

***Title of research study: USDA WHNRC Nutritional Phenotyping Study***

***Investigator: Charles B. Stephensen, Ph.D. and John W. Newman, Ph.D.***

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

We invite you to take part in this research study because you are a generally healthy man or woman, age 18-65 years, with body mass index 18.5-39.9 kg/m<sup>2</sup>.

## ***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.
  - Medical treatment, if any, that is available for complications.
- 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, complaints, or think the research has hurt you in any way, please contact the research team: study coordinator: Eduardo Cervantes at (530) 754-8544, principal investigator: John Newman, Ph.D. at (530) 752-1009, or principal investigator: Charles Stephensen, Ph.D. at (530) 754-9266.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand scientific research is available on-line at

<http://www.research.ucdavis.edu/policiescompliance/irb-admin/>. You may speak directly with an IRB staff member at (916) 703-9151, [IRBAdmin@ucdmc.ucdavis.edu](mailto:IRBAdmin@ucdmc.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 addressed by the research team.
- You cannot reach the research team.

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Document Revision Date: August 15, 2014

- You want to talk to someone other than 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?***

We are investigating a number of processes going on in the body. These processes include: the production of key hormones, the metabolism of fats, proteins, and carbohydrates from food, the conversion of food to energy, immune system function, and cardiovascular health. Together, these processes make up your ‘metabolic phenotype.’ In order to get a whole-body assessment of these processes, we will examine breath, saliva, blood, urine, and stool samples. We will also assess lifestyle characteristics such as diet, physical activity, stress, sleep, and tobacco use. We hope to discover new factors or combinations of factors that might serve as indicators of health.

## ***How long will the research last?***

We expect that you will be in this research study for approximately 2 weeks. You will be asked to complete scheduled testing at our research center for one half-day visit and one full-day visit.

## ***How many people will be studied?***

We expect about 436 people to enroll in this study.

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

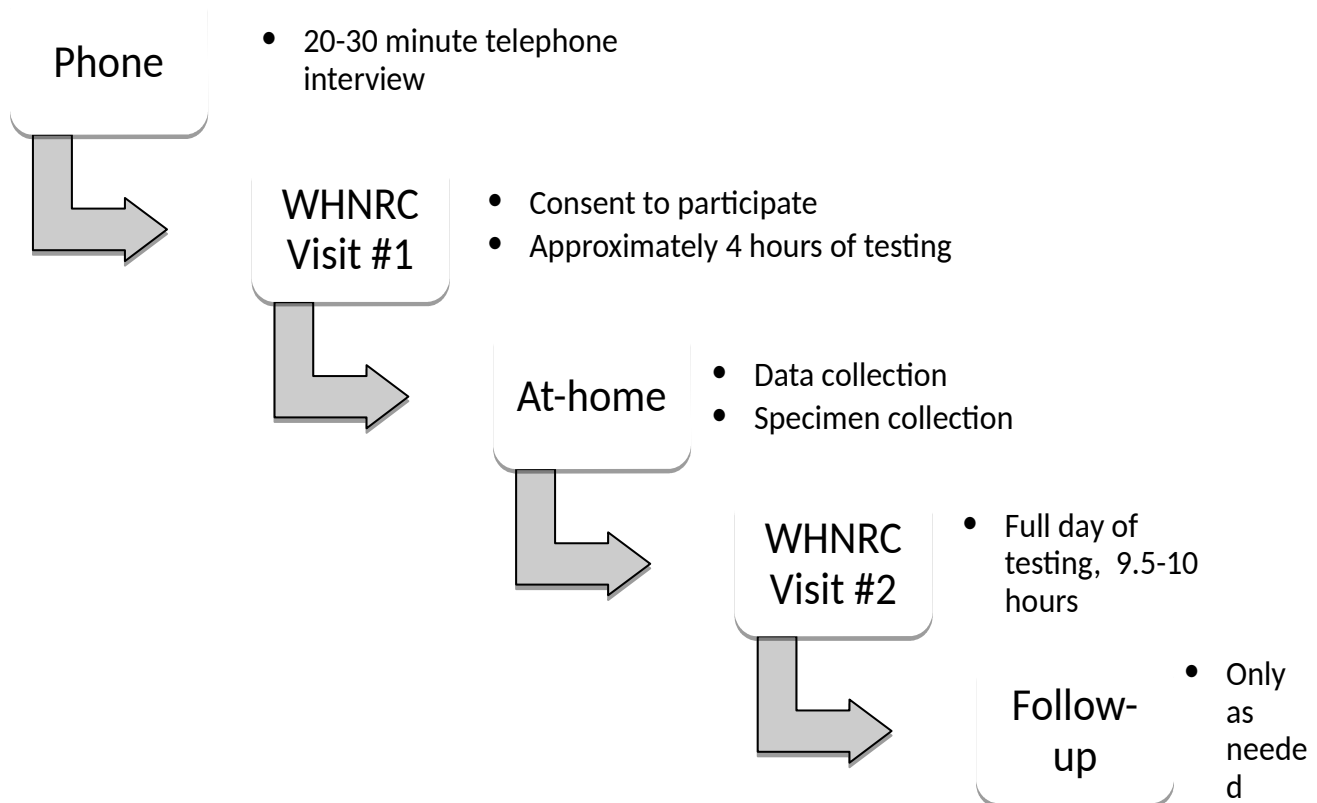
If you decide to take part in this study, you will be asked to come to the Western Human Nutrition Research Center (WHNRC) on the UC Davis campus (430 West Health Sciences Drive, Davis CA 95616) to have the study fully explained to you, to ask questions, and to provide your consent to participate using this consent form. After you consent, the schedule of questionnaires and other procedures will begin.

