Study Title:	Surgical Debulking Prior to Peptide Receptor Radionuclide Therapy (PRRT) in Patients with Well Differentiated Gastroenteropancreatic Neuroendocrine Tumors
Version Date:	14 July 2023 NCT06016855
PI:	Kamran Idrees, M.D., M.S.C.I.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to participate in this research study because you have a type of cancer called a gastroenteropancreatic neuroendocrine tumor (GEP-NET). This is a type of tumor that can form in the pancreas or in other parts of the gastrointestinal tract. For this disease, it is anticipated that you will have debulking surgery to remove as much detected GEP-NET disease as is deemed feasible by surgeons.

This is a single institution pilot study to assess the response rate of a combination of standard of care treatment in GEP-NET by initiating the standard of care treatment of peptide receptor radionuclide therapy (PRRT) with lutetium 177 (177Lu) dotatate within 90 days of removing tumors greater than 3cm.

Patients with GEP-NET disease that has spread to the liver (hepatic metastasis) are asked to participate because their study doctor feels they may possibly benefit from an FDA-approved standard treatment against GEP-NET, called lutetium Lu 177 dotatate (pronounced "loo-TEE-shee-uhm DOE-ta-tate") after standard of care surgery.

Lutetium Lu 177 dotatate (also known as LUTATHERA®) is a radioactive drug that uses targeted radiation to kill cells. Lutetium Lu 177 dotatate includes a radioactive form (an isotope) of the element called lutetium. This radioactive isotope (Lu-177) is attached to a molecule called dotatate. On the surface of GEP-NET tumor cells, a receptor called a somatostatin receptor binds to dotatate. When this binding occurs, the lutetium Lu 177 dotatate drug then enters somatostatin receptor-positive tumor cells, and radiation emitted by Lu-177 helps kill the cells.

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After debulking surgery, each patient in this study is scheduled to receive 4 total doses of lutetium Lu 177 dotatate (one dose by intravenous infusion into a vein every 8 weeks) across 32 weeks of scheduled treatment after surgery.

It is unknown if this study will help you. You may have side effects from the study treatment and feel worse. Your disease may or may not respond to treatment received in this study.

The length of time you receive treatment in this study will depend on the side effects you may experience, and how your disease does or does not respond to treatment received in this study. It is anticipated you may receive treatment in this study until you have intolerable side effects, until your disease gets worse, or for up to about 8 months of lutetium Lu 177 dotatate treatment during participation in this study. You also may withdraw from the study at any time.

If you have side effects, your study doctor may require you to temporarily stop lutetium Lu 177 dotatate and/or reduce your dose of lutetium Lu 177 dotatate. If you have serious side effects, you may be required to permanently stop lutetium Lu 177 dotatate and discontinue participation in the study.

Because lutetium Lu 177 dotatate is a standard drug for your disease, you and/or your insurance will be responsible for the cost of lutetium Lu 177 dotatate treatment you receive in this study, as well as the usual care including surgery for your disease that you would receive even if you were not participating in this study.

About 6 patients are anticipated to enroll in this study at Vanderbilt.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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Screening

You will have the following things done within 90 days prior to surgery, in order to determine if you are a good candidate for the study:

- Review of your general medical history including information about your disease and what previous treatments you may have received.
- Physical exam and questions about your level of activity.
- Measurement of your height and body weight.
- You will be asked about and you should tell your study doctor about any problems you are having and the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Copper Cu 64 dotatate PET/CT scan (within 6 months [180 days] prior to surgical debulking on Day 0) to check your disease and help plan for surgery. Copper Cu 64 dotatate is a radioactive imaging drug (radiopharmaceutical) that you will receive by an infusion into a vein as part of positron emission tomography (PET) scanning. The purpose of this scanning is to help identify locations in your body that are suspicious for disease associated with neuroendocrine tumors (NETs). Specifically, doctors want to see where somatostatin receptor-positive neuroendocrine tumors are detected in your body (based on where the radioactive copper Cu 64 dotatate imaging drug causes the PET/CT imaging scans to "light up"); because tumors with this quality are intended to be specifically targeted by the lutetium Lu 177 dotatate treatment that all patients in this study are scheduled to receive after surgery.

Day 0

If you are eligible for the study, you will return to Vanderbilt for surgery; the following things will be done:

- **Surgical debulking** to remove as much detected GEP-NET disease as is deemed feasible by surgeons.
- During surgery, samples from at least one removed (resected) tumor from each patient will be obtained and subsequently sent to a laboratory for genetic research. More information about this is included in the last pages of this consent form.

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Cycle 1, Day 1

Within 90 days after your surgery on Day 0, you will return to Vanderbilt to start treatment with lutetium Lu 177 dotatate; the following things will be done:

- Physical exam and questions about your level of activity.
- Measurement of body weight.
- Questions about any side effects you are experiencing, and about any changes to your medications.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test (unless already done within the last 28 days).
- Copper Cu 64 dotatate PET/CT scan (within 3 months [90 days] after surgical debulking on Day 0) to check your disease after surgery.
- **Lutetium Lu 177 dotatate**: intravenous (IV) infusion into a vein over about 30-40 minutes. Additionally, for about 30 minutes before your infusion, during your infusion, and for at least 3 hours after your lutetium Lu 177 dotatate infusion, you will likely receive standard medications (such as antiemetics and amino acids) to help against possible side effects like nausea and vomiting, and to help protect your kidneys from radiation in the lutetium Lu 177 dotatate drug.

