CONSENT FORM

Investigation of Mohs surgical margins using two photon fluorescence microscopy

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This consent form describes a research study what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate.

Key Information

- Being in this research study is voluntary **– it is your choice**.
- You are being asked to take part in this study because you are being treated for basal cell carcinoma, a type of skin cancer.
- The purpose of this study is to investigate a more rapid imaging technology during surgery for skin cancer that can be combined with conventional methods to accelerate treatment.
- Taking part in this study will last for the duration of your treatment session today.
- Procedures will include imaging tumor and skin removed during surgery. Tissue will only be imaged after it is removed from your body.
- There are risks from participating.
    - The most common risk is that treatment could take longer.
    - More serious risks include removal of a different amount of tissue during surgery.
    - See the “Risks of Participation” section in this consent form for more information. You should discuss these risks in detail with the research team.
- You might not benefit from being in this research study.
- If you do not want to take part in this study you can decline and receive standard treatment without the additional imaging.

Purpose of Study

In normal Mohs surgery, skin cancer is removed, frozen and then cut into thin pieces to examine under a microscope which is slow and delays the completion of surgery. Two photon fluorescence microscopy can image skin cancer, but does not require freezing the tissue first, and so may be faster. This study will test the use of two photon fluorescence microscopy during Mohs surgery by comparing to normal microscopy.

Description of Study Procedures
If you decide to take part in this study, tissue removed during surgery will be stained using fluorescence contrast agents, imaged with two photon fluorescence microscopy and will then be frozen and imaged under a conventional microscope. If your surgeon sees tumor with two photon fluorescence microscopy, you will receive additional treatment to remove the tumor. If no tumor is seen with two photon fluorescence microscopy, then your surgeon will review the normal microscope images to confirm this result. If there is an error resulting in tumor that was missed on two photon fluorescence microscopy, it will still be detected using conventional microscopy and your surgeon will still be able to remove the tumor.

If your surgeon detects additional tumor using either method, that tumor will be removed and will be imaged with both methods. This will repeat until all tumor is removed. The final determination that your tumor is removed will be made with normal microscopy to ensure that you are fully treated.

Future Use of Information

Microscopic images of tissue removed during surgery (as described above) might be distributed or used for future research studies without additional informed consent. Your name and all identifying information will not be included if microscopic images are used or distributed.

Return of Research Results
In general, we will not give you any individual results from taking part in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Risks of Participation

Your surgeon may alter your treatment based on imaging. Your surgeon will review two photon fluorescence images and may decide to remove additional tissue, resulting in differences in the amount of tissue removed compared to if you had not participated. To reduce this risk, your surgeon will wait for confirmation from normal microscopic imaging if there is uncertainty. Following two photon fluorescence imaging, your surgeon will confirm results using normal microscopic imaging to ensure that your cancer is fully treated.

Your surgery could take longer. Imaging may add several minutes of delay after you are treated in addition to the normal 30-60 minutes. While participation may also save several minutes if treatment decisions are made more quickly, more likely than not your treatment will take a similar amount of time or several minutes longer.

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 summary of the results. You can search this website for information related to this study by using this study's identification number NCT05814900.

Circumstances for Dismissal
You may be withdrawn from the study due to changes in your medical status during surgery or other circumstances that prevent two photon fluorescence imaging.

Early Termination
If you decide to end your participation in the study before the end of treatment today, you can tell your surgeon. At this point, no further imaging with two photon fluorescence microscopy will be performed, and your surgeon will provide you with standard Mohs surgery.

Benefits of Participation
You might not benefit from being in this research study.

Number of Subjects
Approximately 135 subjects will take part in this study.

Sponsor Support
The University of Rochester is receiving money from the National Cancer Institute at the National Institute of Health to conduct this study.

Commercial Profit
We will use images from your surgery for research only. However, the results of this research might someday lead to the development of products (such as new microscopes for surgery) that could be sold by a company. You will not receive money from the sale of any such product.

Compensation for Injury
If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The study investigator's name and phone number are listed in this consent form. The University of Rochester and the study investigator will determine whether your injury was the result of your participation in the study.

We will offer you the necessary care to treat your injuries. The costs of treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of Rochester or other third party, depending on a number of factors. If your insurance is billed, you may be responsible for deductibles and co-payments. There are

no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If the care you receive as a result of your injury is paid for by the University of Rochester or another party, we will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

Costs
There will be no additional cost to you to participate in this study beyond your normal treatment cost.

Payments
You will not be paid for participating in this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester and Rochester Dermatologic Surgery (RDS) makes every effort to keep the information collected from you private. In order to do so, we will store microscopic images recorded during the study and other digital records without direct reference to your identity. Only your surgeon and his office will know the identity of subjects. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
- The investigator will get basic demographic information including your age
- Information about your tumor, including its location on your body
- Research records
- Records about your study visit
- Microscopic images of tissue removed during surgery

Who may use and give out information about you?
- The investigator and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester

- The National Institute of Health and companies working with, on behalf of, or collaborating with the Sponsor
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.
- Rochester Dermatologic Surgery (RDS)

Why will this information be used and/or given to others?
- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

How long will this permission be valid?
This permission will last indefinitely.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no further imaging will be performed and you will receive standard treatment from that point onwards. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Contact Persons

For more information concerning this research or if you feel that taking part in the study has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Sheriff Ibrahim at (585) 222-1400.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date