Official Title: Modeling the Epidemiologic Transition: Energy Expenditure, Obesity and Diabetes

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LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
DEPARTMENT OF PREVENTIVE MEDICINE AND EPIDEMIOLOGY

INFORMED CONSENT

Participant's Name: _____

PROJECT TITLE: Modeling the Epidemiologic Transition: Energy Expenditure, Obesity and Diabetes

THE APPROVAL FOR THIS PROJECT EXPIRES ON 01/16/2020.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. You will not benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If we learn new information that would be important to you, you will be notified.

The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF STUDY: The Loyola University Medical Center is conducting a research project to collect information about physical activity, diet, skin pigmentation and vitamin D status to determine how these factors and genetic factors involved with skin pigmentation and vitamin D levels are related to risk of obesity, diabetes and bone health.

The research is sponsored by the Department of Preventive Medicine and Epidemiology, Loyola University Medical Center, and about 675 men and women will participate. Components of this project are also being conducted by researchers at the University of the West Indies, Kingston, Jamaica; Kwame Nkrumah University of Science and Technology, Ghana; Ministry of Health, Victoria, Seychelles, and the University of Cape Town, Cape Town, South Africa.

DESCRIPTION AND EXPLANATION OF PROCEDURES: You are eligible to participate if you are African American, between the ages of 30 and 50, and do not have a disability that prevents you from being fully mobile.

You may not participate if you are pregnant or nursing.

Your participation in the study will initially last 8 days; you will be contacted for a follow-up visit each year for two years from your initial visit. Your participation in the 1-year follow-up visit will also last 8 days.

Procedures for Initial Visit:

Time Involved:

Day 1 – you will be at the clinic for about 2 hours
Day 8 – you will be at the clinic for about 45 minutes
1 year later – Day 1 you will be at the clinic for 45 minutes
1 year later, Day 8 – you will be at the clinic for about 15 minutes

During the Initial Visit:

1. We ask that you arrive at the clinic after not eating anything from 10 pm the evening before your visit.

2. We will ask you about foods you have eaten in the last 24 hours. We will also ask you about your activity patterns.

3. We will take the following body measurements: height, weight, blood pressure, waist, hip, and percent body fat. Body fat will be measured by bioimpedance analysis. With this method, we place 4 patches on the hands and feet and apply a small amount of electricity to measure the amount of water in the body. This test does not cause any pain or discomfort.

4. Two tablespoons of blood will be drawn to measure substances in the blood that may be related to diabetes, nutritional status and bone health.

5. You will be asked to provide a urine sample. We will use this urine sample to check your kidney function.

6. You will have a complete bone scan using a dual x-ray absorptiometry instrument. If you are a woman, you will be asked to take a pregnancy test and will be excluded from the bone scan if you are unknowingly pregnant.

7. You will be given a small vial in which you will be asked to produce approximately 1ml of unstimulated saliva.

8. We will measure your skin pigmentation using a handheld DSM II ColorMeter at the inner upper right and left arms.

9. You will be given a stool collection kit and the clinic staff will detail the collection method. You will be instructed to provide the sample in the preceding 24hrs prior to your second clinic visit.

10. You will be given a 24-hour urine collection kit and will be instructed to start the urine collection while still at the clinic. Clinic staff will arrange to pick up the urine collection or to have you drop it off at the clinic.

11. An Actical activity monitor will be strapped around your waist by a staff member. This monitor is the size of a watch and is attached to an elastic belt. The activity monitor measures physical activity patterns. You will be instructed to wear the monitor at all times during the next 7 days, including during the night unless you are unable to sleep with it on. You will be asked to remove the monitor for bathing and swimming and to avoid completely submerging the monitor in water.

12. You will be given a light snack and may leave the clinic.

After the First Visit:

After the first night, a staff member will call you at a phone number you provide to insure that you are comfortable with the monitor and to answer any questions you may have.

7 days later (Day 8): You will be asked to return to the clinic. You will have your weight measured, the activity monitor will be removed, and you will be asked about the foods you have eaten in the previous 24 hours.

1 year later (Day 1): You will be contacted and asked to return to the clinic. We will measure your weight, blood pressure, waist, hip and percent body fat. We will strap an activity monitor around the waist. We will also ask about your activity patterns.
1 year later (Day 8): You will be asked to return to the clinic to have the activity monitor removed.

RISKS/DISCOMFORTS: There are no risks with having your percent body fat measured. In addition, there are no risks from wearing an Actical activity monitor. You may experience a minor and temporary discomfort and bruising at the site of the blood draw. There is a small risk of radiation exposure associated with the bone scan. Prior to the scan, female participants will undergo a pregnancy test and pregnant women will be excluded from the scan. The radiation exposure with a bone scan is much less than radiation absorbed by a passenger on a roundtrip cross-country air flight. There are no risks associated with using handheld DSM II ColorMeter in measuring skin pigmentation. If you have a pacemaker, you will be excluded from having your body fat measured and from the bone scan.

REPRODUCTIVE/SEXUAL ACTIVITY INFORMATION: If you are a woman, you will be asked if you are pregnant or nursing at the start of the study. If you are, you will not be able to participate. If you become pregnant at a later point in the study, it will not affect your ability to continue participating. When it is time for your follow-up exams, the research staff will contact

you and will ask if you are pregnant or have given birth within the last 2 months. If either is true, they will change the appointment for your next exam to approximately 3 months after childbirth.

BENEFITS: Your participation will help us better understand the relationships between physical activity, diet, skin pigmentation, vitamin D levels and risk of diseases such as obesity and diabetes among African Americans. Furthermore, it will help us better understand the relationships between genetic factors involved with skin pigmentation and vitamin D levels on one hand and risk of diseases on the other. It is unlikely that you will benefit directly from being in this research project. We will notify you if the blood test indicates high blood sugar or fat, or if your blood pressure is high. We will also provide you the results of your bone scan and if you have an increased risk of kidney disease based on results from your blood test.

ALTERNATIVES: Taking part in this research is totally voluntary. Your decision about whether or not to participate will not affect your care and treatment at Loyola University Medical Center.

FINANCIAL INFORMATION:
To compensate you for time spent in the study, you will be given $75.00. Compensation will be provided at the clinic on Day 8. You will be given $20.00 for the time spent in the study for the 1-year follow-up study.

You will not be charged for any of the research activities in this study.

RESEARCH RELATED INJURY: If you are injured from participating in this project, the doctors will take the necessary steps to diagnose and treat the condition. You will be responsible for the cost of the care of the problems.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you and your test results. The information will be collected by Dr. Luke, the study physician(s), the research nurses, data administrators and secretaries. Information about you will be provided to Loyola University of Chicago, the National Institutes of Health (the research sponsor), its data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration. In this way we will learn about the relationship between physical activity, diet and risk of diabetes, obesity and bone health. The information we will collect and send includes:

- X DEMOGRAPHIC AND QUESTIONNAIRE INFORMATION (e.g., name, address, phone number, physical activity patterns and foods eaten)
- X PHYSICAL ACTIVITY MEASUREMENTS
- X BODY MEASUREMENTS (e.g. blood pressure, weight, height, waist, hip, and percent body fat)
- X RESTING METABOLISM MEASUREMENT
- X URINE AND BLOOD SAMPLES

X SPUTUM SAMPLE

X SALIVA AND STOOL SAMPLES

X BONE MINERAL DENSITY

X SKIN PIGMENTATION

We will collect and provide this information about you for as long as you are in the study which will be about 5 years. Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor, the National Institutes of Health, research nurses, its data collection and/or study verification agencies, data administrators or staff or other National Institutes of Health staff will come to Loyola University Medical Center ("LUMC") and view the research records. They may take notes or copy pages of the research record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw from the study we will ask that you sign the form attached to this consent and send it to Dr. Luke or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the National Institutes of Health may terminate the study at any time with or without your consent. Your study doctor may choose to take you out of the study because of unexpected or serious side effects.

CONSENT

I have fully explained to _____ the nature and purpose of the above described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-327-9018.

_____ _____

(Signature) Date

Dr. Amy Luke, who is the principal investigator for this study, or her associates will be available to answer any questions you may have. Dr. Luke can be reached at: 708-327-9018.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Dr. Kenneth Micetich, Chairman, Institutional Review Board for the Protection of Human Subjects-Medical Center (708-216-4608).

Although you have the right to revoke this authorization except that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:_____

(Signature: Participant)

_____Date:_____

(Signature: Witness)

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REVOCATION OF AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study, *Modeling the Epidemiologic Transition: Energy Expenditure, Obesity and Diabetes,* at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to the National Institutes of Health as outlined on the consent form, which I signed on _____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:_____
(Signature: Participant)

Please return this form to:

Amy Luke, PhD
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153