MAYO CLINIC

Name and Clinic Number
Protocol #: **Subject ID:** **Version #:** **Version Date:**

Approval Date: **January 11, 2019**
Not to be used after: **January 10, 2020**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Intravital Microscopy (IVM) in Human Solid Tumors

IRB#: 18-010370

Principal Investigator: Emmanuel Gabriel, MD, PhD and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Emmanuel Gabriel, MD. Natalie Fares	**Phone:** 904-953-2523 **Phone:** 904-953-3880 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Florida:** (904) 953-7058	▪ Billing or insurance related to this research study

Other Information:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are an adult with a diagnosis of a solid deep space tumor. The plan is to have 50 patients take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to evaluate the microscopic characteristics of the solid deep space tumor. This type of study is investigational and it is our expectation that the use of our special microscope will help visualize tumor-associated blood vessels and blood flow. This may lead to valuable information for physicians in the treatment of patients with your condition. This is an observational study. No treatment will be administered.

3. Information you should know

Who is Funding the Study?

This study is funded by the Mayo Clinic.

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

The timeframe for this research study is limited to your surgery, consisting of your Pre-Operative Visit, Surgery, and your post-operative follow-up. The use of the microscope on your tumor-associated vessels will occur at the time of your surgery. This is expected to take approximately 20-30 minutes during the time of your operation in the operating room while you are under general anesthesia. Keep in mind that this additional time period is quite low compared to the time of the overall procedure, which on average takes 3-4 hours.

After your surgery, staff will continue to monitor you as per the usual standard of care. You can expect your post-operative hospital stay to be between 1-7 days, depending on the type of procedure that you have. After you leave the hospital, you will continue with the standard follow-up monitoring to determine if you cancer recurs.

5. What will happen to you while you are in this research study?

Once you are determined to be eligible for the study, you will undergo careful evaluation. This will be included as part of the standard of care for your specific surgery. All of the following "Before Surgery" items are included as part of the standard of care for your surgery, and are not considered research or investigational.

Before surgery:

- Medical history, with specific information pertaining to prior allergies to iodine or intravenous contrast dye used for computerized tomography (CT) scans.
- Physical exam, including vital signs (i.e., temperature, heart rate, respiratory rate, blood pressure, body weight, and height).
- Blood collection of about 1½ tablespoons from a vein in your arm, for routine safety laboratory tests. The blood test is called a comprehensive metabolic panel or CMP.
- If indicated by anesthesia pre-operative evaluation - Electrocardiogram (ECG) - a recording of the electrical activity of your heart.
- A pregnancy test (urine) will be done if you are a woman capable of becoming pregnant prior to surgery. This is the standard of care for women of childbearing potential who undergo surgery at Mayo Clinic. The test is performed in the preoperative holding area. If the pregnancy test is positive, you would ineligible for this study.

The following item is considered investigational for research purposes:

- A skin-prick test to determine if you have an allergy to fluorescein (performed during your preoperative visit)

During surgery:
During your surgery, a microscope will be used to directly observe the blood vessels associated with your tumor. Intravenous (IV) dye will be administered through your catheters connected to your veins in order to help enhance the microscopic observations. This dye is a substance called fluorescein, which is frequently used dye for a variety of surgical procedures. Because there can be allergic reactions to fluorescein (less than 5% of cases), you will be asked to undergo allergic skin testing to fluorescein prior to enrollment in the study (as listed above). This consists of a skin-prick test with a small drop of fluorescein to determine if you will have an allergic reaction. Various measurements of your tumor vessels will be recorded and blood flow through the vessels. This component is also considered part of the investigational part of the study.

After surgery:
Following your procedure, you will be transferred to the inpatient ward (either ICU or the regular hospital floor) and receive routine care for this type of surgery, as part of the standard of care for your surgery. The microscopic observation is not expected to change your post-operative care.

6. What are the possible risks or discomforts from being in this research study?

It is anticipated that there will be minimal risk of adding a microscopic observation to the surgical procedure. Your doctor will discuss the risks of your specific surgery and the tests and procedures that are part of your standard clinical care. However, this study with our microscope presents no known additional risk.

Pregnant and/or nursing women will not be allowed to enroll on this study

Use of fluorescein may not be recommended in patients with a history of allergic hypersensitivity to fluorescein. Adverse reactions have been reported to occur in 5% or less of patients and are typically mild, including itching or hives, nausea, difficulty breathing, fainting, headache. Other adverse reactions include skin damage or blood clots at the site of injection, though these are even rarer. You may have a temporary skin discoloration at the site of the allergy testing, which lasts a few hours. Your urine may also be temporarily discolored, which also lasts a few hours.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

9. What are the possible benefits from being in this research study?

It is not known if participation in this observational study will help you or not. Possible help may include identifying tumor characteristics that may someday predict response or guide treatment in the future. Microscopic findings observed during the surgical procedure may have a predictive value of tumor response or recurrence. This would potentially result in improved prognostic information for you and other study participants. You should understand that no guarantee of improved outcome can be made to you for taking part in this research study. Future patients may be helped from the results and information gained from this study. It is hoped that information gained in this study will aid in the understanding of cancer and help in the development of new approaches to its treatment.

10. What alternative do you have if you choose not to participate in this research study?

You may choose to proceed with the surgical procedure without the microscopic observation (which is expected to add 20-30 minutes to your procedure). You may also choose other forms of treatment, including systemic chemotherapy, other available clinical trials, or no treatment.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for drug, medical care, tests and procedures which are done just for this research study. These tests and procedures are:

- Allergy testing
- Fluorescein dye
- Human intravital microscopy (HIVM)

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care.

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Research Billing at the telephone number provided in the Contact Information section of this form.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Observational data collected during this study will be analyzed at a later date. This data will be calculated and recorded in a spreadsheet that will also be saved onto a password-protected hard drive on the Principal Investigator's share drive. Additionally, all data will be de-identified and provided to our Biostatistician for later analysis. Generated data and the raw video images will be stored for review to satisfy any audit of the collected data. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report 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.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature