INFORMED CONSENT FORM

Sponsor / Study Title:	**Healthreel Inc. / A Comparison Trial of Computer Vision-Based Approach vs. DEXA Scan to measure body fat percentage**
Protocol Number:	**U1111-1250-0418**
Principal Investigator: (Study Doctor)	**Steven Geller, MD**
Telephone:	**(410) 730-3399 (24-Hour)**
Address:	**Centennial Medical Group 8186 Lark Brown Road, Suite 201 Elkridge, MD 21075**

Introduction

You are invited to participate in an observational research study of a new software application. The software application is being developed to estimate body fat percentage using a video of the subject. This software application is investigational. The information in this document is designed to help you decide whether or not to take part in this study.

This document contains two parts: information about the study and the consent signature page to obtain your agreement to participate if you choose to do so. Participation in the study is your choice. You are completely free to agree or refuse to take part in the study. Take all the time you need to make your decision. If you agree to take part now, you can leave the study without giving a reason anytime in the future. Whatever you decide, any medical care you need to receive will continue. It is important you understand that signing and dating the form at the end of this document does not guarantee that you will be in the study. The study doctor may have to review your medical history to let you take part in the study.

Healthreel is the company, also called the “Sponsor,” that developed the software application being tested in this study. Healthreel is also paying for the study. The study doctor listed on page one of this consent form is responsible for doing the study and is being paid to do so. The study doctor’s office is being paid by the Sponsor for running this study.

Please discuss any questions you may have with the study doctor. All the details and procedures for this study were reviewed and approved by Advarra IRB. The job of this group is to watch over research involving human subjects to protect their rights and safety. Although Advarra IRB has approved the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean Advarra IRB has approved your participation in the study.

Overview of the Study

Why is the study being done?

This study is being done to test whether a computer vision-based software application can estimate body fat percentage with equivalent accuracy to a whole body DEXA scan and InBody scale. The DEXA scan involves lying on a machine for about 6-10 minutes. The InBody scale measurement requires standing on a scale with foot electrodes and holding a bar with hand electrodes for 10 seconds. This study has an open design. The study will also examine whether waist circumference measurement improves the accuracy of the body fat percentage estimate by the computer vision-based application.

How will the study be done?

A total of approximately 492 subjects are planned to take part in this study at one study center.

There will be 10 groups in the study, designated by body fat percentage and sex.

Group 1: Approximately 50 male subjects with a body fat percentage less than 13%

Group 2: Approximately 50 male subjects with a body fat percentage 13.01-18.99%

Group 3: Approximately 50 male subjects with a body fat percentage 19-24.99%

Group 4: Approximately 50 male subjects with a body fat percentage 25-29.99%

Group 5: Approximately 50 male subjects with a body fat percentage 30% or greater

Group 6: Approximately 50 female subjects with a body fat percentage less than18%

Group 7: Approximately 50 female subjects with a body fat percentage 18.01-24.99%

Group 8: Approximately 50 female subjects with a body fat percentage 25-31.99%

Group 9: Approximately 50 female subjects with a body fat percentage 32-36.99%

Group 10: Approximately 50 female subjects with a body fat percentage 37% or greater

Required tests/procedures

During the study, subjects in all groups will have to do the following:

- Allow your study doctor to review your previous medical records and records created during the study.
- If female, you will be asked if you are currently menstruating.
- Undergo a waist circumference measurement.
- Undergo a whole body DEXA scan. You should not take any calcium supplements on the day of the scan.

- Undergo body composition analysis using InBody scale.
- Allow study staff to take a 15 second video of you using the video capture feature on https://data.healthreel.com/. The video processing software will blur your face, and no personally identifiable information will be entered into this website. For this video, male subjects will be wearing fitted shorts, and female subjects will be wearing a bra and fitted shorts.
- Undergo training to take a 15 second video at home, and allow the study site to send you an email with a URL link associated specifically to your study identification number to capture that video. Using your smart device (phone or tablet), access the link and capture the video following the verbal instructions. The video processing software will blur your face, and you will not enter any personally identifiable information. If your regular browser is incompatible with the at-home-video-capture functionality, download a different browser.

Optional tests/procedures

- Undergo training to measure your waist circumference and weight at home. After collecting these measurements, enter them at the same URL used to capture the at-home video.

Benefits and risks

Potential study benefits

Other than getting information about the whole body DEXA scan, this study is not expected to provide a health benefit to you. Information learned from the study may help other people in the future.

Possible risks and discomforts from study procedures

The dual-energy x-ray absorptiometry (DEXA) scan is painless. It involves exposure to small amounts of radiation. Everyone is exposed to radiation as part of their normal living environment (background radiation). Although no amount of radiation exposure is completely safe, the total amount of radiation from the DEXA scan to which you will be exposed during the study is not expected to be harmful to you. Although there are no proven harmful effects from the radiation you will receive during this study, long-term effects of this radiation on your health are not known.

