Official Title: A Phase I Open-Label Dose-Escalation Clinical Trial of CPI-613 in Combination With Modified FOLFIRINOX in Patients With Metastatic Pancreatic Cancer and Good Performance Status
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Wake Forest™
School of Medicine

Section on *Hematology and Oncology*

AN OPEN-LABEL, DOSE-ESCALATION CLINICAL TRIAL OF CPI-613 IN COMBINATION WITH MODIFIED FOLFIRINOX IN PATIENTS WITH METASTATIC PANCREATIC CANCER

Informed Consent Form to Participate in Research
Caio Max S. Rocha Lima, MD, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have pancreatic cancer that has spread to other areas of your body and you have not yet received chemotherapy treatment. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

An investigational drug is one that has not been approved by the U.S. Food and Drug Administration (FDA). CPI-613 is an investigational drug that has not been approved by the FDA for any type of tumor or cancer, and it is currently being studied for the treatment of cancer.

Phase I studies are the first step in testing an investigational medication in humans. These studies look for the best way to give an investigational drug and also try to find out if, and how, it can be given safely. Phase I studies also look for any harmful side effects that occur.

The purpose of this study is to test the safety of the investigational drug CPI-613 ("study drug") when given at different dose levels in combination with a modified dose of a four-drug chemotherapy combination known as FOLFIRINOX. FOLFIRINOX consists of the drugs fluorouracil, folinic acid, irinotecan, and oxaliplatin, all of which have been approved by the FDA for the treatment of various cancers, including pancreatic cancer. CPI-613 is thought to kill cancer cells by turning off their mitochondria. Mitochondria are used by cancer cells to produce energy and are the building blocks needed to make more cancer cells. By shutting off these mitochondria, CPI-613 deprives the cancer cells of energy and other supplies that they need to survive and grow in your body. We want to find out what effects, good and/or bad, CPI-613 has on you and your cancer when given along with FOLFIRINOX. We also want to measure the

amounts of CPI-613 in your blood after it has been given to you, as well as to find the highest dose of CPI-613 that should be used in humans when given along with FOLFIRINOX. In addition, we want to study your tissue (biopsy) sample to see if certain genes can identify patients that would benefit the most from this combination of CPI-613 plus FOLFIRINOX.

How Many People Will Take Part in the Study?

Approximately 21 people at Wake Forest Baptist Health will take part in this study.

What Is Involved in the Study?

Your participation in this study is divided into different visits:

Pre-Study Screening Tests (To see if you are eligible to participate in this study)

After your study doctor has answered all your questions about this study and you have given written consent by signing this form, you will undergo a series of tests to determine if you are eligible to participate in this study.

The following tests may be completed over a four week period before you receive CPI-613:

- You will have imaging scans to determine the extent of your cancer. The first imaging scan will take pictures of the inside of your chest, abdomen and pelvis to determine the extent of your cancer. This imaging scan, known as a computed tomography scan with contrast ("contrast CT scan" or "CAT scan with contrast"), uses computers and x-rays to take detailed pictures of areas inside your body. In addition, a small amount of a special dye called a "contrast material" will be used to help highlight the areas within your chest, abdomen, and pelvis. The contrast material will be injected into your body through a vein in your arm. The other scan that will be performed is a magnetic resonance imaging (MRI) scan. An MRI uses a combination of magnetic fields and radio waves to take detailed pictures of areas inside your body. These scans are part of your routine cancer care and will be billed to your insurance.
- You will have approximately two teaspoons of blood drawn to test for the presence of a tumor marker known as CA 19-9, which is often elevated in individuals with pancreatic cancer.

The following tests may be completed within two weeks before receiving CPI-613:

- The study doctor or study nurse will ask you about your medical history, and obtain a list of all medications that you are currently taking.
- The study doctor or study nurse will examine you and determine your performance status.
- A physical examination with your vital signs (heart rate, blood pressure, breathing rate, and body temperature), height, and body weight will be recorded.
- Approximately 10 teaspoons of blood will be drawn for routine lab tests.
- Approximately two teaspoons of blood will be drawn to evaluate potential heart muscle damage.
- You will undergo a test called an electrocardiogram (ECG) to check the electrical activity

of your heart.

The following test must be completed within one week before receiving CPI-613:

- Pregnancy test for female subjects who can become pregnant. This must be done within one week of starting treatment.

Procedures for Each Cycle of Treatment with CPI-613 and FOLFIRINOX

This clinical research study consists of a minimum of four two-week cycles of treatment with CPI-613 and FOLFIRINOX. The total number of cycles you receive will be determined by how well your cancer responds to the therapy. An overview of the procedures and evaluations that will occur during each cycle is provided below:

Participants may receive different doses of the investigational drug CPI-613 depending on when they are enrolled onto the study. The highest possible dose of CPI-613 is 3,000mg/m^2 and was very well tolerated in another clinical trial done in patients with cancer. In this study, CPI-613 will be given at a lower dose and then gradually increased up to a maximum dose of 3,000mg/m^2.

