V. 12-2019

#PBRC 2020-012

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT
INFORMED CONSENT - PART I

Title of Study: Evaluation of the accuracy of a computer vision-based tool for assessment of total body fat percentage

Study Sponsor: Amazon Corporation

Key Information:

- **Why am I being asked to review this form?**
  - You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.
- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this research study is to develop practical tools that can be used by clinicians to better predict the risk of a patient developing heart disease or diabetes.
  - Your expected time in this study will be approximately 3 hours consisting of 1 study visit.
  - The procedures involved in this study include:
    - bioimpedance analysis (BIA)
    - dual-energy x-ray absorptiometry (DXA)
    - BodPod
    - body circumferences and lengths (by tape measure and two- and three-dimensional [2D, 3D] imaging)
- **What are the possible risks and discomforts?**
  - Circumferences with tape measure and imaging devices - There are no known risks associated with the tape measure nor the 2D and 3D imaging devices.
  - Bioimpedance Analysis Measurements - There is no known risk associated with the BIA measurements. However, patients with medical implants such as a pacemaker or metal joint replacements cannot be measured on the machine.
  - Whole Body DXA Scan - The amount of radiation used for this procedure is very small. The radiation dose for this scan is equivalent to the radiation you are naturally exposed to in the environment in less than one day. DXA Scans will not be performed on any woman who is pregnant, and all women must inform the technologist if there is any possibility that they are pregnant.
  - BodPod - There is no known risk associated with the BodPod measurement. There is a large window so you can easily view outside of the BodPod during

the measurement; however, this measurement may be uncomfortable if you are claustrophobic.
    - A more comprehensive and detailed description of reasonably foreseeable risks to subjects are included later in Section 6 of the informed consent.
- **What are the possible benefits?**
    - We cannot promise any benefits from your being in the study. Your participation may help us gain knowledge that may help people in the future.
- **If you choose not to participate in the study, are there other choices?**
    - You have the choice at any time not to participate in this research study.

Detailed Information:

1- Who is doing the study?

Investigator Information:

Principal & Medical Investigator: Steven Heymsfield, M.D.
(225) 763-2541

24-hr. Emergency Phone Nos.:
(225) 252-8932 (Weekdays 7:00 a.m.-4:30 p.m.)
(225) 765-4644 (After 4:30 p.m. and Weekends)

Dr. Heymsfield is an advisory board member for the Tanita Corporation.

Dr. Heymsfield directs this study, which is also under the medical supervision of Dr. Heymsfield. This is a Pennington Biomedical Research Center study. We expect about 70 people will be enrolled in this study. The study will take place over a period of 2 months. Your expected time in this study will be approximately 3 hours in a single visit.

2- Where is the study being conducted?

This study tapes place in the Outpatient Clinic and the Imaging Department at the Pennington Biomedical Research Center.

3- What is the purpose of this study?

The purpose of this study is to develop practical tools that can be used by clinicians to better predict the risk of a patient developing heart disease or diabetes. To do this, we will collect and analyze body composition data.

4- Who is eligible to participate in the study?

You may be able to be included in the study if you meet the following inclusion criteria:

- Being either male or female

- Being at or over 21 years of age
- Having a body weight of less than 440 pounds
- Being willing to comply with the study procedures
- Able to lie flat on a table for 10 minutes and stand without aid for 2 minutes

You may not be able to be included in the study if you meet any of the following exclusion criteria:

- Being pregnant or attempting to become pregnant
- Having medical implants such as a pacemaker or metal joint replacements
- Having undergone body altering procedures such as breast augmentation or amputation

You may not qualify for this study based on other eligibility criteria not listed. The study coordinator will go over this information in detail.

5- What will happen to you if you take part in the study?

If you are eligible and choose to participate in this study, you will be asked to arrive in gym-style clothing or clothing that is easily removable as the study requires form fitting garments (provided for you) for certain procedures.
What you can expect at your one visit to Pennington Biomedical Research Center:

- The study visit will last approximately 3 hours.
- You will review and sign the consent form before any study procedures may begin. The study staff will be there to discuss the form and answer any questions you may have.
- Your vital signs, height and weight will be taken.
- If you are a female of childbearing potential, a urine pregnancy test will be performed.
- You will be required to change into a form-fitting wardrobe and swim cap (Bod-Pod only) that we will provide to you for the body composition and shape measurement procedures detailed below.
    - Please note: We will have freshly-washed top and bottom garments in sizes small, medium, large, X-large, and XX-large.

The following describes what will happen at each study visit:

Body Composition and Shape Measurement Procedures

<u>Circumferences</u>: <u>(about 15 minutes)</u>:
The clinical staff will measure the circumferences of your waist, hip, neck, upper arms, and thighs. These circumference measurements will be made by a trained observer using a calibrated tape measure.

<u>Imaging: (about 20 minutes):</u>

Your body shape will be imaged and measured through 2D and 3D optical devices. Faces will be de-identifiable. The devices use harmless light waves to capture and measure your body shape. Some devices require you to stand on a turntable that slowly rotates for less than one minute; other devices require you to stand still in a stationary position. Each image is repeated 2 times.

Bioelectrical Impedance Analysis (BIA); (about 10 minutes):
This test will measure the amount of fat in your body. You will be asked to remove all footwear and socks/stockings. Once barefoot, you will be asked to stand on a scale (similar to a large gym scale) and to hold on to hand electrodes on each side of the scale. You will be asked to step off of the scale once the measurement is complete (less than one minute). For another type of BIA system, you will be asked to lie down on an exam table and have electrodes attached to your hands and feet.

Whole Body dual-energy X-ray absorptiometry (DXA) Scan: (about 4 minutes):
This scan measures the amount of bone, muscle, and fat in your body. The scan will be performed using a whole-body scanner. You will be required to remove all metal-containing objects from your body, and to lie down on the table. You will be carefully positioned on the table. A scanner emitting low energy X-rays and a detector will pass along your body. You will be asked to remain completely still while the scan is in progress.

BodPod: (about 30 minutes):
This test will estimate the amount of fat mass, fat-free mass, and volume of your body. You will step onto a scale for a quick weight measurement. Next, you will sit inside of the system like you are sitting in a chair. The door of the system will be closed, but you will have a window so that you can see outside of the system while the measurements are completed.

6- What are the possible risks and discomforts?

Circumferences with tape measure and 3D imaging devices
There are no known risks associated with the tape measure nor the 2D and 3D imaging devices.

Bioimpedance Analysis Measurements
There is no known risk associated with the BIA measurements. However, patients with medical implants such as a pacemaker or metal joint replacements cannot be measured on the machine.

Whole Body DXA Scan
The amount of radiation used for this procedure is very small. The radiation dose for a DXA scan is equivalent to the radiation you are naturally exposed to in the

environment in less than one day. Scans will not be performed on any subject who is pregnant. A pregnancy test will be performed within 72 hours before the scan on females of child-bearing-potential.

Lifetime radiation exposure: We are exposed to radiation in the environment on a daily basis; however, some scientists have suggested that humans have a lifetime maximum exposure limit. Exposure to radiation is not without risk, but it is difficult to quantify the exact amount someone is exposed to. By participating in this study you will be exposed to radiation that will add to this lifetime maximum exposure limit. If you believe you have been exposed to a significant amount of radiation as part of your occupation or due to treatment for a specific medical condition, you should notify the study team to discuss whether or not this study would be appropriate for you

BodPod

There is no known risk associated with the BodPod measurement. There is a large window so you can easily view outside of the BodPod during the measurement; however, this measurement may be uncomfortable if you are claustrophobic.

While every effort will be made to maintain the privacy of your study records, there is also a risk of loss of confidentiality of sensitive information.

Will I be notified if my images result(s) in an incidental finding?

During a research study, a researcher may notice something that he or she was not looking for. This is called an “incidental” or “unexpected” finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.

Researchers may share some or all of their findings with you. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by the medical investigator or trained study personnel and referred to a treatment facility for further testing and/or treatment.

Risks: It can be very upsetting to learn unexpected information about your health. This is especially true if you learn that you have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. You might need more tests and procedures to find out what the information really means. It’s also possible that the information might be incorrect, so you would worry without cause.

7- What are the possible benefits?

We cannot promise any benefits from your being in the study. If you take part in this study, you may help others in the future.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way. You have the right to take part now and change your mind later on.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Dr. Steven Heymsfield at (225) 763-2541. If you think you have a research-related injury or medical illness, you should call Dr. Steven Heymsfield at (225) 763-2541 during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, someone from Pennington Biomedical Research Center may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

We plan as part of this study to share your de-identified data with our collaborators at Harvard University and with our sponsor, Amazon Corporation. Your de-identified imaging data will be shared at no cost with these external researchers to be used solely for research purposes.

ClinicalTrials.gov

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

11- Can your taking part in the study end early?

Dr. Steven Heymsfied or the study sponsor can withdraw you from the study for any reason or for no reason. The sponsor of the study may also end the study early.

You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study.

If your participation in the research ends early because of the investigator or by your choice, termination procedures may need to be completed or follow-up data may need to be obtained to ensure your safety. The study staff will go over the details with you.

12- What if information becomes available that might affect your decision to stay in the study?

Significant New Findings

During the course of this study there may be new findings from this or other research. which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

Clinically Relevant Research Results

In this study, you will be informed of any clinically relevant research results, including your individual results, that may be discovered.

13- What charges will you have to pay?

None.

14- What payment will you receive?

If you agree to take part, we will compensate you $75 *for completion of the study. If you do not complete the entire study, you will not be compensated.* Your check will be requested from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their social security number to receive payment.

You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU will report this income to the IRS.

Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa and 1-94 for payment to be processed.

I authorize that all information provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data may be shared with the Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely.

15- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

16- Signatures

By signing this consent form, I agree to participate in the study as it is described. The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

_____
Printed Name of Volunteer

_____ _____
Signature of Volunteer Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Steven B. Heymsfield, MD
Principal Investigator

Future Contact
If you give permission, we will re-contact you to participate in a future ancillary study associated with this protocol at Pennington Biomedical Research Center. Do you give permission for a representative of Pennington to contact you about future research by this study?

Yes, I give permission _____ _____
Signature Date

No, I do not give permission _____ _____
Signature Date