UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

Title: Feasibility of a Whole-Food, Plant-Based Dietary Intervention for Patients with Low-Risk Chronic Lymphocytic Leukemia (CLL)
Study: #804687

2. Principal Investigator

PI: Ariel Portera, DO; Department of Family Medicine
Co-PI: Michael Choi, MD; Department of Medicine

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

858-249-6896

4. Study Sponsor

The Krupp Endowed Fund (KEF) the study sponsor is paying UC San Diego to perform this research study.

5. Study Overview

This research study is being done to understand if it is possible for patients with low-risk chronic lymphocytic leukemia (CLL) to adhere to a vegan whole-food, plant-based (WFPB) diet using group cooking classes. This diet is centered on plant foods such as vegetable, fruits, whole grain, legumes such as peas and beans, nuts, and seeds. The diet will also avoid animal- based products like meat, fish, and dairy, as well as processed food, added sugar and alcohol. You will receive more detailed information on the dietary intervention once it has been determined you are eligible to participate.

This study will also explore the impact of a short-term, WFPB diet on your white blood cell count and markers of heart disease, kidney disease and diabetes.

We are inviting you to participate in this research study because you have a diagnosis of low-risk chronic lymphocytic leukemia (CLL).

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.

You will first undergo several procedures to determine if you are eligible for the study. If you are eligible, you will meet with a research team member to review your medical history and obtain baseline information about the study. You will then meet with a registered dietitian (RD) to complete a dietary intake, assess for food allergies and learn about the details of the dietary intervention. You will then be instructed to adopt the whole-food, plant-based diet for 8 weeks. Over the course of the study, you will attend weekly group cooking classes via Zoom. You will also meet with a RD again shortly after you begin the study, in the middle of the study and at the end of the study. You will be asked to complete a series of food diaries and food questionaries to track changes in your diet. You will also receive a weekly call from a health coach.

At the beginning of the study, in the middle of the study and at the end of the study you will be asked to provide a blood sample (approximately 20 ml or 4 teaspoon) to assess for changes in your white blood cell count and markers of heart disease, diabetes and kidney disease. We will also assess your height, weight, waist circumference and blood pressure at baseline, in the middle of the study and at the end of the study. Each blood draw and assessment will be about 1 hour. When the study is complete you will be asked to complete a survey about the dietary intervention.

The most common risks or discomforts of this study include risks associated with blood draws such as feeling lightheaded or experiencing pain or bruising at the site of venipuncture.

The most serious risks include the risk of overmedication from certain medications as a result of dietary modification and/or weight loss.

There is also a risk of exposure to food allergens during the cooking classes though the registered dietitian will assess your allergies at the initial intake and each subsequent RD visit and will modify your recipes accordingly.

Additionally, long-term plant-based diets have been associated with vitamin deficiencies. We will monitor blood levels of specific nutrients throughout the study and you may be advised to take a supplement if needed.

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

We cannot promise any benefit to you or to others from you participating in this research. However, the investigator(s) may learn more about the impact of a whole-food, plant-based diet on patients with low-risk CLL. Additionally, a whole-food, plant-based diet has been associated with a decreased risk for heart disease and diabetes.

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 18 people here.

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

As you read this form, ask questions if something is not clear.

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

Baseline Visit #1 (at baseline prior to starting the diet- may potentially be split into two half visits due to lengthy duration of visit, estimated 90-120 minutes). This visit will take place in person, if a second visit is necessary this will be conducted via phone or Zoom.

- Interview: includes a medical history, review of medications and supplements
- You will be provided a blank Food Frequency Questionnaire and a 3 Day Food Diary. You will receive further instructions about these documents at baseline visit #2 with the RD.
- Provided and instructed to complete a physical activity assessment which will take approximately 30 minutes.
- You will undergo a blood draw and vital sign assessment during this week which will be performed by the study staff (study coordinator) who is a Certified Phlebotomist. Approximately 20ml (about 4 teaspoons of blood) will be collected to assess levels of nutrients in your blood, your white blood cell count and markers of heart disease, kidney disease and diabetes. They will also measure your height, weight, blood pressure, waist and hip circumference. This will be done at your home pending accessibility and availability of the study staff and equipment. If the data cannot be collected in your home, you will be scheduled for an onsite assessment at Altman Clinical and Translational Research Institute (ACTRI).

