Permission to Take Part in a Human Research Study
Do not sign this consent if today's date is later than the stated expiration date above.

Northwestern University
Department of Dermatology

Consent Form and HIPAA Authorization for Research

Title of Research Study: ***Diagnostic ultrasound for measuring fat of the body***

Investigator: ***Murad Alam, MD***

Supported By: This research is supported by Northwestern University.

Financial Interest Disclosure: If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have indicated that are in good health, have a Body Mass Index between 18-29.99 and expressed interest in participating in this research study.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research study is to provide information about human fat thickness just underneath the skin at different sites on the body by measuring it with a diagnostic ultrasound and also by linking participant perceptions of body image with the fat measurement. The information may be useful in: looking at age, gender and racial differences in how fat is accumulated. This may help with educating patients and better understanding which procedures may be better for particular patients.

How long will the research last and what will I need to do?
We expect that your participation in this research study will be for 1 day and that the study will last for up to 7 months.

You will be asked to:

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- Come to the study site for 1 study visit lasting approximately 3 hours.
- Sign the consent form.
- Provide information about demographics (e.g. age, race and gender), skin pigment, height and weight.
- Have photographs taken of various regions of your body.
- Have ultrasound images obtained from various regions of the body.
- Fill out a questionnaire about how you feel about your body.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

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

This study involves the use of photographs. There is a possibility that you may be able to be identified from the photographs.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, the knowledge gained from this study could provide valuable information about how condition on the surface of the skin are viewed/represented.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Murad Alam is the person in charge of this research study. You can call him at (312) 695-4761 Monday through Friday, from 9 am to 5 pm. For problems arising evenings or weekends, you may call the dermatology on-call physician at (312) 695-7787.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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How many people will be studied?
We expect about 40 people here at Northwestern University will be in this research study.

What happens if I say "Yes, I want to be in this research"?
As a participant in this study, you will be asked to come to the study site, Northwestern University Department of Dermatology, located at 676 North St. Clair Street, Suite 1600; Chicago, Illinois 60611.

Screening and Imaging visit
If you agree to take part in the study, you will first be screened to determine if you are eligible to participate in the study. You will be asked to come to the study site for 1 Screening and Imaging Study Visit. This visit will take approximately 3 hours. The following procedures will be completed:

- You will be asked to read and sign this consent form.
- You will be assigned a unique number to identify you in the research study.
- A review will be done of your demographics (such as your gender, race and other background information), height and weight.
- Photographs will be taken of your neck region underneath your chin, upper inner arms, upper back, sides of stomach and lower back/hips, stomach (abdomen), inner and outer thighs.
- High frequency ultrasound images will be taken from various regions of the body including, but not limited to your neck region underneath your chin, upper inner arms, upper back, sides of stomach and lower back/hips, stomach (abdomen), inner and outer thighs.
    - During the ultrasound, a probe (transducer) will be placed directly on your skin in the areas where the images will be taken. The probe is connected to a computer. The probe produces sound waves that bounce off body tissues and make echos. The probe receives the echos and sends them to a computer which uses the echos to create an image called a sonogram.
    - Before the probe is placed on your skin, a thin layer of gel will be applied to it. The gel will allow the sound waves to pass through from the probe, through the gel, into the body.
- You will be asked to fill out a brief questionnaire.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, please notify the study doctor.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

Detailed Risks: Is there any way being in this study could be bad for me?
Photographs and ultrasound image risks
This research involves the use of photographs and ultrasound images. There is a possibility that you may be able to be identified from the photographs and ultrasound images.

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Ultrasound

- The probe can build up heat while the probe is not in use (in its holder) causing the probe to be warm to the skin.
- The use of a damage probe can result in injury or increased risk of infection. A damaged probe can also increase the risk of electric shock if solutions come in contact with internal device parts while on.
- An ultrasound can produce harmful effects in tissue and potentially result in patient injury. Exposure time will be minimized per body area and ultrasound levels will be kept low when there is no medical benefit.

Gel

- The gel applied before the images are taken may feel cold.
- There is a possibility that the gel may cause skin irritation or a skin allergic reaction

Please let the study staff know if you have any problems during the procedures.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you. Participation in this study may result in transportation costs. Parking validation will be offered, if you park at the study site.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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 you no longer meet eligibility requirements for the study, adverse events occur that, in the opinion of the investigator, put you at increased risk and it is not in the best interest for you to continue the study.

What else do I need to know?

If you agree to take part in this research study, you will receive a $25 Visa debit card at the completion of the study.

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HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

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- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Murad Alam
Northwestern University, Department of Dermatology
676 N St. Clair, Suite 1600
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent