Permission to Take Part in a Human Research Study

Title of research study:

The Effects of Sucrose-sweetened Beverage in African-American and Caucasian Women (SAAC) Study

Investigator: **Candice Price, Ph.D.**

Co-Investigators: **Kimber Stanhope, Ph.D., R.D. and Peter Havel, DVM, PhD**

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you self-identify as either an African-American or non-hispanic White woman, and are a nonsmoker who does not have diabetes mellitus or liver, kidney or thyroid disorders, or take hypolipidemic, anti-diabetic, anti-hypertensive or anti-depression medication and you are between the ages of 18-45 years. You have reported a stable body weight during the prior 6 months and routinely consume 3 meals per day.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Dr. Candice Price: 530-752-5379 (office)
530-794-8244 (cell)
Study Staff: 530-752-2714 / 530-752-2146 (office)
Dr. Kimber Stanhope: 530-752-3720 (office)
Dr. Peter Havel: 530-752-3114
Dr. Valentina Medici: 916-734-3751 (office)/916-919-1665 (cell)/916-816-5360 (pager)

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Dr. Valentina Medici. In the case of an emergency, dial 911 from any phone.

Do not write below this line. For IRB stamp and version date only.

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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 a 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.

Why is this research being done?

This research is being conducted by Candice A. Price, Ph.D., in the Department of Molecular Biosciences, Veterinary Medicine and is funded by the National Institutes of Health, Office of Research on Women's Health. The main goal of this research study is to learn about metabolism of koolaid beverages that contain added sucrose (table sugar) to help patients in the future. However, no one can guarantee that participating in a research study will help you.

How long will the research last?

We expect that you will be in this research study for 16 days. This is a 16-day study that includes 15 days of consuming a diet that includes sweetened beverages, and 1 day of experimental testing at the beginning and end of the study, plus questionnaires.

How many people will be studied?

We expect about 58 people will be in this research study.

What happens if I say yes, I want to be in this research?

Before you begin the study:

You will be asked to have the following "screening" exams, tests or procedures to find out if you can be in the study. For the tests to be valid, it will be necessary for you to follow these dietary guidelines:

Do not consume alcoholic beverages the day before the screening visit.
Do not eat or drink anything except water before the screening visit starting 12 hours the night before your scheduled appointment time.

These tests will occur at the main campus of University of California, Davis at the Ragle Human Nutrition Research Center (Ragle) or at the University of California, Davis Medical Center (UCDMC) Clinical and Translational Science Center Research Center (CCRC) (located off of Stockton Blvd. in Sacramento). The CCRC is part of the UC Davis Medical Center Hospital (located off of Stockton Boulevard on US 50) and it was built for the purpose of allowing the Physicians and Professors at UCDMC and University California, Davis to conduct research studies such as this one.

- **Questionnaires:** You will be asked to fill out questionnaires regarding your medical history, general physical activity, and psychological experiences that may be challenging for some

people. You will be asked to fill out questionnaires about life experiences you may have had that can be challenging, as well as emotional responses and eating behaviors.

- **Blood drawing (venipuncture):** You will be asked to give a blood sample for laboratory tests. Approximately 3 teaspoons of blood will be drawn by inserting a needle into a vein in your arm for these tests. At this time the nurse will assess the suitability of your veins for the multiple blood draws that are required for some of the experimental study procedures.

- **Pregnancy testing**: Because some of the experimental procedures may affect a fetus, and because pregnancy can affect the study results, pregnant women may not participate in this study. If you have had your first menstrual period, a urine test will be done at the initial visit and subsequently on Study Day 1 and 15 to make sure you are not pregnant.

- **Commitment to participating in study visits**: You will be asked to describe your availability and willingness to participate in experimental procedures (described elsewhere in this document) that require you to spend several hours (approximately 4 hr) two times at the beginning and two times at the end of the study, 2 weeks later. Participation of procedure visits will occur at University of California, Davis Medical Center (UCDMC) Clinical and Translational Science Center Research Center (CCRC). This study requires that you spend a total of 17 hours at the CCRC, consisting of two testing days that includes two 4hr periods at the beginning and end of the study, and 3 meal pick-up visits.

  You will be shown a calendar of study dates, and asked to indicate the dates that you will be available to participate. You will also be given a list of the foods that you will be required to eat the day before you stay at the CCRC and while you are staying at the CCRC, to allow you to determine whether you are willing to commit to eat them.

- **Preparation for study participation:** If the screening exams, tests or procedures show that you can be in the study, and you are selected and choose to take part, there may be a considerable waiting period before the study will actually start. During this period, you will be asked the following:
  - You will be asked to not drink sugar beverages for the 5 weeks before your study start date with the exception of 8 ounces of naturally-sweetened fruit juice/day.
  - You will need to confirm your availability and willingness to participate by responding to emails sent to you 5 weeks, 2 weeks and 3 days prior to your study start date.

  When the study starts, you will have the following tests and procedures done (also shown in **Table 1: Study schedule with procedures, duration and compensation**).

Table 1: SAAC Study Schedule w/Compensation

Study day	$	Duration at study site (hours,	Inpatient/Outpatient status	Diet	Procedures
-1	10	15 min.	Outpatient	Usual diet w/no more than 1 sugar beverage	Study meal pick-up; Body weight, blood pressure and urine collection;
0	5		Outpatient	Standardized meals provided by study; no sugar-sweetened beverages and no alcohol	Complete questionnaires at home
1	$60	Check-in 5PM w/Check-out at 9PM	Procedure Day at CCRC	Standardized meals provided by study; Begin consuming study beverages w/usual diet after check-out	Consume provided study meals. Pre- and Post-dinner blood draws (5PM to 9PM); body weight and urine collection
2	$50	Check-in 7AM w/ Check-out at 11AM	Procedure Day at CCRC	Arrive at CCRC after a 10hr fast. Study beverages with usual diet begins after completion of testing procedures	Body weight, blood pressure, morning blood draws and an oral glucose tolerance test (OGTT) (7A-11AM), urine collection. Begin consuming study beverages w/usual diet after check-out
3	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
4	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
5	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
6	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
7	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
8	10	15 min.	Outpatient	Study beverages with usual diet	Beverage pick-up and urine collection; Sugar beverage with each meal, 3/day
9	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
10	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
11	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
12	5		Outpatient	Study beverages with usual diet	Sugar beverage with each meal, 3/day
13	10		Outpatient	Study beverages with usual diet	Study meal pick-up; Body weight, blood pressure and urine collection; Complete questionnaires at home
14	5		Outpatient	Standardized meals provided by study	Complete questionnaires at home
15	$60	Check-in 5PM w/Check-out at 9PM	Procedure Day at CCRC	Standardized meals provided with study beverages; no alcohol	Consume provided study meals. Pre- and Post-dinner blood draws (5PM to 9PM); body weight and urine collection
16	$50	Check-in 7AM w/ Check-out at 11AM	Procedure Day at CCRC	Arrive at CCRC after a 10hr fast. Usual diet begins after completion of testing procedures	Body weight, blood pressure, morning blood draws and an oral glucose tolerance test (OGTT) (7A-11AM), urine collection
Total=	$305*	*Total compensation upon completion of all inpatient procedures and study questionnaires			

CCRCprocedures

Dietary protocol:

Standardized meals: You will be provided with a standardized diet based on your calculated energy requirement (the amount of calories required to maintain your body weight) to consume

the day before and the day of your procedure days. On study days -1, you will pick up 5 standardized pre-packaged study meals to be consumed on study days 0 and 1, and on study day 13, you will pick up meals to be consumed on study days 14 and 15. You will need to eat all and only the food provided on these days. It is important that you consume breakfast and lunch at specific times provided to you on study days 1 and 15. Research staff will send you a reminder by call or text on these days. You will need to return empty meal packaging and uneaten food. On study days 1 and 15, your dinner meal will be consumed at the CCRC.

Study beverages: Study beverages are sucrose (granulated sugar cane)-sweetened koolaid drinks. Starting on study day 2 (after completion of baseline testing procedures) through day 15, you will drink a study beverage with each of your meals, for a total of 3 beverages per day. However, on study day 2, you will consume only 2 beverages with two meals for the day after completion of baseline testing procedures. You will receive your first set of study beverages upon completion of the oral glucose tolerance test on study day 2. You will be provided with enough study beverages through study day 8, at which time you will return any empty bottles and pick up another supply of beverages to last you until your next meal pick up on study day 13. In order for this study to produce scientifically useful information, it is necessary that you consume all 3 beverages provided each day and no other sugar-sweetened beverages during your participation in the study. The beverages will contain a biomarker (a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease) in order to confirm that the study beverages are being consumed. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Also called molecular marker and signature molecule.

Procedure CCRC Visits

Blood collections: During study days 1 and 15, you have blood drawn after dinner at 4 time points at night (6:00 PM, 7:00PM, 8:00PM, and 9:00 PM). On study days 2 and 16, you will have blood drawn after a 12-hour overnight fast at 6 time points in the morning (8:00 AM, 8:30 AM, 9:00AM, 9:30AM, 10:00AM, 11:00AM). A Registered Nurse will place an intravenous line into a vein in your forearm for drawing blood samples. A needle will be inserted into your vein through which a small, flexible plastic tubing (catheter) is placed into the vein. The needle will be removed leaving the tubing taped in place. This tubing will allow us to collect several small blood samples in one visit without multiple venous punctures. Pre-dinner and post-dinner blood samples collected will consist of approximately 19 tsp total. Fasting and morning blood draws collected on study days 2 and 16 will consist of approximately 14 tsp total. If at any time we are unable to collect all samples because the catheter does not work, we will collect up to five single-tube samples throughout the course of the test day using individual vein punctures. Blood samples collected will be used to measure the level of sugar, fat, a number of hormones and blood markers of metabolism. We will also collect and save the white blood cells from these samples in order to conduct DNA analysis.

Saliva: On Study Days 1 and 15, in the morning (30 minutes after you awake) and evening (just before you go to bed), we will obtain saliva samples by asking you to drool into a tube. You will be provided with instructions to collect this sample. Your sample will need to be stored immediately in the freezer and brought in on ice to your next visit to the CCRC or Ragle. We will measure hormone levels in these samples.

Breath: On Study Days 1 and 15, we will obtain breath samples by asking you to exhale normally into a collection bag for 1-2 seconds. We will obtain these samples once in the morning and hourly at night, from 6:00 PM until 9:00 PM. Your breath samples will be analyzed for gases and compounds that represent microbial activity in your digestive tract or metabolic processes in body organs.

Oral Glucose Tolerance Test (OGTT): On Study Days 2 and 16, we will perform the OGTT procedure. This test will occur immediately after the 8:00AM blood draw. You will drink 11 ounces of a glucose solution. It will be necessary that you drink all the glucose solution within 5 minutes. Your blood will be sampled at 0 (before the glucose solution) minutes and again 30, 60, 90, 120 and 180 minutes later.You will not consume food during this 3-hour period and you will be limited to one cup of water. Blood collected at the start of the OGTT will be approximately 9tsp. Each sample collected during the OGTT will be approximately 2 teaspoons.

Urine collection: On Study Days 1, 2, 15 and 16, you will be asked to provide 2 urine samples (one in the morning before fasting blood draw and one at night following dinner). During the outpatient Study Day 8, you will also provide urine samples during the beverage and study meal pick-up visit.

Stool collection: On Study Days 0 [or 1] and 14 [or 15], you will be asked to provide a stool sample to test the effects of the sweetened beverages on the types of microorganisms contained in the stools. You will be provided with a collection kit in order to collect your sample at home. You will store your sample in the freezer and bring in on ice to your next procedure visit at the CCRC.

Physical activity monitoring: You will be asked to wear a small device (about the size of a quarter) on an elastic band around your waist for one week (Study Days 2-8) during the time you are awake. This device will register your movement and estimate the time you spend in light, moderate, and intense activity. We will show you how to wear the monitor correctly before you leave the CCRC on Study Day 2. We ask you to maintain your normal physical activity during the time you are wearing this monitor. You will return the monitor to use when you come to CCRC for your inpatient test on Study Day 8.

