receives the study treatment as required and to record this as well as any problems you might have on a daily log. If your child is receiving CBT, this includes attending weekly sessions and helping your child practice the materials learned at each session. If your child is receiving pill medication, this includes ensuring your child takes the medication as prescribed, and recording when your child takes the drug. We will also ask that you tell us about any side effects or benefits that your child experiences during the study, as well as to be on time for appointments, or let us know if you will not be able to make them.

HOW LONG WILL I BE IN THE STUDY?

The initial screening assessment phase of the study will be completed over approximately 3 visits, some of which may be done remotely, within a 3-8 week span. The treatment portion of the study lasts approximately 16 weeks. You may receive a follow-up session at a 5 week interval after the end of the treatment portion (21 weeks) and be asked to complete a 3 month follow-up phone call for a total of 28 weeks. For all components of the study, your participation will total just over 7 months.

If your child is in the placebo group you will have the option of continuing in the study for an additional 24 weeks to receive 12 weeks of active sertraline or CBT treatment plus 12 weeks of follow-up. In this case your total participation in the study could be approximately 13 months.

CAN I STOP BEING IN THE STUDY?

You may decide not to take part in the research and it will not be held against you.

Instead of being in this research study, your choices may include:

- Getting sertraline prescribed clinically through your child's pediatrician. If you were to have sertraline prescribed by your pediatrician, it would come with the same risks and possible benefits as being in this study, except that there is no chance of receiving a placebo.
- Getting CBT through a community clinician.
- Getting standard treatment for your child's condition without being in a study.
- Not participating in the study.
- Getting a different experimental treatment/taking part in another study.

You may leave the study at any time and it will not be held against you. You may decide to stop even if you have previously agreed to take part in the research, and you may stop at any point during the protocol. Your decision will not affect your ability to receive medical care for your condition, and you will not lose any benefits to which you would otherwise be entitled.

If you decide to leave the study, contact the research team so that the investigator can tell you how to stop your participation safely. If you decide to leave the research, or if the study medication is stopped for any reason, you may be asked to complete the assessments that would have been done at the end of the study.

The study team may also decide to alter treatment or withdraw your child from the study to ensure the best outcome for your child. If this is necessary, the reasons and options will be fully discussed with you.

If you stop participating in the research, previously collected data may not be removed from the study database. You will also be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

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IS THERE ANY WAY BEING IN THIS STUDY COULD BE BAD FOR ME?

Your child may have side effects while in this study. Everyone taking part in the study will be watched carefully for any side effects.

Therapy (CBT)
Increased anxiety and subjective distress may occur after beginning therapy. This is an appropriate and expected reaction to psychotherapies aimed at anxiety reduction. This effect is usually very transitory and mild, and is thought to be a result of the patient gradually stopping his or her avoidance of anxiety provoking situations while simultaneously allowing one's self to approach and/or think about these situations. If noted or described to the therapist (e.g., on CBT homework forms, during the course of discussion) and specifically described by you or your child as a negative effect of participation, the study team's therapists can make certain adjustments to the pace or intensity of therapy (e.g., do a simpler exposure exercise; conduct further cognitive work before proceeding to exposure; do guided, therapist-assisted exposures) until your child is ready to or asks to approach the anxiety-provoking stimuli again.

Medication treatment
Side effects may be mild or serious. Most side effects go away soon after your child stops taking the study drug. The study drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study. Most children tolerate sertraline well and side effects are usually mild, transient, or can be controlled through dosage adjustment. You should talk to the research team about any side effects your child has while taking part in the study.

Risks and side effects related to the medication we are studying include:

- Gastrointestinal symptoms (nausea, cramps, diarrhea, constipation, change of appetite)
- Central nervous system symptoms (increased motor activity, jitteriness)
- Insomnia or changes in sleep patterns
- Headaches
- Sweating
- Tremor
- Dizziness
- Dry mouth
- Weight changes
- Occasional tiredness
- Some subjects become disinhibited demonstrating silliness or giddiness

There may be risk of allergy to the study medicine used in this study. Signs of an allergic reaction may include redness, itching, swelling or difficulty with breathing, and light-headedness. If you feel that you are having an allergy to the medicine, tell the study doctor right away.

This drug may cause a possibly life-threatening condition called serotonin syndrome. The symptoms of serotonin syndrome include hallucinations and delusions, agitation, coma, fast heart rate, and changes in blood pressure. They also include dizziness, loss of consciousness, seizures, shakiness, muscle tremor or stiff muscles, sweating, nausea, and vomiting.

Antidepressants may increase suicidal thoughts or actions in some children, teens or young adults within the first few months of treatment or when the dose is changed. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. People who have (or have a family history of) bipolar illness, or suicidal thoughts or actions may have a particularly high risk. Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts or feelings. Call your healthcare provider right away if symptoms

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such as anxiety, irritability, impulsivity, trouble sleeping, aggressive behavior or suicidal thoughts are new, worse or worry you. Sertraline has not been evaluated for use in patients under 18 for treatment of anxiety.

In the event of a moderate or severe adverse reaction to the medication, the medication will be reduced or withdrawn and clinical staff will follow your child closely until the adverse reaction remits. In the event of minor side effects (e.g., mild headaches), the medication may be maintained at the current dose levels or reduced.

FDA Warning Regarding Suicidality and Antidepressant Drugs
Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of sertraline or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

To monitor your child for medication-related side effects, the study team will contact you weekly during the treatment period. The research team is available 24 hours per day in the case of medical emergency or serious adverse events. If at any point in the treatment trial the treating clinician determines that a your child‘s symptoms have become sufficiently distressing or dangerous, your child will be withdrawn from the study and other treatments recommended or instituted.

No effect
You may see no improvement, or a worsening of symptoms. This may be due to your child not responding to treatment, or being part of the placebo group. If your child’s symptoms worsen at any point during the study, contact the study team. If your child is in the placebo group, you will be notified at the end of Phase 1 of the study and given the option of participating in Phase 2, during which you will be guaranteed to receive an active study treatment of your choice.

Randomization
You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition. If you are randomized into the placebo group you will be told at the 3 month follow-up and will have the option to stay in the study and receive your choice of sertraline or CBT during Phase 2 of the study.

Blood draw
Blood draws may cause temporary discomfort from the needle stick, bruising and, rarely, infection and fainting.

ECG
The adhesive pads used for recording the activity of your heart (ECG) can sometimes cause skin irritation which clears up soon after.

MRI
The only risks associated with MRI occur if your child has an existing contraindication to MRI. An example of a contraindication would be if your child had any type of metal implant. You will complete a standardized questionnaire to make certain that your child is not precluded from receiving an MRI scan due to existing

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contraindications and warnings. Some individuals experience feelings of anxiety or claustrophobia in an MRI environment. If this occurs, you or your child may ask to stop or pause the procedure at any time.

Medical information
If you tell your family doctor that you are participating in this study, or any specific aspects relating to your participation, this information may then become part of your medical record with this doctor. Insurance companies routinely have access to such records. We may need to obtain or release information to your doctor in order to ensure your child can safely participate in the study. This information cannot be released without your consent. You will be asked to authorize the sharing of this information, and the types of information shared will be explained to you beforehand.

WILL BEING IN THIS STUDY HELP ME IN ANY WAY?

We cannot promise any benefits to you or your child from your taking part in this research. However, there are several potential benefits to participation in this study, including having comprehensive psychiatric and medical assessments and carefully-monitored treatment, at no cost to you. In addition, because both CBT and sertraline have been shown to be effective treatments for anxiety, there is a likelihood that your child's anxiety symptoms will improve with these active study treatments, and as a result you may see improvement in their academic, social, and family functioning.

We will also provide a written report of the results of your child's performance on all standardized developmental, diagnostic, and behavioral procedures used in the study.

Copies of structural MRI scans can also be provided to your child's pediatrician for their medical record upon your request. Scans are used for research purposes and are not routinely reviewed by a radiologist. If any potential abnormalities are identified during the study MRI, our team will have the findings reviewed by an appropriate medical professional and will discuss the findings with you, and, with your consent, your personal physician. With your consent, we can release the radiological read to your child's physician. We do not provide these medical reports directly to you because they should be interpreted.

WILL MY INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that you and your child's personal information, including research study records and medical information, will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

Certificate of Confidentiality
This research has received a Certificate of Confidentiality from the Federal government that will help protect the privacy of the research records. The Certificate of Confidentiality allows the Researchers to refuse to disclose identifying information on your participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in this research. If you have given your consent for an insurer or employer to obtain information about you, the Researcher may not use the Certificate of Confidentiality to withhold this information. A Certificate of Confidentiality also does not prevent a Researcher from disclosing information about you to prevent serious harm to yourself or others, such as reporting to the authorities incidents of child abuse, elder abuse or spousal abuse.

