CONSENT FORM COVER PAGE

STUDY TITLE: Metabolic and Bio-behavioral Effects of Following Recommendations in the Dietary Guidelines for Americans (DGA4ME)

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Title of research study: Metabolic and Bio-behavioral Effects of Following Recommendations in the Dietary Guidelines for Americans (DGA4ME)

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California Experimental Subjects 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.

COVID-19 Safety Notice

We are making efforts to keep you and our team safe when you come to the Western Human Nutrition Research Center (WHNRC) for your study visits. We will continue to follow the policies and guidance of the United States Department of Agriculture (USDA) and UC Davis including adhering to current vaccination policies, wearing masks when indicated by policies and guidance, maintaining physical distance when possible, and reducing aerosol transmission with high efficiency heating, ventilation, and air conditioning (HVAC) filtration.

Key Information about This Research Study

You are invited to participate in a research study. You are invited to be in this study because you are 19-64 years old, are overweight or obese, and have either high cholesterol levels, high blood sugar levels or high blood pressure. The purpose of this research is to see if achieving and maintaining a healthy body weight is the main health promoting recommendation of the Dietary Guidelines for Americans (DGA) for women at risk for diabetes, heart disease or stroke. Your participation in this research will last about 11 weeks. We expect about 160 people at UC Davis will join and about 160 people study wide to participate in this research.

Participation in this study will involve anthropometric measurements (e.g. height and weight), blood

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draws, records of nutrition and food intake, health history evaluation, stress assessments, body fat assessment, blood pressure/pulse readings, saliva, stool and urine collections, liver health assessments, blood vessel health assessments, calorie need assessments, completion of various questionnaires, consumption of meals and beverages provided by the study research institution (WHNRC), and nutrition education sessions. All research studies involve some risk. Risks of this study are minimal. These risks are described in detail later in this document. There is the possibility that you may benefit from participation in this study.

Here are some reasons you may not want to participate in this research: frequent visits to the research site, likelihood of receiving the non-treatment diet, only being allowed to eat certain foods and other risks associated with the study including, physical discomfort while being weighed or measured, personal discomfort while telling the research staff about your health and nutrition history, development of medical conditions as a result of meal intake and/or physical activity, worsening of existing medical conditions as a result of dietary intake and/or physical activity, weight gain, exposure to radiation via the DXA scan (emissions approx. 0.1 mrem- not found to be harmful) and discomfort or pain during blood draws. Over the course of the study, you will have a total of 280 mL (56 teaspoons) of blood drawn, which is less than a pint.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. The only other choice is to not participate in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at
http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?

If you have any questions about this research, please feel free to contact Dr. Kevin Laugero at P: 530-752-4173 or E: kevin.laugero@usda.gov, You may also contact the Study Coordinator, at 530-316-5482 or Ellen Bonnel, Human Studies Coordinator, 530-752-4184.

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 the Internal Med Resident on- call. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at 916-703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

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How is this research funded?

This research is being funded by United States Department of Agriculture (USDA) also called the sponsor. Sponsors may change or be added. UC Davis is being paid to conduct this study. The study investigators are employees of the USDA and hold appointments with the Nutrition Department at UC Davis. Research staff are either UC Davis employees or USDA employees.

Why is this research being done?

Today, about half of all American adults—117 million people—have one or more preventable, chronic diseases, many of which are correlated to poor quality eating patterns and physical inactivity. The Dietary Guidelines for Americans are an essential resource for health professionals and policymakers as they design and start food and nutrition programs that feed the American people. The Dietary Guidelines also provide information that is intended to help Americans make healthy choices for themselves and their families. Continued research is being conducted to help inform on ways to improve strategies for reversing these diseases, and this research includes studies to better understand the role of diet and exercise as solutions for promoting health and preventing of chronic disease. The purpose of this research is to see if achieving and maintaining a healthy body weight is the most important health promoting recommendation of the Dietary Guidelines for Americans (DGA) for women at risk for diabetes, heart disease or stroke. Through your participation in this research, we expect to gain valuable information to better establish if the current guidelines provide the most helpful information for healthier living.

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

If you decide to participate in this research study, the researchers will ask you to participate in the following tasks and assessments over the course of the study:
The approximate timeline for the study is shown below.