The following procedures will be done only **IF YOU DECIDE TO JOIN THE STUDY.**

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### Overview of contact between participants and study personnel



### List of scheduled procedures

#### List of procedures on WHNRC Visit #1

1. Consent to participate
2. Heart rate, temperature, blood pressure measurement
3. Females only: urine pregnancy screening test
4. Height, weight, hip and waist circumference measurement
5. Dual energy x-ray absorptiometry scan: total body, femur, and spine
6. Saliva collection (5 times)
7. 3-minute Step test activity with heart rate monitor
8. Demographic questionnaire
9. Physical activity recall questionnaire
10. Training: at-home recall of 24-hours of food intake
11. Training: accelerometer use, urine, and stool collection
12. Pulmonary function test
13. Cognitive Test #1

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## List of procedures for WHNRC Visit #2

1. 12-hour fast
2. MindWare® electrical system (all-day use)
3. Resting metabolic rate (4 times)
4. Breath collection (hourly, up to 9 times)
5. Saliva collection (up to 10 times)
6. Blood collection (4 times)
7. Hunger and appetite report (11 times)
8. Liquid meal
9. Food behavior questionnaire
10. Food choice questionnaire
11. Cognitive test #2, computer-based game
12. Food frequency questionnaire
13. Emotional response task
14. Eating factor questionnaire
15. Skin reflectance measurement
16. Chronic sources of stress questionnaire
17. Food Preferences activity
18. Discussion of follow-up, if needed (to be completed at home)
19. Snack
20. Cognitive test #3
21. EndoPAT vascular function test
22. Sweet, salty, and bitter taste tests
23. Multiple rest periods, which are scheduled throughout the day
24. Removal of Mindware®
25. Departure

## **Procedure Descriptions**

### Screening Process (20-30 min)

Eligibility for enrollment in the study will be determined by verbal completion of the eligibility screening questionnaire with a trained study staff member. An in-person visit will be scheduled (ideally within the next 1-4 days) based on your availability and USDA WHNRC capacity.

### WHNRC Visit #1 (approximately 3-4 hours)

You will be invited to the USDA WHNRC to review all aspects of the research study with qualified study personnel and provide written consent to participate. After consenting, we will measure your heart rate, temperature, and blood pressure, height, weight, hip and waist circumference.

You will be asked to complete 2 questionnaires: demographics and a brief physical activity recall, requiring about 10-15 minutes total.

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You will be asked to complete a 3 minute step test. A 10-12 inch box will be used as a step and you will be instructed to step up with one foot, bring the second foot up to match it, step down with the first foot and bring the second foot back to floor. Steps will be timed to the rhythm of a metronome so that you complete 24 step-ups per minute. After each minute you will rate your level of exertion using a standard scale. After stepping for 3 min, you will be asked to sit and recover. An electronic heart rate monitor will measure your pulse.