Questionnaires: You will be asked to fill out questionnaires related to psychological experiences that may be challenging for some people. You will be asked to fill out questionnaires about life experiences you may have had that can be challenging, as well as emotional responses and eating behaviors. Upon completion of the study, you will be asked to complete a brief questionnaire inquiring about your initial interest in our study. These questionnaires include:

Self-Report Food Questionnaires: On study days 0 and 14, you will complete a set of 8 questionnaires about eating and eating preferences throughout the your procedure visit at the CCRC. Two of these questionnaires focus on food and snacking preferences in relation to mood.

24-Hour Recall Survey: A 24-hour dietary recall survey using the Automated Self-Administered 24-hour Dietary Recall (ASA24) Researcher Website will be completed on Study Days 0, 7 and 14. You will receive training by the study coordinator on how to complete the online survey on Study Day 0. These surveys take approximately 30 minutes to complete.

Life-Stress Questionnaires: On study days 0 and 14, you will complete two questionnaires about your general mood and life events during the prior 2 weeks.

Participation in Research Questionaire: On study day 16, you will complete one brief questionnaire about your interest in participating in this study.

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

If you take part in this research, you will be responsible to:

- Consume the sweetened beverages per day as required for 14 days (or up through your intervention procedure CCRC visit)
- Consume only the sweetened beverages provided and not any other sweetened beverages
- Consuming all food provided when required
- Consuming only the study meals provided and not any other food on the days instructed
- Picking up study meals and beverages 3 times during the study
- Returning all empty and not empty food packaging/containers
- Reporting any deviations from the dietary protocol to the Study Coordinator

What happens if I do not want to be in this research?

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

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, contact the investigator as soon as possible so that the investigator can be notified of your reasons for leaving (this is for reporting purposes) and can cancel any upcoming scheduled procedures.

If you stop being in the research, already collected data may not be removed from the study database. You will 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.

Is there any way being in this study could be bad for me?

You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, the Researcher may not know all the side effects or risks. Side effects may be mild or very serious. The Researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop consuming the sugar-sweetened beverages. In some

cases, side effects can be serious, long lasting, or may never go away. You should talk to the Researchers about any side effects that you have while taking part in the study. Risks and side effects related to the procedures and the consumption of the sugars we are studying include:

Common:

Diet:

- On study days 0, 1, 14 and 15, you will be restricted to eating only the study meals provided. You may want to eat or drink other things and you will not be able to eat or drink them (with the exception of water and black coffee) during this time. We ask you to consider carefully whether this restriction is one that you can accommodate. If your lifestyle includes many social situations that are centered on eating and drinking, this restriction may be particularly difficult. It could also be difficult if you strongly prefer your accustomed foods over any other foods. You may have to eat some foods and beverages that you do not like very much or at all.
- There may be times when you have to eat when you are not feeling hungry, or there may be times when you feel hungry and you won't be able to eat at that time.
- You may experience indigestion, nausea or changes in your bowel function due to the diet and/or changes in your normal eating habits. If you do experience significant and uncomfortable symptoms, medications such as Colace, Imodium, Gas-X or Pepto Bismol may be used as needed.
- Consumption of the Kool-Aid-flavored beverages may cause your urine to appear dark yellow, or greenish yellow.

Body weight change:
It is possible that the diet may cause changes in weight gain. Following completion of the study, any such changes should return to normal on a healthy meal plan such as the USDA MyPlate. Dietary guidelines will be provided at the end of the study. You may request to meet with the study Dietitian for weight loss counseling if you do not return to your original body weight within one month after the study.

Blood drawing (venipuncture) risks: Drawing blood will cause temporary discomfort from the needle stick. Drawing blood may cause bruising.

Catheter: Sometimes proper insertion of the catheter is not accomplished on the first attempt and additional insertion attempts are necessary. During pre-screening, the nurses will assess your vein to evaluate the likelihood that the catheters can be inserted successfully for the infusions and multiple blood draw procedures. The nurses will need to flush the catheter line with saline solution in order to be able to draw blood. It is possible that flushing the catheter line with saline solution may cause some discomfort at the area where the catheter is inserted. Sometimes a successfully inserted catheter line stops working later during the long 26-h infusions or long blood collection procedures. The nurse will try to prevent this from happening by placing a heating pad on your arm. If the catheter line does stop working, the nurse will insert a new catheter. You may request that prior to doing so, that the nurse review other options. If most of the essential blood samples have been collected, collecting the remaining essential samples using a needle and syringe may be an option. The other option will be to end your participation in the study.

Blood collection procedures: You may become bored and tired during the long blood collection

procedures, where your activity and mobility will be limited due to the catheter lines. There is a moderate risk that you will become irritable, fatigued, anxious or nauseated. We recommend that you bring from home movies and books and any other activities that will help you to pass the time more pleasantly. There are some people whose personalities are not suited to the limited mobility and activity required during the long blood collection procedures. Please carefully consider your ability to undergo these morning and night procedures.

Anemia: Blood drawing results in fewer red blood cells. The loss of too many red blood cells is called anemia, and can cause tiredness, weakness and shortness of breath. To minimize this possibility, the amount of blood that will be collected is within the blood donation guidelines and is equal to less than 1 blood donation.

Less Common:

Lipid changes: It is likely that consumption of the sugar-sweetened beverages will cause your cholesterol (including low density lipoprotein-cholesterol (LDL-C)) or triglyceride concentrations to increase. Elevated concentrations of LDL-C are associated with increased risk for cardiovascular disease, including coronary artery disease.
Blood drawing: Drawing blood may cause infections.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include generating study results that will have a positive impact on public health.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. 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. The Accounts Payable Department will also view your personal information (social security number and address) for payment processing.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

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

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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.

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/legal/privacy/) and in an attached document.

During the course of the research, we will collect blood, tissue, urine and saliva. We would like to keep some of these specimens that will be left for future research purposes. If you agree, these specimens will be stored in the laboratory of the PI and retained for up to 20 year. The PI's study staff will have access to the specimens. Paper copies of some of your data will be stored in your subject file, located in a locked cabinet in a locked office. All information about your identity will be removed from the subject file 5 years after publication of the study results. Electronic copies of data will not contain information about your identity and will be stored on a secure server for up to 20 years.
If specimens, such as blood or tissue, are taken from you for this study, they will become the property of the University of California. The specimens may be used in this research, may be used in other research, and may be shared with other organizations. The specimens could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the specimens.
If you agree to share the biological specimen(s) collected from you, please initial here: _____
Otherwise, your specimen will be destroyed at the end of this study.

The PI, Dr. Candice Price, 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.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include noncompliance in regards to eating and drinking the study meals and beverages provided or failure to show up for scheduled meal and beverage pick-up appointments or experimental procedures, extreme psychological distress, evidence suggesting that participating in the study could cause health risks to you. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institutes of Health, Office of Women's Health, also called the sponsor. Sponsors may change or be added.

UC Davis is being paid to conduct this study, but the study doctor and research staff have not received any direct income from the sponsor.

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.

A Federal law, called the Genetic Information Nondiscimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

Health insurance companies and group health plans may not request your genetic information that we get from this research.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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 may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do 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.

If you agree to take part in this research study, we will compensate you $305 for your time and effort. If you do not complete the study, you will receive a prorated payment based on the number of study days and procedures completed (see **Table 1**). Payments for the study procedure visits, Study Days 1,2, 15 and 16, you will be prorated based on the number of hours you completed. For Study Days 1 and 15 night procedures, you will be compensated $60, or $15 per hour. For Study Days 2 and 16, you will be compensated $50, or $12.50 per hour. Payment will be mailed to you in the form of a check within 4 weeks upon completion of the final set of procedure days (Study Day 16). There will be no compensation for participating in the screening or consenting procedures. There will be no compensation for gas or other study travel-related expenses. You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

Upon completion of participation, the results that will be shared with you include body weight, waist and hip measurements, and copies of your blood clinical tests, which are generated from the blood samples collected during screenings and during the final procedure stay at the CCRC. Other study results will not be shared with you, as they will generally be unavailable until the end of the 12-month study.

Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.

_____(initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____.

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Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Do not write below this line. For IRB stamp and version date only.

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