Week #	Section of the Study	Activities	Time Frame
Week 0	In person screening (TD1)/ Informed consent process/Study orientation (TD2)		1 week
Week 1	Test Day 3 (TD3)	Pre-feeding testing	1 week
	Test Day 4 (TD4)	Pre-feeding testing	
Week 2-9	Feeding Period*		8 weeks
Week 10	Test Day 7 (TD7)	Post-feeding testing	1 week
	Test Day 8 (TD8)	Post-feeding testing	

* Week 2-9 includes Test Day 5 & 6 (TD5 & TD6) which include urine collections

<u>Test Day 1 & 2 (TD1 & TD2)</u>

Test Day 1 (TD1) is the in-person screening visit. If you meet the inclusion criteria, you will be invited

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to participate in the full study.

Test Day 2 (TD2) is an Orientation to the full study. Key aspects of the study will be explained and you will have the opportunity to practice and become familiar with the Resting Metabolic Rate, EndoPAT, and 24-hour dietary recall assessments. You will be provided instructions on collecting various specimens at home, including saliva, urine and fecal samples. Collection kits will be provided to you. We will ask you to obtain a signed release form from your physician or health care provider to ensure that you are healthy enough to start exercising. If you do not have a regular provider, we will arrange for you to have a physical exam at the WHNRC. You will be provided with an orientation to the foods in the study menus, the plan for aerobic activity (walking program) and resistance activities (using resistance bands) and an orientation to the fitness tracker that will be used in the study.

Usual activity monitoring: You will be asked to wear an Actical for one week so that we can determine your usual level of physical activity. We will show you how to place and use a physical activity monitor. This is a small device worn on the left hip, removed only in water (for example, showers or swimming). On the days you wear the monitor we will ask you to keep a simple log of the times you get up in the morning, go to bed at night, and if you take the device off for bathing or swimming.

Phase I: Diet Intervention
Test Day 3 & 4 (TD3 & TD4)

There will be two test days prior to starting the controlled diet portion of the study. The assessments are separated into two days to reduce burden.

Physical Activity: We will provide you with a Polar A370 Fitness Tracker to wear during the study. After providing training on the functions of the tracker, we will ask you to record your physical activity, starting and stopping the fitness tracker for each session. Study personnel will download data weekly when they meet you during the controlled feeding. You will be asked to walk for 150 minutes per week at moderate intensity. The 150 minutes can be accumulated throughout the week. We will ask you to do muscle strengthening activities on 2 days per week using resistance bands and body weight exercises. The study staff will provide an orientation to the study procedures.

Body measurements: Weight will be measured using a calibrated electronic scale. Blood pressure and resting heart rate (pulse) will be obtained via automated instrument and blood pressure cuff. Waist and hip circumference measurements will be measured using a measuring tape. You will have your body composition measured using a harmless, electrical current to evaluate fat mass and fat free mass. You will need to remove your shoes and socks and stand in bare feet on the instrument.

Resting metabolic rate: We will use resting metabolic rate to measure your calorie needs. We will use a metabolic cart that evaluates the oxygen you breathe in and the carbon dioxide you breathe out while resting. This assessment will involve placing a canopy over your head and shoulders while the machine collects the air that you exhale. It will be repeated on the test days before and after the feeding portion of

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the study.

Continuous Glucose Monitoring (CGM): Participation in the study will involve continuous glucose (blood sugar) monitoring using an Abbott Freestyle Libre Pro Sensor. Continuous glucose monitoring occurs via a tiny sensor inserted under the skin on the back of the arm. The sensor will measure your blood sugar levels. The sensor tests blood sugar every fifteen minutes while you are doing your normal daily activities. A trained staff person will attach the device. You will wear this for two weeks at two different time points in the study. Data will be downloaded from the monitor before it is removed. We will place a sterile adhesive dressing over the sensor to prevent it from falling off, but if it falls off, we will replace it with a new sensor to ensure data is collected.

Liver Assessment: A Fibroscan instrument will be used two times. This assessment involves ultrasound to evaluate your liver's health. You will be asked to lay flat on your back with your right hand placed behind your head. Ultrasound gel, followed by the Fibroscan probe, will be placed on your skin on the upper right abdominal area. A series of painless pulses will be applied to the area to collect information about the health of your liver. The whole examination takes less than 10 minutes.

