Clinical Study of the Utility of a Novel Exoscope System for 5-ALA Fluorescence-Guided Surgery for Gliomas

NCT04055688

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CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**Clinical Study of the Utility of a Novel Exoscope System for 5-ALA Fluorescence–Guided Surgery for Gliomas**
Protocol Number:	**MCC 20014**
Sponsor:	**Michael Vogelbaum, MD, PhD** **Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Michael Vogelbaum, MD, PhD**
Telephone: (24 hour number)	**(813)-745-4585** **(800) 456-3434**
Address:	**Moffitt Cancer Center** **12902 Magnolia Drive** **Tampa, FL-33612**

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study. The goal of this clinical research study is to utilize the fluorescence technique to check the tumor status meaning if it's abundant, scarce and not seen. Another purpose is to check if this technique helps the surgeon to remove your tumors. Participant with high grade glioma (high grade brain tumor condition) who are willing to seek this alternative treatment are being recruited in this study.

If you choose to take part in this research you will be asked to sign and date this informed consent document. Your total participation in this study from the time you sign and date the informed consent form through your follow up visit may be up to about 2 weeks. About 15 participants will take part in this study at Moffitt Cancer Center.

Participant will undergo screening procedures that involves routine examination. After screening visit is complete, if you will qualify to continue in the study you will undergo study treatment visit. Study treatment visits will involve tumor surgery using the fluorescence technique. After your study treatment, you will stay overnight for at least 2 days at the study center for study doctors to monitor your health conditions.

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study are later described in this document.

We do not know if you will receive any benefit from your participation. You will not be compensated for your participation. The most common risks that may be related to taking part in this research includes bleeding, swelling of brain tissue, pain, and nausea. The other risk and side-effects associated with study procedures are described later in this consent form.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.
If you are interested in learning more about this study, please continue reading the information below:

WHAT IS THIS STUDY ABOUT?
We are asking you to take part in this research study because you are a patient who, in discussion with a study doctor, is planned to undergo 5-ALA guided surgical resection of a brain tumor with use of the Orbeye surgical microscope equipped with an imaging system for 5-ALA.

5-ALA and the Orbeye surgical microscope are U.S. Food and Drug Administration (FDA) approved products. For this study, however, the Orbeye microscope imaging system is being used with special filters to visualize 5-ALA fluorescence. The FDA currently permits the use of these filters. The purpose of this study is to collect medical information before, during, and after your standard treatment in order to better understand how to make this type of procedure accessible to patients.

This study is also being conducted to determine if use of the Orbeye equipped with these special filters improves the ability of the surgeon to remove your brain tumor.

WHAT WILL HAPPEN DURING THIS STUDY?
The exams, tests, and procedures you will have are part of the usual approach for your cancer. During your procedure you will drink a solution containing 5-ALA about 2 to 4 hours prior to surgery, which is part of standard of care for your planned surgery. You will undergo a standard brain tumor surgery and your surgeon will use the Orbeye with and without the filters used to visualize 5-ALA to determine the utility of the filters. No additional tumor samples will be collected for research purposes. After surgery, you will be kept out of sunlight for 48 hours.

Screening Visit: Before participating in this study, you must sign and date this consent form. Your medical history and medication use will be collected and a physical examination performed.
Standard of Care Treatment Visit: During your study doctor visit, you will undergo a Standard of Care image guided brain tumor surgery. During the surgery, your surgeon will use the Orbeye surgical microscope to visualize your tumor under white-light (normal) and blue-light (investigational) conditions. The use of blue-light permits the visualization of 5-ALA in your tumor. After surgery, you will be monitored in the hospital for at least 2 days (standard of care) during which time you will undergo a standard of care post-operative MRI. You will be kept away from sunlight during the hospitalization.

Post Standard of Care Treatment visit: You will have an office visit between 7 and 16 days after your surgery. This will be a standard of care postoperative visit to evaluate your incision(s) and neurological functioning.