Baseline Visit #2 (prior to the intervention)

- Meet with the RD via Zoom immediately prior to the intervention for approximately 45-60 minutes . This visit will include a dietary assessment including assessment for known food allergies. You will be provided the CLL Whole-Food, Plant-Based Dietary Guide and cooking class manual. The RD will review the materials with you and answer any questions you may have about the dietary intervention.

Week 1 of the intervention- You will be completing the following over the course of this week:

- Cooking Class #1
    - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants via Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Complete a 3 day food diary prior to your meeting with the RD which will take approximately 30 minutes.
- Individual meeting with the RD over Zoom, to help reinforce changes already made and further refine dietary goals and planning. This will take approximately 30-60 minutes.
- Individual phone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 2 of the intervention- You will be completing the following over the course of this week.

- Cooking class #2

  - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants on Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Individual phone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 3 of the intervention-You will be completing the following over the course of this week.

- Cooking class #3
  - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants on Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Individual phone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 4 of the intervention-You will be completing the following over the course of this week.

- Cooking class #4
  - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants on Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- You will undergo a blood draw and vital sign assessment during this week which will be performed by the study staff (study coordinator) who is a Certified Phlebotomist. Approximately 20ml (about 4 teaspoons of blood) will be collected to assess levels of nutrients in your blood, your white blood cell count and markers of heart disease, kidney disease and diabetes. They will also measure your height, weight, blood pressure, waist and hip circumference. This will be done at your home pending accessibility and availability of the study staff and equipment. If the data cannot be collected in your home, you will be scheduled for an onsite assessment at Altman Clinical and Translational Research Institute (ACTRI).
- Complete 3 day food diary prior to your meeting with the RD
- RD visit via Zoom for 30-60 minutes
- Individual telephone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 5 of the intervention-You will be completing the following over the course of this week.

- Cooking class #5
  - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants via Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Individual telephone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 6 of the intervention-You will be completing the following over the course of this week.

- Cooking class #6
  - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants via Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Individual telephone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 7 of the intervention-You will be completing the following over the course of this week.

- Cooking class #7
    - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants via Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Individual telephone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 8 of the intervention-You will be completing the following over the course of this week.

- Cooking class #8
    - Complete a 90-minute group cooking class via Zoom. You will be cooking alongside the RD and other study participants via Zoom. The cooking class will be immediately followed by a 30-minute shared meal on Zoom. All ingredients will be delivered to you prior to the class.
- Complete 3 day food diary prior to your meeting with the RD
  RD Visit via Zoom for 30-60 minutes
- Individual telephone call with a health coach for 15-30 minutes to assist with reinforcing dietary goals, problem solving and self-monitoring.

Week 9 (after the intervention)-You will be completing the following over the course of this week.

- You will undergo a blood draw and vital sign assessment during this week which will be performed by the study staff (study coordinator) who is a Certified Phlebotomist. Approximately 20ml (about 4 teaspoons of blood) will be collected to assess levels of nutrients in your blood, your white blood cell count and markers of heart disease, kidney disease and diabetes. They will also measure your height, weight, blood pressure, waist and hip circumference. This will be done at your home pending accessibility and availability of the study staff and equipment. If the data cannot be collected in your home, you will be scheduled for an onsite assessment at Altman Clinical and Translational Research Institute (ACTRI).
- Complete a physical activity assessment
- Complete Food Frequency Questionnaire
- Complete a satisfaction survey regarding the study

Month 3

- You will be contacted three months after the start of the dietary intervention to complete a Food Frequency Questionnaire. This will take approximately 30 minutes.

Month 6

- You will be contacted six months after the start of the dietary intervention to complete a Food Frequency Questionnaire. This will take approximately 30 minutes.