Day 1

- You will be given CPI-613.
- Immediately after you receive CPI-613, you will be given FOLFIRINOX treatment in this order: oxaliplatin (given immediately after CPI-613); folinic acid and irinotecan (given together immediately after oxaliplatin); and 5-fluorouracil (immediately after the completion of folinic acid and irinotecan therapy)
- Cycle 1 only: Blood will be taken at certain time points to measure levels of CPI-613 (pharmacokinetics) and/or other research. These time points are: just before you receive CPI-613; then at approximately 5 minutes, 30 minutes, 1, 1.5, 2, 4, 6, 8 (optional) and 24 hours after the completion of CPI-613 infusion. The total amount of blood that will be withdrawn during this time is approximately three ounces
- You will have a physical exam and your vital signs will be measured immediately after receiving CPI-613.
- You will have approximately 10 teaspoons of blood drawn for routine lab tests

Day 2

- After you receive treatment with irinotecan on Day 1, you will be continually treated with the 5-fluorouracil infusion for a total of 46 hours.
- You will also have to return to the clinic for the 24 hour blood sample to measure levels of CPI-613 and/or other research.

Days 3

- You will finish the 46 hour 5-fluorouracil infusion and have your pump disconnected.
- You will be given CPI-613. In the event that time will not permit CPI-613 administration following 5FU infusion, you may be treated with CPI-613 at the same time that you are treated with the 5FU. The decision to do this will be up to your doctor and will depend on your individual circumstances.

- You will have approximately two teaspoons of blood withdrawn to measure levels of CPI-613.

Day 4

- You will have approximately two teaspoons of blood withdrawn to measure levels of CPI-613and/or other research.
- As part of your routine care, you will be given a Neulasta injection.

Days 5 through 14

- These days will be rest days where you will receive no treatment.

Monthly

- You will have approximately two teaspoons of blood drawn to check for heart muscle damage
- You will have an ECG test to monitor the electrical activity of your heart

Maintenance Phase

If you are responding to treatment after at least one year on study, you may be eligible to receive maintenance therapy.

Day 1

- You will be given CPI-613.
- Immediately after you receive CPI-613, you will be given FOLFIRINOX treatment in this order: oxaliplatin (given immediately after CPI-613); folinic acid and irinotecan (given together immediately after oxaliplatin); and 5-fluorouracil (immediately after the completion of folinic acid and irinotecan therapy)
- You will have a physical exam and your vital signs will be measured immediately after receiving CPI-613.
- You will have approximately 10 teaspoons of blood drawn for routine lab tests

Day 2

- After you receive treatment with irinotecan on Day 1, you will be continually treated with the 5-fluorouracil infusion for a total of 46 hours.
- You will also have to return to the clinic for the 24 hour blood sample to measure levels of CPI-613 and/or other research.

Days 3

- You will finish the 46 hour 5-fluorouracil infusion and have your pump disconnected.
- You will be given CPI-613. In the event that time will not permit CPI-613 administration following 5FU infusion, you may be treated with CPI-613 at the same time that you are treated with the 5FU. The decision to do this will be up to your doctor and will depend on your individual circumstances.

Day 4

- As part of your routine care, you will be given a Neulasta injection.

Days 5 through 21

- These days will be rest days where you will receive no treatment.

Additional Evaluations and Procedures

After every fourth cycle of treatment, you will have the following performed:

- Contrast CT scan and MRI scan to evaluate the extent of your cancer
- You will have approximately two teaspoons of blood drawn to check your CA 19-9 level

After your participation on the study is complete, you will be contacted twice a month via telephone by the study nurse who will gather information related to any additional cancer treatments you have received, as well as your general health status.

As part of this study, a tissue sample from your original biopsy will be obtained and DNA obtained from that sample will be purified. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. As part of this research project, your DNA will be studied in an effort to find out if there are genes that can identify which patients with metastatic pancreatic cancer will respond the best to treatment with CPI-613 and FOLFIRINOX. Because we do not know how the results of this DNA study relate to your individual health, the results of the research will not be given to you or your doctor without your permission. These results will also not be placed in your medical records.