Cycle 2, Day 1

About 57 days (±7 days) after your first dose of lutetium Lu 177 dotatate, you will return to Vanderbilt for your second dose of lutetium Lu 177 dotatate; the following things will be done:

- Physical exam and questions about your level of activity.
- Measurement of body weight.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- **Lutetium Lu 177 dotatate**: intravenous (IV) infusion into a vein over about 30-40 minutes. Additionally, for about 30 minutes before your infusion, during your infusion, and for at least 3 hours after your lutetium Lu 177 dotatate infusion, you will likely receive standard medications (such as antiemetics and amino acids) to help against possible side effects like nausea and vomiting, and to help protect your kidneys from radiation in the lutetium Lu 177 dotatate drug.

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Cycle 3, Day 1

About 113 days (±7 days) after your first dose of lutetium Lu 177 dotatate, you will return to Vanderbilt for your third dose of lutetium Lu 177 dotatate; the following things will be done:

- Physical exam and questions about your level of activity.
- Measurement of body weight.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- **Lutetium Lu 177 dotatate**: intravenous (IV) infusion into a vein over about 30-40 minutes. Additionally, for about 30 minutes before your infusion, during your infusion, and for at least 3 hours after your lutetium Lu 177 dotatate infusion, you will likely receive standard medications (such as antiemetics and amino acids) to help against possible side effects like nausea and vomiting, and to help protect your kidneys from radiation in the lutetium Lu 177 dotatate drug.

Cycle 4, Day 1

About 169 days (±7 days) after your first dose of lutetium Lu 177 dotatate, you will return to Vanderbilt for your fourth and final scheduled dose of lutetium Lu 177 dotatate; the following things will be done:

- Physical exam and questions about your level of activity.
- Measurement of body weight.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¾ teaspoon of your blood for routine laboratory testing (including blood counts and blood chemistry).
- **Lutetium Lu 177 dotatate**: intravenous (IV) infusion into a vein over about 30-40 minutes. Additionally, for about 30 minutes before your infusion, during your infusion, and for at least 3 hours after your lutetium Lu 177 dotatate infusion, you will likely receive standard medications (such as antiemetics and amino acids) to help against possible side effects like nausea and vomiting, and to help protect your kidneys from radiation in the lutetium Lu 177 dotatate drug.

30-Day Follow-Up

Approximately 30 days after your final treatment in this study (or perhaps earlier if you begin new anti-cancer treatment after this study), you will have the following things done as part of follow-up:

- Physical exam and questions about your level of activity.
- Measurement of body weight.
- Questions about any side effects you are experiencing, and about any changes to your medications and any new anti-cancer therapy you may have started.

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Long-term Follow-Up

About every 3 months (12 weeks) after your last treatment with lutetium Lu 177 dotatate in this study:

- You and/or your doctor's office may be contacted, for example by telephone or a clinic visit, to check on how you are doing and to learn about any new anti-cancer therapy you may have started.

These long-term follow-up procedures are intended until one of the following occurs (whichever occurs first): study ends, you withdraw your consent, your death, or until 2 years after your final dose of lutetium Lu 177 dotatate in this study. Additional follow-up beyond two years may occur if deemed medically necessary by your study physician. Note: this same long-term follow-up procedure and schedule is also intended (about every 3 months after surgery on study Day 0) if you receive surgical debulking on study Day 0, but do not initiate lutetium Lu 177 dotatate within the study (for example, due to post-operative surgical complication or your decision to not initiate lutetium Lu 177 dotatate within the study after surgery).

Side effects and risks that you can expect if you take part in this study:

You may have side effects while on this study. Everyone participating in the study will be watched carefully for side effects. However, study doctors do not know all the side effects that may happen and there may be risks that we do not know about at this time.

Side effects may be mild or very serious. Some side effects could begin soon after you begin treatment in the study. Other side effects could be delayed and occur later in the study, or even after you stop treatment in the study. Your health care team may give you medicines to help decrease the frequency or severity of side effects. In some cases, side effects can be serious, long lasting, or may never go away.

There is also a risk of death.

You should tell your study doctor or study nurse right away about any possible side effects that you experience while participating in this study. Getting medical treatment right away may help keep side effects from becoming more serious.

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Information for women who could become pregnant (Women of Child-bearing Potential):

- Before starting treatment in this study, tell your study doctor if you are pregnant or plan to become pregnant.
- You will have a pregnancy test before starting treatment in this study.
- Together with your partner, you must use effective birth control during treatment in this study and for at least 7 months after your final dose of study treatment. Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor right away if you think you may be pregnant, or if you become pregnant during treatment in this study.
- Tell your study doctor if you are breastfeeding or plan to breastfeed. It is not known if the study treatment passes into your breast milk. Do not breastfeed during treatment in this study and for at least 2.5 months after your final dose of study treatment.