The overall duration of your participation is estimated to be about 25 hours during the 8-week period.

All cooking class meals are offered free of known food allergies as needed for individual participants.

Participation in this study will require Zoom access and live video with participants' faces and names present in front of UCSD research personnel and other study participants for the duration of the class and shared meal.

You will be asked to complete a physical activity questionnaire prior to the start of the study and at the end of the 8 week intervention. You will be instructed to maintain your baseline level of physical activity throughout the duration of the 8 weeks (ie same frequency, duration and intensity of exercise as reported at baseline).

You will also be asked to complete a survey at the end of the 8 week dietary intervention to provide feedback.

Personalized dietary counseling sessions with a registered dietitian will each take about 45 minutes. These sessions will occur prior to the start of the intervention (baseline), at the beginning of the intervention (week 1), the middle (week 4) and at the end (week 8) of the intervention.

Each visit for the blood draw and vital sign assessment will take 30 to 60 minutes. These visits will take place before the intervention (at the baseline), in the middle of intervention (week 4), and after the intervention (week 9).

Additionally, the information presented in this study is not intended to replace the advice of your medical doctor or other health care professionals with whom you consult. You will be advised to continue to follow up with your oncologist and primary care doctor for management of your medical conditions.

9. What are the risks and possible discomforts?

Participation in this study may involve some added risks or discomforts. These include the following:

There is a risk of overmedication from certain medications (ex: for blood pressure or diabetes) that could result from dietary modification and/or weight loss. The most likely of these are the risks of low blood pressure or low blood sugar as a result of diet and/or weight loss induced improvements in blood pressure and blood sugar. If your blood work or vital signs indicate that there is a need for medication adjustment, you will be contacted by Dr. Portera and advised to schedule a follow-up appointment with your primary care doctor for further evaluation. Symptoms of low blood pressure include dizziness, lightheadedness, feeling weak or ill and/or fainting. Common symptoms of low blood sugar include sweating, hunger, fatigue, lightheadedness and/or fainting. If you experience signs or symptoms of low blood pressure or low blood sugar during the study, contact your primary care doctor immediately for medical advice. Following medical evaluation contact the research team to notify them of any symptoms or treatment you received.

Additionally, long-term plant-based diets have been associated with vitamin B12 deficiency. The most common symptoms of Vitamin B12 deficiency are anemia, numbness and tingling in the arms or legs, or difficulty walking. Other less common symptoms may include pain or swelling of the tongue, forgetfulness, irritability, depression or psychosis. We will assess your B12 levels prior to the study and at the end of the study. In order to prevent Vitamin B12 deficiency, you will be instructed to take a daily oral vitamin B12 supplement throughout the study to meet the minimum recommended dietary allowance of 2.4mcg daily. If your baseline B12 level is low, Dr. Portera will contact you and recommend a higher dose. If you plan to continue a whole-food, plant-based diet at the end of the study, please notify the RD at your final visit and you will be advised to continue the vitamin B12 supplement.

It is also important to note that plant-based diets may be associated with gastrointestinal symptoms due to increased fiber consumption. These symptoms may include gas, bloating, increased frequency of bowel movements or loose stools. If you experience these symptoms, the RD may make recommendations to modify food preparation to alleviate symptoms. If your symptoms persist, you may be advised to follow up with your primary care doctor.

We anticipate contact with food allergens to be of low risk, however, it is valuable to be aware of the most common food allergens which include milk, wheat, soybean, fish, crustacean shellfish, peanuts, tree nuts and eggs. To minimize risk of exposure, all participants will be screened for known food allergies prior to the start of the study and will be reassessed for any new symptoms of food allergies at subsequent RD visits. Nutritionally equivalent dietary modifications that exclude food allergens will be provided under the supervision of a Registered Dietitian. Personal injury or illness may result from consuming or handling food allergens. Signs and symptoms of food allergy may include itchy rash, swollen lips, scratchy throat, nausea, vomiting, abdominal pain or difficulty breathing and in rare cases death. If you experience any of these symptoms during a cooking class, seek immediate medical attention.