OPTIONAL BLOOD AND PLASMA SAMPLES

We are asking that you provide samples of your blood and plasma to the study team for future research. If you agree to participate in the optional blood and plasma banking portion of this study, we will draw approximately four teaspoons of blood and plasma to use for future research during pre-study screening and before each restaging scan. This sample will be kept and may be used in future research to learn more about how CPI-613 works. Your sample will be obtained in the department of Hematology and Oncology at Wake Forest University Baptist Medical Center. The sample will be stored in the Tumor Tissue Core Facility of Wake Forest and it will be given only to researchers approved by Dr. Caio Max S. Rocha Lima. An Institutional Review Board (IRB) must also approve any future research study using your blood and plasma samples. You do not have to provide blood and plasma samples for future research to be able to participate in this study.

Your blood and plasma sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be performed with your blood and plasma sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood and plasma will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood and plasma sample will not affect your care.

Your blood and plasma sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

____YES I would like to allow for collection and storage of my blood and plasma samples
____NO I would not like to allow for collection and storage of my blood and plasma samples

HOW LONG WILL I BE IN THE STUDY?

You will receive CPI-613 and FOLFIRINOX two days a week for one week, followed by a week of rest. This two week period is considered "a cycle." CPI-613 will be given over a two-hour infusion into your vein through a central venous catheter (a catheter that is put into a larger vein in your body and will remain in place for the duration of the treatment). FOLFIRINOX treatment will be given over a six hour infusion.

Your treatment with CPI-613 will continue if you receive benefit from the CPI-613, until you have an unacceptable side effect to the drug or your cancer gets worse.

You can stop participating at any time. It is important to tell the study doctor if you are thinking about stopping so that any risks from CPI-613 can be evaluated by your study doctor. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks Related to CPI-613

The study drug is in the very early stages of development for use in humans. The main purpose of this study is to learn about the safety of the drug when given with FOLFIRINOX. Please carefully read the sections on risk and benefits below. Not all of the side effects are known at this time. If you choose to take part in this study, it is very important that you let the study team know of any symptoms you have.

Some potential risks associated with CPI-613 have been determined from previous animal studies. These side effects include vomiting and some temporary heart damage. CPI-613 has also caused inflammation around the area where the experimental drug is given, causing swelling,

redness, and pain. To avoid this potential side effect, CPI-613 will be given to you through a central venous catheter. There may be other more severe side effects such as significant inflammation throughout your body. The study drug could cause changes in certain chemicals in your blood that could indicate liver problems. Significant side effects have also caused some deaths in test animals at dose levels that are higher than those to be used in this study. Many side effects may go away shortly after being given CPI-613 but in some cases, side effects may be severe, long lasting, or may not go away. Although not yet reported in any human subjects, it remains possible that CPI-613 might cause your disease to progress or produce a fatal side effect. CPI-613 may also cause side effects that we have not yet seen and cannot predict.

Some side effects observed in approximately 10-40% of patients taking CPI-613 include:

- Allergic reaction at the place where you receive your drug
- Vomiting
- Diarrhea
- Fatigue
- Nausea
- Changes in liver function
- Changes in kidney function, which can be kidney failure if severe
- Too much or too little calcium in the blood
- Anemia
- Low levels of white blood cells
- Low levels of platelets (blood cells that help to form clots)
- Electrolyte imbalance

There are also rare side effects observed in patients taking CPI-613, and they include:

- Headache
- Constipation
- Light-headedness
- Abdominal pain
- Jaundice (temporary yellowing of the skin and eyes)
- Flushing

There may be other, more severe side effects, such as inflammation throughout your body. The study drug could cause changes in certain chemicals

Pregnancy Risks Related to CPI-613

The effects of CPI-613 on a fetus are unknown. You should not become pregnant or father a child while on this study. If you are able to become pregnant or father a child, BOTH you and your partner must use effective birth control methods during the study period. Effective birth control methods are outlined below.

Women subjects who have never been pregnant can use one of the following methods:

- Abstinence
- A barrier method (diaphragm, cervical cap, sponge, or condom with a spermicidal foam or jelly) plus hormonal birth control (oral, patch or injectable).
- A barrier method (diaphragm, cervical cap, sponge, or condom with a spermicidal foam or jelly) plus and intrauterine device (IUD).

Women subjects who have previously been pregnant at least once can use one of the following methods:

- Abstinence
- A barrier method (diaphragm or condom with a spermicidal foam or jelly) plus hormonal birth control (oral, patch or injectable).
- A barrier method (diaphragm or condom with a spermicidal foam or jelly) plus and intrauterine device (IUD).

Male subjects can use one of the following methods:

- Abstinence
- Condom with spermicide

For male subjects, you should also advise your partner to use an effective birth control method such as those outlined above for women subjects.

If you suspect that you have become pregnant, you must notify the study doctor immediately.

Female subjects should avoid becoming pregnant for at least 10 weeks following completion of the study. Male subjects should avoid fathering a child for at least 10 weeks following study completion.