Cardiovascular tests: An Endopat (PAT) test will be conducted three times. It is a non-invasive measurement of your overall cardiovascular health. We will put a finger "probe" on one finger of each hand and, after a 30-minute rest period, a baseline reading will be recorded while lying on your back. After this baseline reading, a blood pressure cuff will be placed on one arm, and the cuff will be tightened in a way that is similar to having your blood pressure taken; however, we will keep the cuff tight for about 5 minutes. At the end of the 5-minute period, the cuff will be released, and data collected by the finger probes will be recorded for an additional 5-10 minutes. This will complete the PAT measurement and the finger probes will be removed and discarded. The information we collect from this PAT test will help us learn more about the health of your blood vessels and how the diet might affect this. For this procedure, you will be asked to cut your fingernails on your index fingers short in order for the finger probes to fit properly.

Dual energy x-ray absorptiometry or DXA scan: You will have a DXA scan a total of 2 times. The x-ray exposure is comparable to the exposure you would receive on a cross-country airplane flight. The scan time takes less than 10 minutes for the whole body. The total radiation exposure is approximately 0.1 mrem. You may be asked to change into clothing that is free of metal such as zippers. All participants capable of becoming pregnant will be required to take a spot urine pregnancy test prior to each DXA scan. Urine samples will be collected in sterile containers provided by the WHNRC and a highly sensitive commercial human chorionic gonadotropin immunoassay will be used to determine pregnancy status. Pregnant women will be excluded from further participation in the study.

Meal challenge Test Day: The meal challenge test day will occur twice in the study. It involves periods when we collect resting metabolic rate (4 times) and blood draws (5 times). After a fasting blood draw, we will give you a liquid meal and then we will collect blood again at one, two, three and six hours after the liquid meal. The liquid meal consists of oil, sugar, egg white, and flavoring and has the consistency of a milkshake. You will be provided water to drink throughout the day.

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Specimens: The study will involve blood draws by venipuncture. A licensed phlebotomist will conduct all blood draws. Information provided from these samples give the scientists information about your cholesterol and sugar levels, genetic makeup and hormonal status. There will be a total of 10 planned venipunctures. The total blood volume collected over 7 months will be 280 mL (a little over half a pint). Additionally, if you decide to participate in this research study, you will provide multiple saliva, urine, and fecal samples. We will show you how to collect urine and fecal specimens. The urine specimens will require you to collect 12 hours of continuous urine output. During the controlled diet portion of the study, we will ask you to collect urine at home on two occasions, Test Day 5 & 6 (TD 5 and TD6). You will drop off the urine collections at your regular food pick-up. We will provide written instructions, collection kits, and a checklist to track the completion. You will be asked to provide fecal samples, collected at home and transferred to three tubes using a small scoop in the lid of each tube. At least one tube will be empty and one filled with an RNA stabilizing solution (clear liquid). Information provided from these samples gives the scientists information about your cortisol levels, intestinal microorganisms and can help verify recent meal intakes.

Questionnaires: Questionnaires will be completed throughout the study. You will complete several questionnaires about your general health, eating habits, and stress level. On Test Days 4 & 8, you will be asked about your feelings of hunger and appetite and you will record them using a touch-screen tablet. Additionally, all participants will need to provide study staff with an email address so that certain questionnaires can be emailed to you. The questionnaires may take 10-15 minutes each and will be spread out throughout the day.

Cognitive Tests: You will take a series of computer-based tests in the form of games and puzzles. They evaluate psychomotor and motor speed, reasoning and planning, memory and attention. This cognitive test utilizes Amazon Web Services for their secure platform cloud services, storing data in AWS US-East 2, Ohio, US. Data flows securely using HTTPS to/from the tablets and desktops at study site via the internet. All data are processed in accordance with regulation and transmitted via encryption, with data secured at rest. The measurement will take seventy-five minutes to complete. This will be repeated two times during the study.

Food Choice Task: This computer-based task focuses on different components of food preference. It will be repeated twice during the study.

Continuous Noninvasive Arterial Pressure or CNAP: Blood pressure will be measured continuously by a noninvasive and continuous blood pressure monitor (Continuous Noninvasive Arterial Pressure or CNAP). The first blood pressure reading will include the use of a standard blood pressure cuff and a sensor placed around the finger. For the remaining duration of the test, only the finger sensor will be used to assess arterial blood pressure, unless we need to re-calibrate the finger sensor using the standard cuff measurement. The CNAP system also allows us to assess other features of cardiovascular function from these blood pressure readings, which will include the amount of blood the heart is pumping out to the circulation (cardiac output and stroke volume), as well as fluid status. Lastly, on test days that you have the CNAP assessment, we will ask you a few questions about your last menstrual period (or if you

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have reached menopause) and if you are using any hormonal contraceptive agent.

Heart Rate Variability: Heart rate variability will also be evaluated during the study. You will be asked to wear a MindWare device, which is used to monitor heart rate and assess how the nervous system is regulating your heart beat. The 3 ½" x 4" MindWare device will be placed in a fanny pack that will be worn around your waist or hips. A trained research staff member will place the electrodes, which will be attached to your chest, back, neck, and sides. The electrodes are prepackaged electrodes with a sponge material, sticky adhesive and gel in the center. While we are collecting data using the MindWare device, we will ask you to sit quietly, resting, with minimal distractions (no cell phones, no reading material, etc.) for two 15-minute intervals. Lastly, on test days that you have your heart rate variability assessment, we will ask you a few questions about your last menstrual period (or if you have reached menopause) and if you are using any hormonal contraceptive agent.

Controlled diets:

There is an 8-week controlled diet provided by the study. All of your foods and beverages will be provided. The menus will include foods containing milk, poultry, beef, fish, shellfish, tree nuts, peanuts, wheat and soy. We will ask you to eat everything we provide and to not eat anything else. The meals will be prepared in the Metabolic Kitchen and Human Feeding Laboratory (MK & HFL) at the WHNRC, which is not a dedicated allergen-free facility. Meal pick-ups will occur twice per week during the 8-week feeding portion of the study. The food will be refrigerated or frozen and intended to be heated up and eaten on specific days. The meals will contain essential nutrients and will be tailored to your specific calorie needs. Due to nature of the study you could be assigned to a Dietary Guidelines style diet (for either weight stability or weight loss) or a typical American diet for weight loss. Your assignment will random. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study investigator will choose what treatment you get. You will have a one in three chance of being given one of these diet treatments. The "treatments" refer to the three different diet assignments that you may get during the 8-week feeding portion of the study. All other aspects of the study are the same for all participants.

Test Day 7 & 8 (TD7 & TD8)

All of the tests and measurements made during Test Day 3 & 4 (TD3 & TD4) will be repeated.

Study Payment Information:

Payment Forms: Below are forms to fill out in order to receive payment for participating in this study.

- IRS W-9 form - This form is required to collect social security number for payment and tax purposes. It will not be used for any other purpose without your permission and will be destroyed immediately after the completion of the payment.

How is being in this study different from my regular health care?

This study is not part of your health care.

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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 for:

- Arriving on time to appointments at the facility
- Following protocols prior to exams and assessments (e.g. fasting)
- Following physical activity recommendations
- Reporting all physical activity completed
- Completing consumption of feeding study foods and beverages
- Reporting all foods and beverages consumed and not consumed
- Communicating with the research team (e.g. phone calls or emails)
- Reporting any and all health concerns as a result of participation in this study
- Reporting information that will dismiss you from the study openly and honestly (e.g. pregnancy)

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study. We will ask you to come in for a final study visit to check your health and to return any research property.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and staying on the study is no longer in your best interest;
- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.
- your Body Mass Index (BMI) drops to a value of 20 during the study

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

There are risks to participating in this research. The investigators and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

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- Physical Risks
    - It is possible that you will feel too full, too hungry, or experience an upset stomach, gas, constipation, diarrhea or other gastrointestinal symptom as a result of consuming the test meals and changing your diet. These effects are expected to be temporary. - ***RARE***
    - Starting or increasing physical activity presents a risk of a musculoskeletal injury, such as a muscle strain or inflammation. However, study staff and the study coordinator will be in close communication with you throughout the study to ensure that if a problem occurs, it can be addressed. - ***LESS COMMON***
    - Weight gain – ***LESS COMMON***
    - Exposure to radiation via the DXA scan (emissions approx. 0.1 mrem). The total amount of radiation exposure is below the levels that are thought to result in a significant risk of harmful effects. - ***RARE***
    - Physical discomfort and/or pain during blood draws or with the placement of the Continuous Glucose Monitor. – VERY COMMON
    - There is a risk of infection when the skin is broken, however we will be using sterilized equipment to minimize this risk. - - ***RARE***
    - You may experience headache or dizziness from fasting for 12 hours or from not drinking caffeine – ***VERY COMMON***
    - The PAT (peripheral arterial tone) procedure to measure vascular function may cause discomfort while the blood pressure cuff remains inflated. This feeling may be similar to having your blood pressure taken for an extended period of time. - ***RARE***

    - The CNAP (continuous blood pressure monitoring) may cause some discomfort while a calibration blood pressure cuff is inflated, similar to getting your blood pressure taken at the doctor. While wearing the finger sensor may cause some discomfort when being asked to hold the hand and arm still, it is expected to be minimal discomfort. - ***RARE***
    - The MindWare device may cause minor skin irritation as a result from the electrodes being on the skin for long periods of time. While you are wearing this device, you will be monitored continuously, and if a rash emerges or you experience discomfort from the electrodes, the device will be removed. – ***RARE***
    - In addition to these risks, this research may hurt you in ways that are unknown.

- Psychological risks
    - Embarrassment or personal discomfort while answering certain sensitive questions on questionnaires. – ***LESS COMMON***

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- It is possible that you will feel disappointed if you do not get randomized to one of the diets that includes a calorie reduction. - ***LESS COMMON***
- The cognitive tests generally pose no risk, but if you have strong emotional reactions to them, you can stop the task at any time. - ***RARE***

- Privacy risks
  - Personal Identification Information (e.g. name, contact information) loss or theft – ***RARE***
- Legal risks
  - No legal risks are associated with this study.
- Social risks
  - Physical discomfort while being weighed or measured. – ***LESS COMMON***
  - Personal discomfort while telling the research staff about your health and nutrition history –***LESS COMMON***
  - Personal inconveniences from only having to eat specific meals during the 8 week controlled diet portion of the study – ***VERY COMMON***
  - Personal discomfort collecting urine or fecal samples – ***LESS COMMON***
- Economic risks
  - Need to pay for childcare when you have site visits. No children allowed in the facility. – ***LESS COMMON***
  - Occasional loss of salary when you have study visits – ***VERY COMMON***

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will record a code on the bio-specimen and information, and we will keep a link between the code and your identity in a different location.

If this consent form was emailed to you, the Study Coordinator will schedule a time by phone or video, to explain this study to you and will conduct the informed consent process. If you agree, you will sign this consent form using DocuSign, a UC Davis Institutional Review Board-approved electronic signature software. You will email this signed document back to the study coordinator. The study coordinator will then sign the document and email it back to you for your records. We will print a hardcopy of this consent form with both signatures and store it in a locked file cabinet in a locked office in the WHNRC that has controlled access (by card key) only to approved WHNRC employees working on human studies. The electronic version of the document will be deleted.

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Researchers will use your specimens for genetic or genomic testing. There is a risk that your information could become known to someone not involved in this study.

Will information or leftover specimens be used for other research?

We will keep the data we collect about you and we will keep your data and samples for an indefinite time period.

Keeping data or samples for future research is called "banking." The banked data and samples will be kept in a secure location for use by researchers.

This is what will happen with your banked data and samples:

- We will use the data and samples in other research projects.
- The data and samples may be shared with other researchers at UC Davis and with researchers outside of UC Davis.
- The banked data and samples will be labeled with a code instead of your name.
- When we give your data and samples to other investigators for research projects, they will not be able to use the code to figure out which data and samples are yours.
- The research team will maintain a link between your data and samples and your identifiable information kept by the study team.
- You can request to have your data and samples removed from the bank by contacting the research team at any time.
- You will not be given the results of any of the studies done using your banked data and samples. Also, banked data and samples will not be shared with your health care providers or used in your treatment outside this study.

Please initial one of the lines below to indicate whether or not you agree to the optional data and samples banking:

____ Yes, I agree to have my data and samples banked for future research purposes.

____ No, I DO NOT agree to have my data and samples banked for future research purposes.

Will genetic research be done as a part of this study?

Some of the tests we will perform on your blood will be genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be.

We will do whole genome testing for this study. Your "genome" is the complete DNA instruction book. "Whole genome testing" means making a list of the entire order, or sequence, of the DNA in your genome.

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The DNA samples and information sent to other researchers will not include personal information like your name or your birthdate. However, even without your name or other identifiers, your genetic information is unique to you, like a fingerprint. Scientists expect that over the next few years, researchers will be able to look at your genetic information and be able to trace the data back to you (and potentially also to your blood relatives).

There may be other risks related to genetic testing that we don't know about right now. This is because the field of genetics is moving forward very quickly.

Will My Genetic/Genomic Data Be Shared With Repositories?

At some point in the future, we may be required to share genetic data with federal repositories. Because this research receives funding from a federal sponsor, we will submit your genomic information to a public repository approved by the National Institutes of Health(NIH). NIH is a national research agency and is part of the federal government. The NIH and other central repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body.

These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at UCD. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

What about Birth Control?

Women who are pregnant, planning to become pregnant within the duration of the study or breastfeeding are not permitted in the study. If you feel birth control methods are anticipated to affect your nutrition or physical activity, let the research team know as soon as possible.

Contraception Requirements for Women

The study radiation emitted from the DXA scan may harm a fetus. If you are pregnant, you cannot take part in this study. If you think you may be pregnant, you should not volunteer for this study. If you are able to become pregnant, you must have a pregnancy test before you begin the study and while you are in the study. You will be evaluated for pregnancy with a urine test upon arrival to the facility for your first test day. Urine samples will be collected in containers provided by the facility and a highly

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sensitive, commercial human Chorionic Gonadotropin (hCG) immunoassay will be used to determine your pregnancy status. You must not get pregnant or breastfeed while you are in this study. If you are a woman who can become pregnant, you must take measures to avoid becoming pregnant while you are in this study. The following are acceptable measures to avoid becoming pregnant:

One of the following forms of birth control should be used:

- Abstinence (not having sexual relations with a person of the opposite sex)
- Implantable hormone (e.g. Norplant)
- Intrauterine Device
- Male partner must have a vasectomy
- Female sterilization
- Hormonal injection
- Oral contraceptives

Will being in this study help me in any way?

Being in this study may not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about the factors that contribute to successful weight management. The following are potential benefits to you as the participant, they include weight loss, learned knowledge about nutrition, physical activity and healthy living, information regarding your current health and nutritional status, and health benefits associated with increased physical activity.

Will being in this study cost me anything?

You will have to pay for basic expenses like any childcare (if with children) and transportation related to facility visits.

Will I be paid or receive anything for being in this study?

We will pay you $730.00 for completion of the study. Payment will be provided at the end of your participation in the study in the form of electronic funds transfer. If you complete all the study visits, you will receive $730.00 for being in this study. If you choose to leave or we take you off the study for any reason, you will receive a pro-rated amount based on time dedicated and tests completed in the study. The compensation pro-ration will depend on the individual task and the number of tasks completed. If you have any questions regarding compensation, please contact the study coordinator.

You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for participating in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

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Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UC Davis Health, your local provider, or emergency services.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency issues, you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the Internal Med Resident on-call.

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the 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 contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity but the link will be kept in a location that is separate from your study data, we will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

While this study does involve banking the data and/or specimens we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data or specimens to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data or specimens in additional research.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state

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laws may permit or require us to show information to university or government officials and to the United States Department of Agriculture responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study
- U.S. Office for Human Research Protections
- The study sponsor, the United States Department of Agriculture (USDA)

A description of this clinical trial will be available on http://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.

Will I receive any results from this research?

Results of the fasting blood analyses performed at the UCDMC CLIA-certified laboratories (clinical chemistry panels, lipid panels) from the screening appointment will be shared with you upon completion of the study. We will be sharing anthropometric data with you including weight, height and body fat% analyzed by the InBody or DXA scan technology. Additionally, the participants will receive information on the results of their continuous glucose monitoring and resting metabolic rate.

Will information or leftover specimens be used for other research?

During this research, the study team will obtain information about you. They will also collect biological specimens from you such as blood. The information and specimens will be used for this research and may also be used for other research studies here at UC Davis. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

May we contact you by e-mail?

We are requesting your email address so we can monitor your participation in the study, evaluate and encourage diet adherence, answer questions, provide nutrition materials and remind you of upcoming appointments. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Study Coordinator at 530-316-5482. You do not have to provide your email address to participate in this study. Please initial one of the lines below.

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_____ Yes, may use email to contact me for this study. My email address is: _____

_____ No, I do not want to be contacted by email.

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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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	

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