We will collect saliva using a sterile swab (1-2 minutes each) at 5 different time points.

You will have a full-body scan using dual energy x-ray absorptiometry (DXA). After the full body, there will be two site-specific scans: one of the femur bone in your upper leg and one of your spine to determine bone mineral density. 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, and about 5 additional minutes for each specific site. The total radiation exposure is approximately 1.0 mrem. All female participants will be asked to report the first day of their last menstrual period and required to take a spot urine pregnancy test prior to the scan, except in cases of reported hysterectomy or self-reported menopause, to be used as a screening to prevent radiation exposure in pregnant women. 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.

We will train you to complete at-home dietary recalls of your food intake over the past 24 hours. We will show you how to place and use a physical activity monitor and how to collect one stool specimen and 12 hours of urine output. We will provide written instructions, collection kits, and a checklist to track the completion of at-home tasks.

There will be a pulmonary function test, for which you will be asked to breathe in deeply and exhale as hard and as fast as you can into a sterile mouth piece attached to a measuring device called a spirometer. The test takes approximately 5 minutes.

Lastly, you will be asked to perform a task that involves recognizing vocabulary, images, patterns and similarities between things. The test takes approximately 30 minutes to complete.

#### At-home data and specimen collection (approximately 2 hours)

We ask that you wear a physical activity monitor (accelerometer) for approximately 1 week prior to your 2<sup>nd</sup> study visit day. 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.

We will also randomly select 3 days during the 10-14 days after your enrollment visit for you to complete a 24-hour dietary recall online (you can come in to the WHNRC to complete these, if you prefer). You will need to provide a stool sample, collected and stored on ice in a provided kit and also a 12 hour urine collection begun on the evening before your scheduled study visit. This way, you can bring the stool and urine specimens with you to the research center and avoid any extra trips.

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Lastly, you will be provided foods to consume by 6:00 pm the night before your scheduled Visit #2. Please consume all of this food, nothing more and nothing less, except for water. Water should be consumed according to your normal intake amount throughout the evening.

WHNRC Visit #2 (approximately 9.5-10 hours)

You will be asked not to eat or drink anything, except water, for 12 hours prior to the study visit. You will arrive at the USDA WHNRC by 6:45 am and stay until 4:30 pm.

We will place an electrode system (MindWare®) on your torso and one hand which will remain in place for the entire day. Men may need to shave sites on the torso at home prior to arriving: left and right collarbone areas, sternum, bottom of the neck right above shoulders, middle of back on spine at lower rib, right and left lower rib; please refer to the diagram provided and prepare sites before your arrival. In the event that electrode placement sites require additional hair removal, we will provide electric hair clippers for shaving on-site. We will provide a medical scrub top for you to wear during your visit, which may be more comfortable for you and will allow a study technician to apply electrodes to your upper body. Electrodes will also be placed on one of your hands. You will not be able to wash this hand with water while the electrode is in place. Sanitizer and sanitizing wipes for your hands will be provided for you to sanitize your hands around the electrodes.

Your resting metabolic rate will be measured 4 times by breathing normally into a face mask fit snugly over your mouth and nose for approximately 15 min.

You will be asked to consume all of a provided liquid meal around 8:00 am and will be provided a snack in the afternoon, around 2:30 pm. The liquid meal consists of oil, sugar, egg white, and flavoring. After the meal, you will be given a small volume of fresh water but you will be restricted from additional water intake until the blood draw 30 min later. After this blood draw, fresh water will be continually available for you throughout the remainder of the day.

Hourly breath samples will be collected by breathing normally into a bag for 1-2 seconds. Saliva will be collected 10 times using a sterile mouth swab for 1-2 minutes.

Blood samples will be collected four times throughout the day. The first (fasting) sample will be the largest sample and no more than 10 tablespoons will be collected. The remaining 3 blood draws will be no more than 5 tablespoons of blood each; the total blood drawn will not be more than 300 mL or 1.3 cups. The blood samples will be used to measure a standard clinical chemistry panel, lipid panel, complete blood count, and several other indicators that may change with diet.

Throughout the day, you will be asked 11 times about your feelings of hunger and appetite and you will record them using a touch-screen tablet. You will also complete several questionnaires about your general health, eating habits, and stress level. The questionnaires will take about 10-15 minutes each and will be spread out throughout the day.