WHILE YOU ARE IN THE STUDY, YOU MUST:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.
- Not take any other drugs or remedies unless the study doctor has approved them beforehand as part of your standard of care treatment. This includes prescription drugs and over the counter medicine (including vitamins and herbal remedies) that you buy without a prescription.
- Not participate in other medical research studies.
- Not get pregnant or cause your partner to become pregnant.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

WHAT HAPPENS WHEN I COME FOR STUDY VISITS?

After you sign and date this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

- **Medical History:** The study doctor will ask you about past/present diseases and surgeries. The questions may also include any allergies, birth control procedures and medicines. Any other studies you were in may also be asked. Other questions may include any medical conditions or side effects which may occur during the study.
- **Physical examination**: including symptoms of your disease will be performed at Screening, prior to receiving study treatment on, at the end of study treatment visit and at each follow-up assessment.

WHO IS PAYING FOR THIS STUDY?

The principal investigator (study doctor) of this study, Michael Vogelbaum, MD, PhD, is the sponsor of the study. Olympus is funding the study, and providing the filters to be used with the Orbeye surgical microscope system.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You and/or your insurance company will be financially responsible for hospital inpatient, outpatient and follow-up visits that would normally or routinely occur in the management of your disease. Inpatient and outpatient visits could include charges for treatments, medications, physician visits, laboratory tests and procedures. You and/or your insurance company will be responsible for paying for the charges which are considered routine, since you would have received these services even if you were not participating in this study. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments and all out-of-pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.

You and/or your insurance company will not be responsible for paying for study related items and services that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center.

You and/or your insurance company will be responsible for the drug 5-ALA that is commercially available. You and/or your insurance company will be responsible for the charges related to the administration of the commercially available drugs.

If you would like more information on the costs of being on this study or have other insurance related questions, please let your clinical trial coordinator know or contact our Business Office at 813-745-8422.

WILL BEING IN THIS STUDY HELP ME?
If you agree to take part in this study, there may or may not be direct medical benefit to you. Your condition may even get worse during the study. The information collected during this study will help the study doctors and researchers to learn more about Orbeye microscope imaging system used with special filters to visualize 5-ALA fluorescence. This may benefit you and other people with glioma. However, there is no guarantee that this will happen.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?
The 5-ALA surgical and MRI procedures conducted during this study are part of your standard treatment for your cancer regardless of study participation. The study doctor will review these risks with you, and you may be asked to sign and date a separate consent form for these procedures.

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

- You may lose time at work or home and spend more time in the hospital or study doctor's office than usual
- There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

Unforeseeable Risks
There may be other risks of study participation that are unknown.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?
If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience a side effect or a change in the way that you feel, call the study doctor at the telephone number listed on the first page of this form.

By signing and dating this informed consent and research authorization form, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-7882. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law.

WILL I GET PAID?

You will not be paid for taking part in this research study. You have no rights to and will not receive payments of any kind for discoveries, patents or products that may be developed from this study.

WHILE YOU ARE IN THE STUDY, YOU MUST:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.
- Not take any other drugs or remedies unless the study doctor has approved them beforehand as part of your standard of care treatment. This includes prescription drugs and over the counter medicine (including vitamins and herbal remedies) that you buy without a prescription.
- Not participate in other medical research studies.
- Not get pregnant or cause your partner to become pregnant.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study requirements
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

ARE THERE REASONS THE STUDY DOCTOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If at any time while you are participating the study doctor discovers that your disease has worsened.
- If you develop side effects that the study doctor considers unacceptable.
- If you refuse to participate or return for follow-up as recommended by your study doctor, or do not follow the study doctor's instructions.
- If you refuse to have tests that are needed to participate.
- If you require treatment with drugs that are not allowed on this study.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing and dating this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: Olympus, Inc., funding the study.
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.
Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?
By signing and dating below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a signed and dated copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you 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.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Participant 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 Participant Adviser: Pro00034132.

WHERE CAN I GET MORE INFORMATION?
You may call the National Cancer Institute's (NCI) Information Service at:
1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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 Web site at any time.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

Printed Name of Participant

Signature of Participant | Date | Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT / RESEARCH AUTHORIZATION

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent | Date | Time