CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT
INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Amazon / "Evaluation of the accuracy of a computer vision-based tool for assessment of total body fat percentage"**
Protocol Number:	**001**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study
- The main goal of research studies is to gain knowledge that may help people in the future
- You have the right to refuse to take part or agree to take part now and change your mind later on
- Please review this consent form carefully and ask any questions before you make a decision
- Your participation is voluntary
- By signing and dating this consent form, you agree to participate in the study as it is described

This is a multi-center clinical trial lead by the study doctor listed on page one of this consent form. We expect approximately 132 people to complete this study. The study will take place over a period of 3 months. Your expected time in this study will be approximately 3 hours over one day.

What is the purpose of this study?

The aim of this study is to evaluate a computer vision-based (VBC) tool with a cellphone. This device is intended to be used for the assessment of total body fat percentage. The study will evaluate its accuracy by comparing it to other established methods of evaluating body fat percentage. The new tool, which is not approved by the

United States Food and Drug Administration (FDA), could be used by clinicians to better predict a person's body composition, and through these measurements, predict the risk of developing conditions like heart disease and diabetes.

To accomplish this aim the VBC imaging will be compared to the following devices, based on local availability:

- Bioimpedance analysis (BIA)
- Dual-energy x-ray absorptiometry (DXA)
- Bod Pod
- Body circumferences (by tape measure)

Definitions of these measurements can be found on page 4 of this consent form.

The study is funded by Amazon.

Who is eligible to participate in the study? Who is ineligible?

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

- Being either male or female
- Being from at or over 21 years of age
- Having a body weight of less than 400 pounds
- Being willing to comply with the study procedures

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 total knee or hip joint replacements
- Having arm or leg prosthesis or amputation or breast augmentation
- Having a body weight greater than 400 pounds
- Diagnosis of heart failure
- Loop diuretics, if taken within 6 hours of study enrollment
- Active cancer treatment

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

If you are eligible, you may choose to participate in this study. You are free to decline participation or to contact the listed investigators should you have any questions. If you decide to participate, you will be asked to arrive to the clinical trial site location wearing easily removable gym-style clothing after a 4-hour fast (nothing to eat or drink besides water for 4 hours prior to your appointment). The study visit will take approximately 2 to 3 hours. You will need to fast for 4 hours before the visit, but you may drink water. A snack will be provided upon completion of fasting-dependent procedures. During the visit, you will complete the informed consent process, have urine (if you are woman of child-bearing potential) and you will complete several body measurements and body composition procedures immediately afterwards.

Sequence	Procedure
Arrive at clinical trial site; check in at reception.	Consenting Process
Begin in Outpatient Clinic	Complete Study Forms; vital signs; urine pregnancy testing in women of childbearing potential; questionnaire
Baseline Measurements	Body Weight/Height
Anthropometrics	Circumference with tape measure
VBC imaging	Automatically measure body dimensions
Dual-Energy X-ray Absorptiometry	Measure body composition
Bioelectrical Impedance	Measure body composition - 4 devices
Bod Pod	Measure body volume (based on availability)

The visit will take about 2-3 hours to complete.

Description of study procedures

Preparation for the Study Visit:

Fasting:
You must fast (no food or fluids except water) for 4 hours before you arrive for your study visit. If you take medications, make sure you drink water as you would normally.

Study Attire
You will be asked to arrive in gym- style clothing or clothing that is easily removable as the study requires form fitting garments for all VBC scans, bioelectrical impedance, tape measurements, and Bod Pod evaluation.

Study Visit Procedures:
You will be required to change into a form-fitting wardrobe and swim cap that we will provide for the Bod Pod evaluation. We will have five freshly-washed top and bottom garments in small, medium, large, X-large, and XX-large sizes.

Check in and Baseline Measurements: (about 15 minutes):
Once you complete the consent process, your weight, height, and vital signs will be measured by the study staff. Your body mass index will be calculated from these measurements. Urine (women of child bearing potential) will be collected. You will fill out an electronic questionnaire about dietary history and physical activity.