Information for men with sexual partners who could become pregnant (Partners of Childbearing Potential):

From the time you start treatment in this study until at least 4 months after your final dose of study treatment you must:

- Tell your sexual partner about your participation in this clinical trial. Together with your partner, you must use effective birth control during treatment in this study and for at least 4 months after your final dose of study treatment. Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor immediately if your partner becomes pregnant during this clinical trial.

Risks of Procedures

Blood Collection

Risks of taking blood include pain, a bruise at the point where blood is taken, redness and swelling of the vein, infection, and a rare risk of fainting.

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Copper Cu 64 Dotatate PET/CT Scan

Positron emission tomography (PET) scanning in this study will use a radioactive form of copper (Cu 64) as a tracer to help identify locations in your body that are associated with neuroendocrine tumors (NETs). Specifically, doctors want to see where somatostatin receptor-positive neuroendocrine tumors are detected in your body (based on where the radioactive copper Cu 64 dotatate imaging drug causes the PET/CT imaging scans to "light up"); because tumors with this quality are intended to be specifically targeted by the lutetium Lu 177 dotatate treatment that all patients in this study are scheduled to receive after surgery.

Copper Cu 64 dotatate is a radioactive imaging drug (radiopharmaceutical) that you will typically receive by an infusion into a vein (IV). The needle is often inserted on the inside of your elbow. The tracer travels through your blood and collects in organs and tissues. This helps the radiologist see certain areas more clearly.

You will need to wait as the tracer is absorbed by your body. This often takes about 1 hour. Then, you will lie on a narrow table that slides into a large tunnel-shaped scanner. The PET scan detects signals from the tracer. A computer changes the signals into 3D pictures. The images are displayed on a monitor for your health care provider to read.

You must lie still during the test. Too much movement can blur images and cause errors. How long the test takes depends on what part of the body is being scanned.

Potential side effects associated with radiotracers typically include pain at IV site, infection, bleeding, low blood pressure, changes in blood sugar levels, and allergic reactions.

Intravenous (IV) Catheter

Prior to beginning lutetium Lu 177 dotatate, your study doctor may need to insert an intravenous (IV) catheter for the delivery of pembrolizumab and to take blood samples. IV catheters can usually be placed in a hand, arm, or leg. These are known as "peripheral" IVs. IVs placed in the central circulation, like the internal jugular vein (neck) or subclavian vein (just beneath the collar bone), are known as "central lines." You should discuss this with your study doctor. For both types of intravenous catheter, the area will be numbed (with an anesthetic) before the catheter is inserted. During the insertion, you could feel a pinch and shortly thereafter bleeding, redness, or a bruise could develop. Rarely, an infection could occur if not kept clean. For central catheters, although rare, they can sometimes cause collapse of a lung or cause bleeding. Lung collapse is usually treated by putting a tube into your chest for a few days to allow your lung to expand. Pressure is placed on any area that might bleed.

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Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Participating in this study may help patients with cancer get better care in the future.

The benefits you might get from being in this study: Participating in this study may or may not have direct medical benefit for you. You may or may not receive therapeutic benefit from participation in this study. Your condition may get better but it could stay the same or get worse.

Payments for your time spent taking part in this study or expenses:
You will not be paid for your participation in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

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If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact [redacted]. If you cannot reach the research staff, please [redacted].

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your study doctor might take you out of the study for reasons such as:

- You are unable to tolerate the treatment, or you have a side effect and the study doctor feels should end the treatment.
- Your disease spreads or gets worse (progresses).
- You have another serious illness or need major surgery.
- You do not follow the study doctor's instructions.
- Your health changes or new information becomes available and the study doctor feels it is no longer in your best interest for you to continue in the study, or decides to stop the study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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.

Confidentiality:
All efforts within reason will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a code. Dr. Idrees, his staff, and other authorized people will be the only people who know your personal information.

Study data will be recorded in a Vanderbilt electronic database which is maintained by a research coordinator and data manager at Vanderbilt. The electronic database is password protected in order to help protect your identity. Your study records will be locked up in the clinical trials office. Vanderbilt

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may share your information, without identifiers, with others or use it for other research projects not listed in this form. Vanderbilt, Dr. Idrees and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Dr. Idrees to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

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There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).
Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it
Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let him know by using the contact information provided in this consent form. Dr. Idrees's mailing address is:

[redacted]

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[redacted]

Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

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Consent for Genetic Research

A purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, samples from at least one removed (resected) tumor during your surgery will be obtained and subsequently sent to a laboratory for genetic research. You are being asked for your permission to allow this.

It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

What we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Idrees and his staff helping with the study will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

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Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Idrees to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below. A question with only a 'Yes Box' indicates a required part of the study:

My blood/tissue/fluid samples may be used for current gene research in cancer related to lutetium Lu 177 dotatate:

☐ **Yes** ☐ **No**

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ **Yes** ☐ **No**

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ **Yes** ☐ **No**

Signature: _____ Date: _____