Unforeseen risks

Since the study is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you are pregnant. You must not participate if you are pregnant.

Alternatives to participation

This research study is for research purposes only. The only alternative is to not participate in this study.

Your rights and regulatory requirements

What if I decide to stop my participation in the study or if the study is stopped?

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you decide to stop your participation in the study for any reason, you simply have to inform the study doctor. The data already collected will be analyzed and used as initially planned.

If you leave the study for any reason, the study doctor may recommend that you come back for certain tests or examinations to check on your health.

In case you decide to stop your participation in the study and no longer authorize any further use of your personal data (consent withdrawal), your coded data already collected will be kept as required by clinical regulations.

Also, the study doctor may remove you from the study at any time. This could happen for many different reasons; for example, if there are concerns about your health, if you are not following study instructions, or if the study gets stopped. If this happens, the study doctor will inform you and ensure that your participation in the study is stopped properly. The data that have already been collected will be analyzed and used as initially planned.

Compensation

Subject will be compensated for their time and travel with $50.00 USD. You will receive this compensation after you upload the 15 second video taken at home.

If you have any questions regarding your compensation for participation, please contact the study staff.

Cost

There will be no charge to you for your participation in this study. The study-related procedures and study visits will be provided at no charge to you or your insurance company.

Compensation for injury

The Sponsor has insurance to cover serious medical problems that may develop as part of your study participation. If the event or condition was caused by the study procedures, you will be paid back all medical costs that are directly related to your medical care. Your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

In the event that the sponsor is required to pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and

if you do, report the payment it makes to Medicare.

Potential new findings concerning your health

The study doctor will keep you informed during the study of any changes or new information that could make you change your mind about your participation in the study.

The study doctor may share the results of the DEXA scan and InBody measurement with you.

Confidentiality and privacy

Why are my data being collected and analyzed?

The data collected from your participation in the study will be analyzed with those of all other study subjects. To determine the accuracy of the measurement of body fat composition via the computer vision application, and as requested by regulatory authorities, the Sponsor may also have to use your data, including race and ethnicity data, for other things, such as to plan other studies.

Who will have access to my data?

The Sponsor and its partners involved in the study will not know who you are; they will receive all the data collected during the study only after they have been coded (data that may identify you is removed and cannot be linked back to you) to protect your privacy. Your coded data and the study results may also be shared with scientific journals and the scientific community. Confidentiality of your information (data) will be maintained even if they are sent to countries that do not have the same level of data privacy requirements. Your identity and contact details (name, address, etc.,) will remain confidential and will only be known by the study doctor/staff and authorized individuals. The study doctor may grant direct access to your original medical records to study monitors, auditors, Advarra IRB, and regulatory authorities (such as the FDA) for verification of clinical study procedures and/or data.

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

Your coded data (all information that can be linked to you has been removed from your data) may also be shared for the purpose of scientific and medical research separate from the purposes of this particular study.

Does my authorization to use and share my data end?

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 information

You have the right to access, correct and limit the access to your personal data at any time during the study. You can exercise those rights by contacting the study doctor or any other doctor.

Your data will be stored for 25 years after the end of the study or more if required by regulations. Your coded data will be shared with the Sponsor only if you consent to participating in the study.

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

Study information
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 scientific summary of the results. You can search this Web site at any time.

Study results
When this study is completed, a simple summary of the overall results will be prepared for the general public. If you do take part in the study, you will be informed at your last visit about the internet address where the summary will be available via the internet.

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 this form.

NAME (ALL CAPITAL LETTERS) _____

SIGNATURE_____DATE_____
(Month/Day/Year)

PERSON OBTAINING AUTHORIZATION

NAME (ALL CAPITAL LETTERS) _____

SIGNATURE_____DATE_____
(Month/Day/Year)

Whom to contact about this 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 Investigator 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00043197.

THANK YOU

The Sponsor would like to thank you for considering taking part in this study. We understand your time is valuable and appreciate your participation.

INFORMED CONSENT STATEMENT

I declare that I have read and understand all the above information related to this Study. A copy of this signed and dated consent form will be provided to me. All information, including the reasons for conducting the study, its organization, all required and/or optional tests and procedures as well as the associated risks were explained to me. I am aware that the study doctor may provide additional important health information associated with my participation or information that may affect my willingness to continue in the clinical study. I am aware that my withdrawal from this study for whatever reason will not affect in any way the quality of health care provided to me. By signing and dating this informed consent, I agree to participate in the study and understand that I am not giving up any of my legal rights. I declare that I have truthfully answered all questions about my medical history and that I will follow all rules listed in the document. If I want to get any additional information about this clinical study, I can ask the study doctor.

SUBJECT'S NAME

NAME (ALL CAPITAL LETTERS) _____

SIGNATURE_____DATE_____
(Month/Day/Year)

PERSON OBTAINING CONSENT

NAME (ALL CAPITAL LETTERS) _____

SIGNATURE_____DATE_____
(Month/Day/Year)