Risks associated with phlebotomy (when a health care professional inserts a needle into your vein to draw blood) include:

- Feeling lightheaded or fainting
- Irritation of the vein such as redness or swelling
- Pain
- Bruising or bleeding at the site of the blood draw
- Slight risk of infection

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Contact the phone number listed on this form if you experience side effects from the intervention, if you are diagnosed with nutritional deficiencies (ie iron deficiency, vitamin deficiencies) by a healthcare provider, or if you are notified by your physicians that your white blood cell count is increasing/CLL has progressed during the study.

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 primary physician. If you do not have a primary 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 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.

You would be asked to maintain confidentiality regarding other study participants.

There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, research records will be collected and shared following standards of confidentiality. All patient data will be encrypted, password-protected, stored, and analyzed on UC San Diego Health computers. Research records may be reviewed by the UCSD Institutional Review Board. You will be assigned a participant number that will be used, instead of identifying information, in all datasets for analysis. Should the results of this study be published, you will not be identified through your name or personal information. We expect this study will be completed in two 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.

This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance at UC San Diego 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 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.

You will be asked to sign separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study. Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a 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 be required to report such information to the appropriate authorities.

We may need to report information about known or reasonably suspected incidents of abuse or neglect of a 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.

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

You will be provided with the ingredients for the cooking classes at no cost to you. A box with ingredients will be delivered to you in advance. If you are traveling on short notice and still plan to attend the class virtually, you may be required to purchase the ingredients for that class if they are unable to be delivered to you in a timely manner. Additionally, you will also be responsible for the cost of meals outside of the cooking classes while in this study. You and/or your health plan/insurance company will need to pay for all costs of treating your condition while in this study.

You will also be responsible for obtaining a computer or tablet with Zoom capabilities to participate in the cooking classes, this will not be provided by the research team.

Phlebotomy and vital sign assessments will be conducted in your home by a mobile phlebotomist. If the blood draws and vital signs assessment must be held at ACTRI, you will be responsible for the cost of your gas to and from the visits as well as parking.

You will also be responsible for the cost of the over-the-counter vitamin b12 supplement.

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 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.

If you decide to stop participating in the study, we would like to know why and may schedule a follow-up call or you can e-mail us.

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.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

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 it is in your best medical interest, or if you do not follow the instructions given to you by the study personnel. Dr. Choi will review your complete blood cell count (CBC) at baseline, at week 4 and at week 8. If there is concern that your CLL may be progressing based on your CBC, we will notify you and contact your primary oncologist. If this occurs, you may subsequently be removed from the study.

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

Biospecimens obtained from you will be sent directly to the lab for processing and the sample will not be stored for future use. The results obtained from biospecimens with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study will not be shared with other researchers or institutions.

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

If you take part in this research, you will be responsible for adhering to the dietary intervention for the duration of the study, attending the weekly cooking classes, attending study visits as described above and completing your food diaries.

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

If you agree to take part in this research, we will pay for and provide you with the necessary ingredients for each cooking class. We will not pay for any additional out of pocket expenses related to your participation, such as travel costs or meals outside of the cooking classes.

16. What else is important for me to know?

You will be provided any clinically relevant information that may pertain to your health. You may choose to be provided a summary of the research findings including the results of your blood tests at the end of the study.

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?

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

We would like to offer you the option to receive any relevant individual results including biomarkers obtained from this study such as a complete blood cell count (CBC), complete metabolic panel (CMP), lipid panel, hemoglobin A1c (HbA1c), as well as nutritional assessments for iron (iron panel and ferritin), vitamin B9 and vitamin B12. Results will be provided at the end of the study.

You may also change your mind about this choice. Please initial your choice below:

_____YES, send me my individual results

_____NO, do NOT send me my individual results

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

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.

Printed Name of Participant

Signature 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.*

Printed Name of Person Obtaining Consent

Signature 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 participant. The participant appears to have understood and freely given consent to join the research.

Printed Name of Witness

Signature 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.

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