



Name and Clinic Number

Approval Date: **March 30, 2018**
Not to be used after: **March 29, 2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Intravital Microscopy (IVM) in patients with peritoneal carcinomatosis (PC)

IRB#: 17-009823

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	Phone: (904) 953-2523 Institution Name and Address: Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 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.



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

Peritoneal carcinomatosis (PC) is a condition where cancer spreads along the lining of the abdominal wall, also known as the peritoneum. The cancer can originate from different organs within the abdomen, including the appendix, colon, ovary, and sometimes even from the peritoneum (abdominal lining) itself (in cases of abdominal mesothelioma). PC produces a significant impact on patients and can be difficult to treat. Current treatment options include what is known as cytoreductive surgery with hyperthermic peritoneal chemotherapy (CRS-HIPEC). This involves removing the areas of tumor in the abdomen followed by chemotherapy that is circulated through the abdomen. Your doctors have identified you as an appropriate candidate for this treatment. This study investigates a new application of a special microscope, called an intravital microscope, used to evaluate cancer cells and the blood vessels around cancer in human subjects with PC.

2. Why is this research study being done?

The purpose of this study is to evaluate the microscopic characteristics of the blood vessels associated with tumors that grow along the peritoneum. 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.



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

The timeframe for this research study is limited to your surgery, consisting of the CRS-HIPEC, and your post-operative follow-up. The use of the microscope of your tumor-associated vessels will occur at the time of your surgery. This is expected to take approximately 15 minutes during the time of your operation in the operating room while you are under general anesthesia. Keep in mind that this additional 15 minute time period is quite low compared to the time of the overall procedure, which on average takes 8 hours (480 minutes).

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 7-14 days, with a potential 1-3 days in the intensive care unit. 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 include the following.

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.
- A skin-prick test to determine if you have an allergy to fluorescein (performed during your preoperative visit)
- 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 be ineligible for this study.



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During surgery:

During your surgery (CRS-HIPEC), a microscope will be used to directly observe the blood vessels associated with the tumor implants lining the peritoneum (abdominal lining). Intravenous (IV) dyes will be administered through your catheters connected to your veins in order to help enhance the microscopic observations. These dyes include a substance called fluorescein and indocyanine green, which are two generally safe and frequently used dyes 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.

After surgery:

Following your procedure (CRS-HIPEC), you will be transferred to the inpatient ward (either ICU or the regular hospital floor) and receive routine care for this type of 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-to-no increased risk of adding a microscopic observation to the surgical procedure (CRS-HIPEC). There are, however, inherent risks to CRS-HIPEC itself. Studies have shown the complications for which patients undergoing CRS-HIPEC are at risk, including: leaking from any bowel reconnections (only in the case that bowel removal is considered part of your procedure), prolonged recovery time of bowel function (known as an ileus), and/or a decrease in your blood counts (such as your white blood cells, known as neutropenia) that would be temporary. However, this study with our microscope is unlikely to increase these risks.

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. Adverse reactions to indocyanine green have been reported to be even lower with the incidences of mild, moderate and severe reactions to be 0.15%, 0.2% and 0.05%, respectively. Indocyanine green can cause an allergic reaction in patients who are allergic to iodine-based IV contrast dye, typically given during a CT scan. If you have an allergic reaction to iodine-based IV contrast dye, then you will not be eligible to participate in this study. Please let the study investigators know if you have an allergy to iodine-based IV contrast dye.



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In addition to allergic reactions, other potential side effects to either fluorescein or indocyanine green include nausea, vomiting, upset stomach, a strong taste in the mouth, excess saliva production, headache, skin damage at the site of injection, or pain at the injection site. Some of these side effects may also be related to the surgery and anesthesia, such as nausea, vomiting, upset stomach, or headache. If you experience any of these side effects, you will be treated appropriately.

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.



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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 CRS-HIPEC may have a predictive value of PC 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 CRS-HIPEC procedure without the microscopic observation (which is expected to add 15 minutes to your procedure). You may also choose other forms of treatment, including systemic chemotherapy, other available clinical trials, or no treatment.



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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
- Indocyanine Green Angiography
- 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.



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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.



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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.



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ENROLLMENT AND PERMISSION SIGNATURES

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

Printed Name	/ /	:	AM/PM
	Date		Time

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	/ /	:	AM/PM
	Date		Time

Signature