Memorial Sloan Kettering Cancer Center
IRB Number: 19-098 A(4)
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Participant Informed Consent for Clinical Research

Study title for participants: A Study of a Device Used to Take Pictures of Skin Blood Flow

Official study title for internet search on http://www.ClinicalTrials.gov: Feasibility Study of a Hyperspectral Imaging System in Detection of Human Skin Perfusion and Oxygenation

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If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this study because you are healthy and between the ages of 18-45.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered. See the *Where can I get more information?* section of this document for more information about research studies and for general information about cancer.

Why is this study being done?

This study is being done to answer the following question:

Can the hyperspectral camera system (HCS) measure skin blood flow (perfusion and oxygenation) in healthy people?

What is the usual approach?

Healthy people who are not in a study or undergoing medical care would not usually have their skin blood flow measured.

What are my other choices if I decide not to take part in this study?

You may choose to not take part in this research study.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will have 2 study visits (3-28 days apart). During these visits, we will measure the skin blood flow on your arms using the HCS. We will take these measurements at several times and under different conditions, including applying pressure to the skin and using an over-the-counter cream on the skin.

Your participation in this study will be complete after the end of the second study visit.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

There are no common, expected side effects from use of the HCS, but there may be some risks that the study doctors do not yet know about.

There is also a risk that you could have side effects from the over-the-counter cream used in this study (capsaicin). Some of the most common side effects of these creams that the study doctors know about are:

- Skin irritation where the cream was applied
- Pain where the cream was applied
- Skin redness where the cream was applied

Benefits

This study is not likely to help you. However, what we learn from this research may help us understand how the HCS works and if it can be used in future studies.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest

- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to see if a camera device called the hyperspectral camera system (HCS) can measure skin blood flow (perfusion and oxygenation) in healthy people.

The HCS is investigational, which means the FDA has not approved the device.

The HCS uses halogen light to take pictures of blood flow in the skin. During the procedure, this device remains outside your body. It does not require an invasive procedure.

Researchers think the HCS may be a reasonable option for measuring blood flow in the skin because of the types of 3D images and information it can create in a short amount of time. The information gained from this study will help researchers decide whether future studies should be done to see if the HCS may be useful to doctors during surgery.

About 8 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

All study participants will take part in the same study procedures, which will include measuring of skin blood flow under different conditions by the HCS.

What extra tests and procedures will I have if I take part in this study?

Before you begin the study:

If you join the study, you will have exams, tests, and procedures done only for research purposes. The exams, tests, and procedures are a necessary part of this research study. These procedures are listed below:

- Review your medical history
- Measure your weight
- Measure your blood pressure
- Measure your heart rate

During the study:

You will have 2 study visits on separate days (between 3-28 days apart). We expect each visit to take a maximum of 2 hours. You will have the same HSC procedures at both visits.

You must avoid alcohol and caffeine for 12 hours before Visits 1 and 2. Both substances could influence the blood flow in the skin.

The study doctor or study staff will measure your skin blood flow using the investigational HCS. The study doctor or study staff will take these measurements under the following conditions at both visits:

- Pressure applied to the arm: First, we will take measurements by the HCS on both your right and left forearms. Next, we will use an inflatable blood pressure cuff to apply pressure to your right or left arm for 5 minutes. We will take HCS measurements while the cuff is on your arm, and again after we remove the cuff.
- Cream applied to the arm: We will use a capsaicin-based cream. This is an FDA-approved cream typically used to relieve muscle or joint pain. This cream works by relaxing the blood vessels. We will put this cream on the same forearm. About 30 minutes after we put the cream on your skin, we will wipe it off. About 20 minutes after we wipe off the cream, we will take HCS measurements of your arm.

Exams, Tests and/or Procedures

You will need the following extra exams, tests, and/or procedures. Some exams, tests, and procedures are a necessary part of this research study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Blood pressure before HCS measurements
- Heart rate before HCS measurements
- HCS measurements

After you finish the second visit, your participation in this study will be complete.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

There is also a risk that you could have side effects from the over-the-counter cream/study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may be mild. Others may be very serious.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

We do not expect you to have any side effects from the use of the HCS.

Possible side effects of capsaicin-based cream:

Occasional, some may be serious In 100 people receiving capsaicin-based cream, between 4 and 20 may have:
• Skin irritation where the cream was applied • Pain where the cream was applied • Skin redness where the cream was applied

Rare, and serious In 100 people receiving capsaicin-based cream, 1 or fewer may have:
• High blood pressure • Irregular heartbeat • Fast heartbeat

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments.
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study

Is there a conflict of interest for this study?

This study is sponsored by MSK. No conflicts of interest have been identified for either the institution or the investigator(s) in this study.

What are the costs of taking part in this study?

You will not be charged for participating in this study.

You will be offered $50 gift card (after the second visit is complete) for your participation in this study.

This research may lead to the development of new tests, drugs, or other products for sale. If it does, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK. All requests for data sharing will be reviewed by MSK, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.
Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

In the future, your information (data) may be de-identified, which means that your data will be assigned a unique code, and the list that links the code to your name will be stored separately from your data. Your de-identified information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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 any information that can identify you. At most, the web site will include a summary of the study results. You can search this web site at any time.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are in this study, call the Memorial Sloan Kettering Cancer Center Institutional Review Board (IRB) at 212-639-7592. Jorge Capote, RN, is MSK's Patient Representative; you may call him if you have concerns, complaints, or input on research, or for more information about the consent process, at 212-639-8254.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

A Study of a Device Used to Take Pictures of Skin Blood Flow

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator(s): Michelle Bradbury, MD and Roger Wilson, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study procedure.
- Other research doctors and medical centers participating in this research
- Anonymized images from the hyperspectral camera will be electronically sent to Quest Diagnostics for analysis.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)

Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you. Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.