Informed Consent Form

WINSHIP4441-18: Weight Loss in Patients with Advanced Stage Pancreatic Cancer: Role of Serotonin and Effects of Telotristat Ethyl

NCT Number: NCT03910387

Document IRB Approval Date:
1/10/23

EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Weight Loss in Patients with Advanced Stage Pancreatic Cancer: Role of Serotonin and Effects of Telotristat Ethyl **(Group 1)**

IRB #: IRB00105292

Principal Investigator: Gehan Botrus, MD

Investigator-Sponsor: Gehan Botrus, MD

Study-Supporter: Lexicon

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
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You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to evaluate weight stability in advanced stage pancreatic cancer patients by utilizing Telotristat Ethyl (a drug approved to decrease bowel movements in another cancer) in combination with chemotherapy for patients who had an estimated weight loss of 10% before diagnosis or treatment. The aim of this study is to show stable weight when adding Teloristat Ethyl to combination chemotherapy.

What will I be asked to do?

Majority of pancreatic cancer patients lose weight before the diagnosis. Telotristat Ethyl is a medication approved to decrease bowel movement in a different cancer. By decreasing bowel movements, patients might gain weight. We are studying the use of this oral medication in combination with chemotherapy for patients who had lost approximately 10% of their weight before the diagnosis or treatment of their advanced pancreatic cancer. The aim of weight stabilization is to help patients tolerate the chemotherapy better and get longer time of treatment which might help with improving longevity. You will be asked to take the study medication (Telotristat Ethyl) three times a day starting the first day of your chemotherapy. This will be given to you at the time of your clinic visit. Telotristat is FDA approved for a different type of cancer (neuroendocrine tumor) to control diarrhea associated with this cancer. The study medication will be given to you with the standard of care chemotherapy until disease progression or intolerance to chemotherapy/study medication.

There are also blood and urine tests that are needed to check the effect of the study medication (Telotristat) on certain proteins in the blood and urine. We will be checking the levels of 5-HIAA (the protein) by collecting blood samples (about 1 teaspoons [5 mL]) and a urine (24 hr urine collection) sample to check for baseline levels of these proteins and follow up on these levels every month until disease progression or intolerance to chemotherapy/study medication. You will be asked to get these blood test and urine test before starting the treatment and every month until disease progression or intolerance to chemotherapy/study medication after your initial visit.

In addition to the blood and urine samples, we will need to check the circumference of your arm using a measuring tape to check if you are gaining or losing weight. There will be no scans or radiation exposure other than the standard of care scans that are needed to check on the cancer response to your treatment.

You will also be asked to fill a quality of life questionnaire at every visit.

Your first visit will make sure that you are able to participate in this study. The visit will take place within 28days before you have your first treatment with the study drug. The following tests and procedures must be done. Most of the tests are part of your routine medical care. Your doctor, with the help of study staff, will:

- Obtain your complete medical history
- Review any medications you have taken or are currently taking
- Do a complete physical examination (including height and weight)
- Record your vital signs (body temperature, heart rate, blood pressure and breathing rate)
- Record your performance status (how well you are able to perform your everyday activities)
- Collect blood samples (about 3 teaspoons [14 mL]) and a urine sample (over 24 hrs) to check blood cell counts, organ function, and baseline levels of other chemicals. If you are a woman who is able to have children, a pregnancy test will be performed in this blood to see if you are pregnant.
- A computed tomography (CT) scan or magnetic resonance imaging (MRI) to find out the size and location of your tumor(s) at the beginning of the study.

CT Scan: A CT scan allows your doctor to see inside your body to look at the size of your tumor(s). For the CT scan, you may be given a contrast liquid to drink. Or, an IV (intravenous) line may be started by a needle stick in the arm so a contrast liquid can be injected through the line. The IV contrast liquid is a special dye used to get clearer pictures of your body. You will lie flat on a table that will move you into the CT scanner, which is a large, tunnel - shaped machine. You will be asked to lie still and may be asked to hold your breath for a few seconds. The CT scan takes about 30 to 60 minutes and is considered a part of your standard medical care.

MRI Scan: An MRI scan also allows your doctor to see inside your body to see the size of your tumor(s). You may be given gadolinium (a contrast liquid) through a vein in your arm. Gadolinium is a liquid that causes some tumors to appear much brighter than normal tissue on MRI scans. Before gadolinium is injected, the tumor may not be visible. An intravenous (IV) catheter (a tiny tube) may be placed in your arm to inject the contrast liquid. You will then lie on a table that will move into a large tunnel - shaped machine (similar to a CT scan). The MRI scan uses radio frequency waves (like those in an AM/FM radio) and a strong magnet to create a picture of your tum or(s). The MRI scan takes about 60 minutes and is considered a part of your standard medical care.

The results of the screening tests will show whether you are able to take part in this study. If you are able to take part and still want to participate, you will plan another visit to start your treatment.

Treatment:
You will get your first dose of study drug within the 14 days after your screening visit. You will be receiving the study drug (Telotristat ethyl) oral pill to take 3 times a day on the day of your chemotherapy visit.

40 patients will be enrolled: All patients with pancreatic cancer will receive the study drug (No placebo) in combination with chemotherapy.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?
If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study. The information about tolerance to the treatment, progression of the disease, response to treatment, muscle mass measured by the circumference of the biceps and size of certain muscles on the scans, extra blood and urine tests to check specific levels, and longevity will be collected and stored in a password file. Your data will be given a number to remove your identity (name). The data will be analyzed after enrolling 40 patients.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time.

There is a possibility that telotristat might affect one of the chemotherapy efficacy. This might affect response of the cancer to the treatment. Any side effects from the study medication might delay the chemotherapeutic treatment plan.

The most common risks and discomforts expected in this study are:

- Central nervous system: Headache (11%)
- Gastrointestinal: Nausea (13%)
- Cardiovascular: Peripheral edema (7%) [swelling of the legs]
- Central nervous system: Depression (9%)
- Endocrine & metabolic: Increased liver proteins (9%) [GGT]
- Gastrointestinal: Decreased appetite (7%), flatulence (7%), abdominal pain (≥5%), constipation (≥5%)
- Hepatic: Increased serum alkaline phosphatase (<5%), increased serum ALT (<5%), increased serum AST (<5%)- Liver Enzymes
- Miscellaneous: Fever (7%)

Rare but possible risks include: intestinal obstruction, intestinal perforation

Radiation-Related Risks:
You will be exposed to radiation from CT scans. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 3 years. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study and 90 days after last dose. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for 28 days after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
This study is not designed to benefit you directly. Your cancer may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about your weight while you are getting the treatment. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this study.

What are my other options?
If you decide not to enter this study, there is care available to you outside of this research study. You will still receive the same chemotherapy proposed by your doctor as approved treatment or possibility of enrolling onto other studies. The study doctor will discuss these with you if these are available options. You do not have to be in this study to be treated for pancreatic cancer.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record
If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you get medical treatment. Emory and Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Gehan Botrus at telephone number 404-778-1900. You should also let any health care provider who treats you know that you are in a research study.

Emory and Saint Joseph's Hospital have not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee.

Costs

The study supporter will pay for certain items and services that you may receive if you take part in this study.

Lexicon, the study-supporter, will provide Telotristat Ethyl medication. The study supporter will pay for the serotonin testing.

You will have to pay for the items or services for which the study supporter does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover.

Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Saint Joseph's Hospital and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate in.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Gehan Botrus is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - The study-supporter, Lexicon.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will

be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. Gehan Botrus
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The study supporter, and people and companies working with the study supporter on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Dr. Gehan Botrus at 404 778-1900:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ____:____ **am / pm**
Signature of Subject (18 or older and able to consent) **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ____:____ **am / pm**
Signature of Person Conducting Informed Consent Discussion **Date** **Time (please circle)**

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Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Weight Loss in Patients with Advanced Stage Pancreatic Cancer: Role of Serotonin and Effects of Telotristat Ethyl **(Group 2)**

IRB #: IRB00105292

Principal Investigator: Gehan Botrus, MD

Investigator-Sponsor: Gehan Botrus, MD

Study-Supporter: Lexicon

Introduction

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- Please carefully read this form or have it read to you
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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.

What is the purpose of this study?

The purpose of this study is to evaluate the blood and urine levels of a protein (5HIAA- a derivative of serotonin) in advanced stage pancreatic cancer patients receiving chemotherapy. We are interested in studying what this protein entails in terms of response to therapy and how it changes with therapy. We will also evaluate the effect of the weight changes and quality of life with the specified protein levels. The aim of this study is to evaluate the blood and urine levels for patients receiving combination chemotherapy (standard of care) in pancreatic cancer and correlate the levels to survival.

What will I be asked to do?
Majority of pancreatic cancer patients lose weight before the diagnosis. The quality of life is affected by the cancer diagnosis and the treatment. We are studying the effect of combination chemotherapy for patients with advanced pancreatic cancer on the protein (serotonin or 5HIAA) levels in the blood and urine. We will correlate the levels to survival.

Who owns my study information and samples?
If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study. The information about tolerance to the treatment, progression of the disease, response to treatment, muscle mass measured by the circumference of the biceps and size of certain muscles on the scans, extra blood and urine tests to check specific levels, and longevity will be collected and stored in a password file. Your data will be given a number to remove your identity (name). The data will be analyzed after enrolling 40 patients.

What are the possible risks and discomforts?
We will be collecting an extra 5 ml (1 teaspoon) of blood at the initial visit and monthly until disease progression or intolerance to the standard of care chemotherapy. This might require a needle stick to draw the blood but we are anticipating to get the 5 ml (1 teaspoon) at the time the laboratory personnel is taking blood as the standard of care testing before chemotherapy.

We are also asking you to collect the urine for 24 hrs (in a gallon container) the day before the initial chemotherapy and every month until disease progression or intolerance to the standard of care chemotherapy.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
This study is not designed to benefit you directly. This study is designed to learn more about changes of protein levels (serotonin or 5HIAA) in the blood and urine while you are getting chemotherapy for the treatment of your advanced pancreatic cancer. The study results may be used to help others or medical professionals in the future.

Will I be compensated for my time and effort?
You will not be offered compensation for being in this study.

What are my other options?
If you decide not to enter this study, there is care available to you outside of this research study. You will still receive the same chemotherapy proposed by your doctor as approved treatment or possibility of enrolling onto other studies. The study doctor will discuss these with you if these are available options. You do not have to be in this study to be treated for pancreatic cancer.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you get medical treatment. Emory and Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Gehan Botrus at telephone number 404-778-1900. You should also let any health care provider who treats you know that you are in a research study.

Emory and Saint Joseph's Hospital have not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee.

Costs

The study supporter will pay for certain items and services that you may receive if you take part in this study.

The study supporter will pay for the serotonin testing.

You will have to pay for the items or services for which the study supporter does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the supporter does not cover. Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Saint Joseph's Hospital and the supporter will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate in.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.

- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Gehan Botrus is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - The study-supporter, Lexicon.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. Gehan Botrus
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The study supporter, and people and companies working with the study supporter

on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Gehan Botrus at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject (18 or older and able to consent) **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ____:____ am / pm
Signature of Person Conducting Informed Consent Discussion **Date** **Time (please circle)**