Body Composition and Shape Measurements

Circumferences: (about 15 minutes):
The study staff will measure the circumferences of your neck, chest, waist, hip, right upper arm, and right thigh. These circumference measurements will be made using a calibrated tape measure.

2D (VBC) Imaging: (about 5 minutes):
Your body composition will be imaged and measured through the VBC study device. Faces will be de-identified. The study device uses harmless light waves to capture and measure your body shape. Each image is repeated 2 times. The total time this test will take will be about 5 minutes.

Bioelectrical Impedance Analysis (BIA); (about 15 minutes): Up to 4 devices
These tests 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, or you will lie down for the temporary attachment of adhesive electrodes on the hand and foot, depending on the BIA system available. Each measurement is completed in less than one minute. You will be asked to complete this measurement twice per device and the total test time is about 15 minutes.

Whole Body dual-energy X-ray absorptiometry (DXA) Scan: (about 20 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. The scan takes approximately ten minutes. You will do this scan once.

BodPod: (about 30 minutes):
**** Of note, this test will not be applicable to one of the clinical sites: MGH*
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. This test will be done twice. The actual test will be completed in about 15 minutes.

What are the possible risks and discomforts?

Circumferences with tape measure and VBC imaging study device
There are no known risks associated with the tape measure or the VBC imaging study device.

Bioimpedance Analysis Measurements
Participants with medical implants such as a pacemaker or metal joint replacements cannot be measured on the machine.

Rarely, it is possible to have an allergic reaction to the electrodes on some of these devices. You should let the study staff know if you have any allergy to metals.

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
**** Of note, this test will not be applicable to one of the clinical sites: MGH*
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.

Privacy risks
Participation in research involves some loss of privacy. We will take all available measures to ensure that your personal information is kept confidential. Your name will be replaced by a code in the study data. If information from this study is published or presented at scientific meetings, all names and other personal identifying information will not be used.

All study electronic data including the optical images will be stored on the password protected computers. These are kept in locked rooms.

There may be study risks that are unknown.

What are the possible benefits?
We cannot promise any benefits from your being in the study.

You will be given the results of the testing with the DXA, including Bone Density, and you will be told your body composition.

If you do not want to take part in the study, are there other choices?
This study is for research purposes only. The only alternative is to not participate in this study.

You have the choice at any time not to participate in this research study. If you choose not to participate, there will be no penalty, and any health benefits to which you are otherwise entitled will not be affected in any way. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Whom to contact about the study
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00042668.

What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, a member of study staff from the clinical trial site, and under certain circumstances, the United States Food and Drug Administration (FDA), 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. Your de-identified data will be shared at no cost with Amazon.

Can your taking part in the study end early?

The study doctor or the study sponsor can withdraw you from the study for any reason or for no reason. Some reasons may include:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

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

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

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.

What charges will you have to pay?

None.

What payment will you receive?

If you agree to take part, we will pay you up to $75. Your compensation will be requested when you complete the study or at the appropriate milestone if you are compensated during the course of the study. You should receive your compensation within 3-4 weeks of completing the study.

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

No form of compensation for medical treatment or for other damages (for example, lost wages, time lost from work, etc.) is available from the clinical trial sites. 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 (for example, Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage.

Signatures

This 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 doctors. I agree with the terms above and acknowledge that I will be given a copy of the signed and dated 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 Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Future Contact

If you give permission, we will re-contact you to participate in a future ancillary study associated with this protocol. 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

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include

- Representatives of Amazon
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other US federal and state agencies
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study
- Other research doctors and medical centers participating in this study, if applicable
- A data safety monitoring board which oversees this study, if applicable

Your health data will be used to conduct and oversee the research, including for instance:

- To compare the study devices to other devices
- For other research activities related to the study device

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date