Risks Related to Continuation of CPI-613 Treatment for Two More Cycles After Imaging Scans Indicate Disease Progression

When imaging scans indicate that you have progression in your disease, you will continue to receive CPI-613 for two more cycles as long as you still meet eligibility criteria and you do not have worsening of your biliary function or symptoms of disease progression. There is no evidence that this will benefit you and continued treatment may expose you to toxicities of CPI-613 that are described above. The reason for that is because CPI-613 can cause first swelling of your tumor that cannot be easily distinguished with the first scan.

Risks Related to FOLFIRINOX Therapy

Patients treated with FOLFIRINOX as standard of care can experience increased susceptibility to serious and potentially fatal infections. To reduce this risk you are receiving support with Neulasta injection on Day 4 to decrease the risk of persistent low white cell counts. Despite this support, you may have an overwhelming infection that can be fatal. This treatment is only appropriate for patient with a good fitness level.

You may also experience other side effects of FOLFIRINOX. Some common side effects observed in patients who received FOLFIRINOX include:

- Anemia
- Low white blood cells
- Low platelets
- Fever
- Fatigue
- Vomiting
- Diarrhea
- Nerve damage
- Liver damage
- Blood clots

Other Risks

It is possible that you could experience an allergic reaction to CPI-613 or to any combination of the drugs used in this study. An allergic reaction can be mild, or it can be serious, leading to shock with loss of consciousness, or it can be life-threatening.

Certain drugs, when taken together with the study drug, may increase side effects. It is possible that CPI-613 could increase the side effects of FOLFIRINOX and other drugs. It is important that you inform your study doctor of any prescription, over-the-counter, or alternative medications you are taking while in this study.

Drawing blood may cause pain, bruising, lightheadedness, or, on rare occasions, infection.

Risks of a central venous catheter may include pain, bleeding, infection, and damage to lungs or other tissue.

You may experience what is known as a "tumor flare" reaction of your tumor as a result of your treatment in this study. Tumor flare reactions are usually characterized by pain and swelling in the tissues surrounding your tumor. Occasionally, this can lead to a blockage or clog in your bile duct. Your bile duct is a short tube that transports bile from your liver and gallbladder to your intestines, where it helps to digest the fat in foods that you eat. If your bile duct becomes clogged, you may be treated with a stent, which is a tube inserted into the bile duct to unclog it. However, even if this side effect occurs, you will still be able to participate in the study if you choose to do so.

Your condition may not get better or may become worse during this study. Due to changes in your condition, you may also have increased susceptibility to serious and potentially fatal infections with FOLFIRINOX.

If you have questions about risks and side effects, ask your study doctor. ***You should talk to your study doctor about any side effects that you have while taking part in this study.*** The study doctor will take steps to try to treat any side effects, if they appear. If the study drug causes

severe side effects or if your disease worsens, the study drug will be discontinued. In that case, your study doctor will discuss treatment options with you.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: improvement in your cancer.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: Other chemotherapies.

Comfort care, which is an option if you decide that you do not want any more active treatment for your cancer. Comfort care includes pain medication and other types of support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends, and your doctor.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your health history, medical images, genetic information, how you respond to study procedures, laboratory and other test results, and physical examinations.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) The U.S. Food and Drug Administration (FDA); Cornerstone Pharmaceuticals, Inc.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Caio Max S. Rocha Limathat you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Caio Max S. Rocha Lima, [redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health

Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE THE COSTS?

The investigational study drug, CPI-613, is being provided to you at no cost from the pharmaceutical company (Cornerstone Pharmaceuticals, Inc.). However, taking part in this study may lead to added costs to you or your insurance company. We will give you an estimate of what the added cost may be based on your particular situation and insurance carrier.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. Parking validation will be provided for all study-related visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Science. Cornerstone Pharmaceuticals, Inc. is providing the investigational drug (CPI-613) to Wake Forest University Health Sciences to help conduct this study. Boris Pasche, MD, the Director of the Comprehensive Cancer Center of Wake Forest Baptist Medical Center serves on the board of directors for Rafael Holdings, Inc., which owns the manufacturer of the drug that is being studied. Timothy Pardee, MD holds a part-time position as Chief Medical Officer for Rafael Pharmaceuticals, Inc, the study drug manufacturer. Dr. Bayard Powell serves on the Scientific Advisory Board for Rafael Pharmaceuticals, Inc.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security

number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Caio Max S. Rocha Limaat [redacted].

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest, you do not follow the study rules, the study is stopped, you do not later consent to any future changes that may be made to the study plan, or your become pregnant.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Caio Max S. Rocha Limaat [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm