HealthPartners, Inc
Consent to Participate in a Research Study

Study Title	Pilot Study: Prospective comparison of ICG microangiography and conventional angiography in severe frostbite
Study Investigator	Alexandra Lacey, MD RD FACS Burn Center Regions Hospital 651-254-1501 (office) Alexandra.m.lacey@healthpartners.com
Study Team Coordinators	Regions Research Staff (651) 254-9900 (24/7 contact number) CCRCresearch@healthpartners.com

Introduction

You are invited to participate in a research study for the Regions Hospital Burn Center and the Critical Care Research Center. In order to participate, you must be 18 years or older, and have a diagnosis of severe frostbite. Taking part in this research study is voluntary.

Important Information about the Research Study

Things you should know:

- The purpose of the study is to compare two different imaging techniques for their ability to inform physicians about tissue affected by frostbite. You will be undergoing one of these imaging procedures as standard of care. If you choose to participate in this study, you will be asked to undergo a second imaging procedure immediately after the standard of care imaging procedure. This additional imaging session will take approximately 5-10 minutes.
- Risks and discomforts from this research include a possible reaction to the imaging dye.
- The study will not benefit you directly.
- Taking part in this research project is voluntary. You don't have to participate, and if you choose to participate, you can stop at any time.
- Alternative procedures or course of treatment include having only one conventional imaging session as part of your routine care.

Please take time to read this form and ask questions before deciding whether to take part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you decide to take part in this study, you will be asked to sign and date this form and will be given a copy of the signed and dated consent form for your records.

Why am I being asked to participate?
You are being asked whether you would like to participate in a research study about different imaging techniques in severe frostbite injury. You are being asked because you are 18 years of age or older, have severe frostbite, and are currently undergoing catheter-directed thrombolytics, which require daily conventional angiograms. Catheter-directed thrombolytics are a minimally invasive treatment that dissolve abnormal blood clots in blood vessels to help improve blood flow and prevent tissue damage. An angiogram is an imaging technique that allows doctors to visualize the inside of your blood vessels to determine how well your blood is flowing. This procedure, which you are receiving as standard of care, is one of the two imaging techniques we are studying. If you agree to participate in this study, you will also receive a second imaging procedure called Indocyanine Green (ICG) microangiography, allowing us to compare these two imaging techniques directly. This second imaging procedure involves no radiation exposure.

What is the purpose of the study?
In this study, we want to find out if two different imaging techniques for severe frostbite injury give comparable results. In severe frostbite, conventional angiograms have long been the standard imaging technique. However, a newer imaging technique called ICG microangiography has been used in severe frostbite and may have comparable accuracy. We are hoping to compare the conventional angiography you are already undergoing to ICG microangiography imaging. This will allow us to determine the best imaging technique for severe frostbite.

Where will the study take place?
This study will take place in the Interventional Radiology (IR) suite directly following your scheduled conventional angiogram. It will take 5-10 minutes to complete.

What is involved if I take part?
If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions and look at the results of your medical tests to see if you qualify to be in the study.

As a subject, you will be responsible for:

- Follow the directions of the investigator and the research team.
- Telling your medical team if you have any new symptoms after this imaging study is completed.

What will happen at the study visit?
When you go for your conventional angiogram as standard of care, the study Principal Investigator (PI) Dr. Alexandra Lacey, will be notified. She will meet you in the IR suite and prepare for the ICG procedure, which is part of this research study. She will explain the procedure to you before beginning, but in short, Dr. Lacey will use an existing peripheral IV that was placed as part of standard care to provide 5 mg of ICG dye followed by a 10 mL normal saline fluid flush. The room will be darkened to

optimize the imaging. Using the specialized infra-red camera, Dr. Lacey will examine all areas of your body that were just examined during the conventional angiogram. There is no ionizing radiation associated with this procedure and it is not painful. After the ICG procedure is complete, you will return to your inpatient room and continue your normal cares. There is no additional follow up or extra monitoring required for this study.

Are there any risks to me?
There may be risks, side effects, and discomforts if you choose to participate in this study. These can be physical, emotional, financial, or social. The ones we know about are below:

- Discomfort related to staying on the angiography suite table for 5-10 additional minutes
- Rare chance of allergic reaction to the ICG dye
    - If this occurs, it could be as mild as a rash or as severe as anaphylaxis, which is a life-threatening allergic reaction
    - This is treatable in a hospital setting and would be quickly detected
    - The chance of this reaction is very rare (<0.05%)
- Rare chance of cross reaction between the contrast dye and the ICG dye.
    - There has never been a documented interaction between ICG and conventional dye, but you should be aware that it is a possibility

Are there any benefits to me?
You will not benefit directly from being in this research study. It is possible that your condition could stay the same or even get worse. We hope the information learned will help other patients with severe frostbite in the future.

How much will it cost to participate?
There is no cost to you for participating in this research study. You will not pay for any of the procedures or materials used in the study.

Will I be paid to participate?
You will not be paid to participate in this study.

How long will I be in the study?
You will be in this study from the time you sign the consent until 72 hours after the ICG imaging or upon discharge from the hospital, whichever comes first. You will not be required to stay in the hospital any longer than is required for your standard care.

The study may be stopped early by the investigator. You could be asked to stop being in the study for any of the following reasons:

- For your safety
- If you do not or can not follow directions for the study

Will I find out about the results of the imaging?
You have the right to see the results of the imaging. To request results, please contact the Principal Investigator, Dr. Alexandra Lacey.

Do I have to be in the study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you do not want to participate, and your decision will not affect your regular medical care.

You may decide to participate now but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw, please let the investigator know. If you withdraw, any data that were collected from you will be used in the study, but no new data or information will be collected from you.

Your only choices are to participate or not to participate. It is up to you whether you want to be in this study.

What if I am harmed from being in the study?
If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible. You or your insurance company is responsible for paying for the cost of your medical treatment. The study team will assist you in contacting your insurance company if necessary. By signing this form, you are not giving up any of your legal rights.

Will my records be kept confidential?
Your study records will be kept as confidential as possible. This is further described in the HIPAA Authorization, below. Please know that at any time, your study records may be reviewed by the United States Food and Drug Administration (FDA), the HealthPartners IRB, the study Sponsor and/or the Sponsor's representatives.

What if there is new information about this study?
If we learn any new information about this study that might make you change your mind about participating, we will tell you.

A description of this trial will be available on ClinicalTrials.gov, as required by US Law. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website anytime.

Who oversees this study?
HealthPartners Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards. IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends, and personal physician before you decide.

Who do I contact?

If…	You should contact	Contact information
You are harmed by the research, have questions about the clinical procedures in the study, or would like to see the results of your imaging.	Alexandra Lacey, MD RD FACS	651-254-1501 Alexandra.m.lacey@healthpartners.com
If you would like to speak to someone who is unaffiliated with this study to discuss problems, concerns, and questions; obtain information and offer input.	Amy Fehrer, Senior Manager of the Research Subjects Protection Program	952-967-5025 Amy.A.Fehrer@HealthPartners.com

Information about Confidentiality and HIPAA Authorization
The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?
To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information may be collected and used?
We may collect health information about you from your hospital, clinic, or doctor, and from external healthcare organizations or providers involved in your care. The information collected may include:

- Information about your medical conditions and history, including the treatments you received and your response to these treatments

- Results of tests and procedures
- Dates of hospital admissions, clinic visits, and/or medical procedures performed
- Demographic information, such as your age, race, and gender
- Personal identifiers such as your medical record number or date of birth
- If you receive any payments for taking part in this study, HealthPartners accounting department may need your name, address, social security number, and payment amount for tax reporting purposes

Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for HealthPartners to obtain, use and disclose your personal health information as described above.

Who will see my protected health information?
By signing this Authorization, you allow Dr. Alexandra Lacey and the research team to use your personal health information to conduct and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at HealthPartners) to the following:

Who may have access:	**Purpose:**
HealthPartners consultants and employees including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections, or similar government agencies in the US and other countries)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For HealthPartners to remains accredited

Will you keep my information confidential?
We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves HealthPartners, we cannot control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?
If the results of this study are published, your name and other personal information will not be included.

How long will my personal health information be used?
Access to your personal health information begins as soon as you sign this form. This authorization expires when the study is finished, data analysis is complete, and the study records have been destroyed.

What if I change my mind?
If you do not want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the HealthPartners IRB office at 952-967-5025.

If you withdraw permission for us to use your personal health information:

- You cannot continue in the research study
- We will stop collecting health information from you
- We will not sue or disclose any information we gathered while you were a subject
- There will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?
You have the right to see and get a copy of your study records. You may see these records at any time during or after the research study.

Subject Name (PRINT):

- I have read this form and the research study has been explained to me
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions
- I agree to be in the research study described above
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record
- I am not giving up any of my legal rights by signing this form

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Subject Signature Date

-OR-

Name of Legally Authorized Representative (PRINT) Telephone number

- I have read this form and the research study has been explained to me
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record
- I am not giving up any of my legal rights by signing this form

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Signature of Legally Authorized Representative Date

Relationship or Authority of Legally Authorized Representative to Patient

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For site use only:

- I have carefully explained to the subject the nature and purpose of this study
- The subject has been given enough time and an adequate place to read and review this form
- The subject has had a chance to ask questions and receive answers about this study
- I have explained and discussed the nature of this research
- I have explained and discussed potential risks and benefits
- I have explained the alternate treatments available to the subject and the benefits and risks of each

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Name of the person obtaining informed consent (PRINT) Title Phone number

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Signature of person obtaining informed consent Date