There will be 2 additional cognitive tests during the day. The first activity asks you to complete a decision-making game on the computer and takes approximately 30 min. The second task also involves

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simple tasks on a computer. A trained study staff member will guide you through about 45 minutes of activities, covering several different modules.

One task is designed to elicit an emotional response for no more than 5-10 minutes. You will be asked first about your current mood and then to perform recall tasks of a specific event that is currently unresolved for 5 minutes. After recalling the event, you will again be asked about your mood state.

We will measure the light reflected from your skin (due to skin pigmentation) to determine how easily vitamin D is made in your skin. People with lighter skin make more vitamin D after the same sun exposure than do people with darker skin. Three measurements will be taken (on the inside of the upper arm, on the back of the hand, and on the middle of the forehead) in a private exam room using a hand-held device. Each measurement takes about 10 seconds. A small (the size of a dime) window on the instrument touches your skin, flashes light like a camera flash, and measures the light reflected from your skin.

A standard snack will be provided in the afternoon and you should consume all of it. The snack does not contain any of the major allergens.

To measure your vascular function, we will conduct an EndoPAT test. The test consists of placing a blood pressure cuff on one of your arms and sensors on your index fingertips. You will have to cut your fingernails on your two index fingers short for this test. You will rest for 15 minutes before the test. The blood pressure cuff will be inflated and kept tight for 5 minutes, then released to record the measurement for another 5 minutes, you will be asked to lie as still as possible for all aspects of this test.

If there is any follow-up needed, in order to complete the at-home data or specimen collection, we will explain and provide materials for these activities.

Lastly, we will evaluate how sensitive you are to sweet, salty, and bitter tastes by having you taste solutions of each flavor dissolved in water. You will taste a few drops of each solution, spit out what you tasted, and rinse your mouth with water before tasting the next sample. The amount of table sugar in the most concentrated sugar solution will be about the same as that found in regular sodas. The amount of salt in the most concentrated solution will be about 10 times that found in chicken broth. We will also evaluate how sensitive you are to a bitter taste by having you taste solutions of caffeine dissolved in water, using the same taste, spit and rinse procedure as above. The amount of caffeine in the most concentrated solution will be similar to the amount in brewed coffee. These taste tests will take about 20 minutes.

At the end of the visit, around 4:30 pm, you will be given a take away meal as a thank you. You do not have to eat the meal as part of the study.

One blood sample will be used for DNA isolation. Your DNA will be analyzed to look for genetic changes that might be associated with all clinical traits collected in the study. These include: body mass, body weight, satiety, blood levels of metabolites and dietary patterns, among others by a scientific approach known as Genome Wide Association (GWAS).

A genome-wide association study (GWAS) is an approach used in genetics research to associate specific genetic variations with particular diseases. The method involves examining genetic variations

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(genotypes) across the complete sequences of DNA, or genomes, of many different people to find genetic variants associated with a disease or trait (phenotypes). Researchers can use the information to better understand how genetic variation affects the normal function of genes, in addition to helping develop better disease prevention strategies.

The human genetic library contains millions of genetic markers; only some of these are associated with disease. Technology has advanced such that we can now search the entire human genetic library for all possible genetic markers that might be related to a specific condition. An outside lab designated by the USDA-ARS will search the entire human genetic library of markers using your DNA sample in order to reduce the number of possible markers associated with phenotypes collected in this study from several hundred million down to those most likely to be associated with that phenotype (i.e. Obesity). Then we will perform more analyses to deduce which of those markers are actually associated with disease. Your coded genetic information and information from more detailed analysis of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from the Department of Agriculture- Agricultural Research Service (USDA-ARS).

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. If you agree to take part in the Phenotyping study, some of your genetic and health information might be placed into one or more scientific databases in order for researchers to be able to share information and learn even more about health and disease. There are many different kinds of scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply to and get permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Follow-up (0-7 days, as needed per individual)

There is no follow-up required except in the event that you were unable to complete the at-home data or specimen collection.

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

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

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

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

If you decide to leave the research, please contact the investigator so that the investigator can cancel your scheduled visit(s) and/or collect any equipment you have been given.

Data that has been collected during your time enrolled in the research study will be used for its intended purposes, when possible.

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

There is a small risk of loss of balance, dizziness, or shortness of breath and discomfort associated with an increase in heart rate, increased body temperature, and sweating that could result from a 3 min physical fitness test (YMCA Step Test). Individuals with knee or hip pain, injuries, or weakness should not participate in this particular test. The YMCA Step Test is a low stress physical fitness assessment but may present additional risks to individuals in very poor cardiovascular health or with undiagnosed cardiovascular risk factors such as family history of heart disease, hypertension, high cholesterol, diabetes, harmful use of alcohol, tobacco use, stress, physical inactivity, obesity or an unhealthy diet. Before you perform the test we will evaluate your risk level by asking you questions about your health and symptoms related to heart disease. It is very important that you answer these questions as truthfully as possible to avoid serious adverse events. If our staff determines that you are in a high risk category, we will not do the test. Potential cardiovascular-related serious adverse events include stroke and heart attack, which could result in death.

To measure body fat, muscle, and water, we will use a dual energy x-ray absorptiometry. This device scans your body using a low-dose radiation exposure that in total will be similar to the amount of ionizing radiation you would receive on an airplane flight across the US. The amount of radiation exposure received in this study is below the level known to result in a significant risk of harm. Female participants will be asked to complete a urine pregnancy test before the scan. Pregnant women may not participate in the scan because the radiation may pose risk to the fetus. Pregnant women will not be included in the study.

There is a small risk of faintness, dizziness, or difficulty breathing during the pulmonary function test. A qualified physiologist or nurse will perform and monitor this test.

At-home collection of urine and stool samples may be inconvenient and may be viewed as distasteful and/or burdensome. We will provide you with medical grade latex-free gloves and plastic bags to be used as a protective barrier in collection and handling of the samples.

You will be asked to fast for 12 hours before the second study visit day. You may experience a headache, feelings of hunger or low energy as a result of fasting or lack of caffeine.

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We will continually monitor your heart rate and nerve conductance using an electrical device. Electrodes will be placed at several points on your torso and on one hand. Men may be asked to shave sites on the torso in order to apply the electrodes. We ask that shaving be performed at home prior to arrival for the study visit, but in some cases, additional hair removal may be required for proper placement of the electrodes. We will provide electric hair clippers that have been disinfected with benzalkonium chloride (Benz-all ®), an instrument disinfectant used in dentist and physician clinics. There is a risk of infection, including methicillin-resistant *Staphylococcus aureus* (MRSA) that could result from sharing personal items such as electric hair clippers that have been in contact with infected skin. Participants may decline the use of hair removal tools.

Each placement site will be cleaned immediately prior to electrode placement using single-use alcohol prep pads. There is a small risk of stinging that may occur as a result of alcohol exposure to a skin abrasion.

There is a small risk of skin irritation that may result from the electrodes being in contact with your skin for an extended period of time. You will be monitored continuously and if a rash develops or you experience excessive discomfort from skin irritation, the device will be removed. There is a small risk of pain or discomfort during removal of electrodes due to the adhesive material on the skin.

The measurement of metabolic rate uses an air collection mask that fits snugly over the nose and mouth. This may create a feeling of claustrophobia in some individuals. Participants may request that the mask be readjusted or removed at any time.

There is a small risk for bruising as a result of blood sample collection. During the blood drawing procedure, there is the possibility that you might experience some momentary pain or stinging sensations or bruising, or very rarely an infection around where the needle was inserted. However, blood will be taken only by experienced and licensed staff, and sterile methods will be used at all times.

There is a small risk of discomfort that might arise when participants consume the liquid challenge meal prepared by the research Metabolic Kitchen and Human Feeding Laboratory. Participants may not like the taste or consistency of the liquid meal, or it may make them temporarily feel overly full. The intake of a novel or unusual food may temporarily upset the gastrointestinal tract. All study foods were designed by a Registered Dietitian and are ovo-vegetarian. **Note: The WHNRC Metabolic Kitchen and Human Feeding Laboratory is not an allergen- or gluten-free facility; we cannot ensure no cross-contamination of study foods with allergens.**

It is possible that you may experience temporary distress while completing questionnaires that ask about personal information, stressors, or emotions or that pose intellectual challenges. You may choose not to answer certain questions or to end participation in any test activity that causes you excessive distress. If you experience distress, please tell the investigator. The investigator will give you a list of local resources for stress management, psychotherapy and psychiatric crisis lines, if the need arises.

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During the 5-10 minute emotion-inducing recall task, there is the possibility of psychological or emotional distress related to memory of the experience.

The EndoPAT procedure to measure cardiovascular function involves discomfort that may result from the inflation of a blood pressure cuff around the upper arm to stop blood flow to the hand for 5 minutes. You may experience transitory tingling or a loss of sensation in the selected arm. There is also a risk of psychological or emotional distress resulting from the procedure. You will be continuously monitored during the challenge.

There may also be risks to your privacy. The research team will limit the collection of personally identifying information on the study visit days and your forms will be identified only by a randomly generated participant identification code. Your blood and other samples will be labelled with participant identification code which will allow the researchers to link your sample to the other information that you provide through questionnaires or other study activities. The key to the code linking you to your samples ,including DNA, will be maintained in confidential files and will be stored in a locked file in a locked and secure location. The key to the code will never leave Western Human Nutrition Research Center. Some of the tests performed on your samples may be done by affiliated researchers or laboratories outside of Western Human Nutrition Research Center, but they will never know who you are or have access to the code linking samples to you. Your date of birth will only be used to calculate age and none of the data collected beyond the initial screening interview will be identified by your name. However, just like with other personal information kept by your health care providers, banks, and others, even these safeguards cannot guarantee absolute protection of the data. Although rare, there are reported cases of breaches that have resulted in discrimination in insurance or employment. Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study coordinator about any questions or concerns you may have.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group 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 when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

For more information about risks and side effects, contact the research study team.

### ***Will being in this study help me in any way?***

We cannot promise any benefits to you or others from your taking part in this research. We will provide body composition data (distribution of body fat and lean tissue) resulting from the full-body scan and bone mineral density from the site-specific scans, which may be of personal interest to you. In addition, we will provide summary reports of your measured resting metabolic rate, recorded physical activity energy expenditure, and nutrient intake over the past year based on the dietary information you provide throughout the study. Genetic data will not be returned to participants. We anticipate that results from this research will help inform future dietary guidelines for Americans.

### ***What happens to the information collected for the research?***

Efforts will be made to limit use or disclosure of your personal information (see description above), 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 United States Department of Agriculture (USDA), who sponsors this study, may have access to your participation records.

If specimens, such as blood or biological samples, are collected from you for this study, they will become the property of the USDA. 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 USDA 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. Your samples and genetic information may be used for research for many years in the future by the USDA or designee.

**If you agree that biological specimen(s) collected from you may be shared or used in other research, please initial here:** \_\_\_\_\_

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Otherwise, your specimen will be destroyed at the end of this study.

**If you agree that Genetic Data collected from you may be shared or used in other research, please initial here:** \_\_\_\_\_

Otherwise, your genetic data will not be used for this study.

You can decide later to withdraw permission for future data or specimen use. If you decide to withdraw permission for data or specimen use, you must notify the USDA investigators or study coordinator in writing. In this case, your data will not be used for future research, but data that has already been distributed to researchers or deposited in a repository cannot be retracted.

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

## ***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 health risks, an inability to complete critical study components, lack of cooperation with study personnel, etc. 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 United States Department of Agriculture (USDA), also called the sponsor. Sponsors may change or be added.

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 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.

If you volunteer to take part in this study, you will be compensated by check up to \$250, if you complete all aspects of the study, for your time and effort. Should you choose to withdraw from the study or are unable to complete all procedures, your compensation will be pro-rated to reflect your time and effort contributed. The rate of pay offered is scheduled as follows:

<u>Visit or Task</u>	<u>Hours</u>	<u>Compensation</u>
Enrollment visit (half-day)	3	\$45.00
Study visit day (full-day)	10	\$150.00
At-home 24 h diet recall x 3	2	\$30.00
Return of equipment	n/a	\$25.00
<b>Total</b>	Approximately 15	\$250.00

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You will be asked for your social security number or Taxpayer ID number (TIN) for payment purposes. It will not be used for any other purpose without your permission.

The results of this study, including specimens collected, may have commercial value to the sponsors, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

***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: \_\_\_\_\_.

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

For IRB Use

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
691654	March 14, 2017