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Research Use of Data
All participants will be assigned a study ID number, and only research personnel who need to see you or your child's names will see them. If information from the study is published or presented at scientific meetings, no information will be included that reveals the identity of you or your child.

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

NDAR
Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior and in some cases, your genetic information, to NDAR. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDAR. The information provided to NDAR may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDAR data. However, you will not be contacted directly about the data you contributed to NDAR.

You may decide now or later that you do not want to share your information using NDAR. If so, contact the researchers who conducted this study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://data-archive.nimh.gov.

Medical Records
If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. 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 EMR 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.

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Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Blood Samples
Your child's blood samples will be used studied by different researchers associated with the project. Sometimes specimens are used for genetic research (about diseases that are passed on in families). Normal and disease producing genetic variations are found among all individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future Your child's samples will be coded with a numerical ID, and any researchers analyzing the samples will be only provided this number code and no personal identifying information. Samples collected for exploratory measures will only be used for research purposes. Please be aware that you will not have any property rights or ownership interests in products or data, which may be derived from the use of your specimens.

Exceptions to Privacy
The privilege of confidentiality does not extend to information about sexual or physical abuse of a child. If any member of the program staff has, or is given, such information, he or she will report it to the authorities. The obligation to report includes suspected abuse. You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about your child, yourself, or your involvement in this research. Note that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

WILL I BE COMPENSATED FOR BEING IN THIS STUDY?

You will be compensated with visa or electronic gift cards of $100 per day for each of five planned assessment visit days, including the screening visit, post visit and follow-up visit up to a maximum of $500 for your time and effort. In addition, travel reimbursement is available for participants for whom traveling for study visits poses a financial burden affecting their ability to participate in the study. In this case participants traveling 25 miles or less round trip to the visit location will be provided with $25 per visit and those above 25 miles roundtrip will be provided with $50 per visit in the form of a visa gift card or electronic gift card.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

If you choose to leave the study after the treatment phase has begun, consult the study team to ensure your child is taken off treatment as safely as possible.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment either may be covered by University or may be billed to your insurance company just like other medical costs. The University does not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.
We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study.

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WHAT ELSE DO I NEED TO KNOW?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

Bio-specimens (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.

CAN I BE REMOVED FROM THE RESEARCH STUDY WITHOUT MY PERMISSION?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include, but are not limited to:

- Non-compliance with study protocol
- Severe reactions to the study drug
- If you develop another serious illness
- If your physician or the study team believes that continuation in the study is not in your best interests

We will continue to tell you any new information that may affect your health or welfare, even if you are removed from the study.

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?

The Investigator does not have any personal or financial interest in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have questions, please ask us. You can talk to the Investigator or Project Manager about any questions or concerns you have about this study at:

Investigator: Marjorie Solomon, Ph.D. at 916-703-0270 or marsolomon@ucdavis.edu
Project Manager: Brianna Heath, Ph.D. at 916-703-0452 or bheath@ucdavis.edu
Project Manager: Erika Bickel, CCRP at 916-703-0389 or esbickel@ucdavis.edu

For after hours emergencies related to the study, including severe side effects or symptoms, you can call 911 or contact the study team 24 hours a day at:
Murat Pakyurek, M.D. – 916-846-0340

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011). In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to an IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
Medical Research Studies

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1) To be told what the study is trying to determine.
2) To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.
4) To be told if you can expect any benefit from participating and, if so, what the benefit might be.
5) To be told the other choices you have and how they may be better or worse than being in the study.
6) To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.
7) To be told what sort of medical treatment is available if any complications arise.
8) To refuse to participate or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9) To receive a copy of the signed and dated consent form.
10) To be free of pressure when considering whether you wish to agree to be in the study.

If you have other questions, please ask the researcher or research assistant. In addition, you may contact the Institutional Review Board, which is concerned with protecting volunteers in research projects. You may reach the IRB office by calling (916) 703-9151, from 8:00 a.m. to 5:00 p.m., Monday through Friday, or by writing to the Institutional Review Board, CTSC Bldg., Suite 1400, Rm. 1429, 2921 Stockton Blvd., Sacramento, California 95817.

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Protocol	APPROVED
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My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

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.

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

For IRB stamp and version date only

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