Informed Consent Form

RAD4516-18: Advanced PET-CT Directed Post-Prostatectomy Radiotherapy to Enhance Prostate Cancer Outcomes

NCT Number: NCT03762759

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You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 140 people who are being studied, at Emory and elsewhere.

Why is this study being done?
This study is being done to answer the question: Will using a PET scan (either fluciclovine or GaPSMA PET scan) be useful in planning radiation treatments. You are being asked to be in this research study because of your Prostate Cancer.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for about 5 years (40 study visits). The researchers will ask you to do the following:
• History and physical
• A CT (Computed Tomography) scan or MRI (Magnetic Resonance Imaging) of your abdomen and pelvis to determine if there is any evidence of cancer spread to the pelvic lymph nodes. A CT scan is a study using x-rays to look at one part of your body. An MRI is imaging using a strong magnetic field to look at one part of your body.
• A bone scan to determine if the cancer has spread to the bones.
• Review of the tissue from your prior surgery to remove your prostate to determine your Gleason score (a value that helps determine the aggressiveness of your prostate cancer).
• You will be asked to complete a form that asks questions on your urinary, bowel hormone, and sexual functions.

Some of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Taking part in this research study may not benefit you personally. The outcome for patients randomized to Group 2 may or may not be as good, or may be better, than patients in Group 1 receiving standard of care. We do know that the information from this study will help researchers learn more about how best to treat men who have a rising PSA after surgery to remove their prostate. This information could help future cancer patients

What are the risks or discomforts you should know about before deciding?
The study will take time. The procedure that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen requiring additional procedure or surgery, such as a colostomy (bag for stool)
- Intestinal obstruction requiring surgery

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

• Getting treatment or care for your cancer without being in a study; this could include the following options (any of which could involve getting the conventional radiotracer [fluciclovine] off study), either alone or in combination with each other:
  - External beam radiation therapy (typically, to the prostate bed)
  - External beam radiotherapy plus hormone therapy
  - Hormone therapy
• Taking part in another study
• Getting no treatment (With this choice, your tumor could continue to grow and your disease could spread)

Talk to your doctor about your choices before you decide if you will take part in this study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

The study sponsor will pay for certain items and services that you may receive if you take part in this study. You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care.

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study. You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care.

There is more information in the "Costs" section further below.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

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

Title: RAD4516-18: Advanced PET-CT Directed Post-Prostatectomy Radiotherapy to Enhance Prostate Cancer Outcomes

IRB #: 00106863

Principal Investigator: Ashesh B. Jani, MD, MSEE

Investigator-Sponsor: David M Schuster, MD

Study-Supporter: National Institute of Health. Telix Pharmaceuticals (US) Inc. (Kyzeo Imaging LLC) will be providing Ga-PSMA gratis to Emory University.
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Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not 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 see if (1) using a PET scan (either fluciclovine or GaPSMA PET scan) will be useful in helping your doctor plan your radiation treatments and (2) if, as a result of using the PET scan to plan your treatments, the outcome of radiation treatment will be improved.

Fluciclovine is a radiotracer that is injected into the vein. After the substance is injected, scans called PET or Positron Emission Tomography are done. This is similar to having CAT scans or x-rays. In recent studies, fluciclovine has been

shown to enter prostate cancer cells. Fluciclovine has been approved by the FDA (Food and Drug Administration) for recurrent prostate cancer.

GaPSMA is also a PET radiotracer, and has been approved by the FDA and has also been shown to enter prostate cancer cells.

External beam radiation therapy is one of the standard treatments for men with prostate cancer who have a rising PSA after surgery. Different methods of radiation therapy are used, and it is not known which one is best. Most commonly, the area where the prostate was originally located before being removed (the prostate bed) is treated, without treating the lymph nodes in the pelvis. Prostate cancer can spread to the lymph nodes. There is some evidence in men who have not had surgery that radiotherapy to the pelvic lymph nodes may stop the cancer from spreading under some conditions. Since treating the pelvic lymph nodes can result in increased side effects, the benefit of this method of radiation therapy needs to be tested.

What will you be asked to do?

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor

- History and physical
- A CT (Computed Tomography) scan or MRI (Magnetic Resonance Imaging) of your abdomen and pelvis to determine if there is any evidence of cancer spread to the pelvic lymph nodes. A CT scan is a study using x-rays to look at one part of your body. An MRI is imaging using a strong magnetic field to look at one part of your body.
- A bone scan to determine if the cancer has spread to the bones.
- Review of the tissue from your prior surgery to remove your prostate to determine your Gleason score (a value that helps determine the aggressiveness of your prostate cancer).
- You will be asked to complete a form that asks questions on your urinary, bowel hormone, and sexual functions.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance (like drawing straws). A computer program will place you in one of the study groups. You will be randomized to one of two groups of treatment.

If you are in group 1 (often called "Arm 1" or “Arm A”):

You will have a fluciclovine PET scan that will be used to plan your radiation treatment.

On the day of the scan,

- You will be required to fast for 4 hours before the scan.
- You will be given oral contrast to drink; this allows the abdominal organs to be better visible.

If you are in group 2 (often called "Arm 2" or “Arm B”):

You will have a GaPSMA PET scan that will be used to plan your radiation treatment.

On the day of the scan,

- You will be required to drink about 2 cups of water 2 hours before the scan.
- You will be given oral contrast to drink; this allows the abdominal organs to be better visible.

In either arm, you will receive radiation treatments to the prostate bed once daily, 5 days a week, Monday through Friday, the exact number will be decided by your study doctor. Each radiation treatment will take about 15-30 minutes.

PET scan (Fluciclovine or GaPSMA PET scan):

The scans will be performed at the Emory Center for PET located in the Nuclear Medicine Department on the first floor of the Emory University Hospital or in the Winship Cancer Institute or Emory-affiliated site. The entire procedure will last about 2 hours, including set up and preparation time. Before the fluciclovine PET scan, you will be asked to not eat or drink for four hours. This will allow the fluciclovine radiotracer to get in your blood system easier. You will meet with a technologist and doctor who are approved to work on this study, and who will be performing the procedures on you. An intravenous tube called a catheter (IV) will be inserted in a vein in your arm to be used later for injection of the radiotracer (fluciclovine or GaPSMA). One hour prior to scanning, you will drink 1 bottle (500 ml) of oral contrast over 1 hour to allow for better pictures of your abdomen and pelvic structures.

After placement of the IV for fluciclovine, you will lay down on a mobile couch that will slide into the scanner. The scanner has the appearance of a large box containing a large round opening into which your body is placed. An initial "transmission" scans lasting about 1 minute in which the couch will move. This transmission scan is similar to a CAT scan and is used to correct for the effect of your body on the PET scan in order to produce better images. This transmission scan is done on the PET scanner and will look no different to you. You will then receive an injection through the IV tube of the radiotracer fluciclovine. A set of PET scans (pictures) will be done over thirty minutes. The couch will move. When finished, the IV will be removed. You will be able to leave the PET Center after this time.

After placement of the IV for GaPSMA, you will be brought into a quiet room and you will then receive an injection through the IV tube of the radiotracer GaPSMA, as well as a small dose of furosemide (Lasix) to help clear the radiotracer from your kidneys and bladder. You will wait in the quiet room for approximately an hour. After this, you will then lay down on a mobile couch that will slide into the scanner. The scanner has the appearance of a large box containing a large round opening into which your body is placed. An initial "transmission" scans lasting about 1 minute in which the couch will move. This transmission scan is similar to a CAT scan and is used to correct for the effect of your body on the PET scan in order to produce better images. This transmission scan is done on the PET scanner and will look no different to you. A set of PET scans (pictures) will be done over thirty minutes. The couch will move. When finished, the IV will be removed. You will be able to leave the PET Center after this time.

If you are medically eligible, depending on the results of your scan, you will receive radiation treatment to the prostate bed (and possibly, the pelvic lymph nodes) once daily, 5 days a week, Monday through Friday, the exact number of treatments and area to be treated will be decided by your study doctor. Each radiation treatment will take about 15-30 minutes. Also depending on the results of the PET scan (fluciclovine or GaPSMA PET scan), your doctor may recommend biopsy of suspicious areas or other therapies.

Follow-Up

All patients will also be followed for a minimum of two (2) years with blood draws for PSA levels every six (6) months. We may follow your medical progress for up to five years total.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or

very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop radiation). In some cases, side effects can be serious, long lasting, or may never go away. In addition, some of the side effects may be life threatening and, in rare instances, may cause death.

In addition to radiation therapy, you will receive additional radiation from diagnostic procedures to evaluate your condition. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. However, the additional risk of radiation-induced cancer from these diagnostic procedures is low compared to the risks from the radiation therapy.

The procedures described in this study may cause all, some, or none of the side effects listed here. These are common procedures that are considered relatively safe. Previously unknown side effects can also occur. If new side effects are reported, you will be told. It is also important that you give us accurate and complete information about your past medical history.

You may also find it uncomfortable to lie motionless during the approximately 30 minutes necessary to complete the scan. If you believe you cannot lie still for 30 minutes, you should not participate in this study.

Although the risk is small, it is possible to develop an allergic reaction to the fluciclovine or GaPSMA. This can result in hives, rash, itching and difficulty breathing which may require emergency medical treatment. There have been no previous instances of allergic reaction.

Fluciclovine: In previous studies with many hundreds of patients, there were no problems reported. However it is important to report any unusual side effects that you are having such as itching, skin rashes, fever, chills, nausea, dizziness, and vomiting. Please also see the risks of radiation exposure below.

GaPSMA: In previous studies, there were no problems reported. However it is important to report any unusual side effects that you are having such as itching, skin rashes, fever, chills, nausea, dizziness, and vomiting. Please also see the risks of radiation exposure below.

Furosemide: The furosemide (Lasix) which is given with the GaPSMA will temporarily cause increased urination. Though unlikely, other side effects may include: nausea or vomiting, diarrhea, constipation, stomach cramping, feeling like you or the room is spinning (vertigo), dizziness, headache, blurred vision, itching or rash. Please let us know if you have an allergy to furosemide (Lasix).

Nuc Med/PET: For your bone scan or PET-CT scan, a small amount of radioactive material will be injected by either a hand-held needle or a machine. Such injections are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The radioactive material could also leak from your veins a little, causing swelling and discomfort. After injection and a waiting period for the drug to circulate within your body, you will be asked to lie very still for several minutes while the scan takes place.

MRI: MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

Contrast Agents: Your CT, PET-CT or MRI procedure may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of

them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

Risks and side effects related to the radiation therapy include those which are:

Likely

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue
- Abdominal cramps
- Frequent bowel movements, sometime with urgency, or diarrhea
- Rectal cramps and irritation with pain on defecation
- Mild rectal bleeding that does not require treatment
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Small amounts of blood in the urine

Less Likely

- Urinary obstruction requiring the placement of a temporary urinary catheter and/or dilatation because of stricture (narrowing)
- Less ability to control urine (increased incontinence)
- Inability to achieve an erection (inability of the penis to become hard)
- Rectal bleeding that requires medication or laser treatment to stop

Rare but serious

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen requiring additional procedure or surgery, such as a colostomy (bag for stool)
- Intestinal obstruction requiring surgery

Reproductive risks

You should not father a baby nor donate sperm while on this study or during the first 3 months after cessation of therapy because the drugs and radiation in this study can affect an unborn baby. Check with your study doctor about what kind of birth control methods to use and how long to use them.

Intravenous Catheter: One tube will be placed in your vein (arm or hand.) It is called an intravenous catheter or IV. It is placed under sterile conditions by piercing the skin and underlying vein with a needle, over which is threaded the IV catheter and then the needle is withdrawn. When the catheter is placed or removed, the site of insertion may become sore or bruised. Rarely, bleeding or infection can occur at this site; however, this is highly unlikely. A small gauze pad or bandage is placed over the site after the IV catheter is removed. This is similar to what happens when one donates blood.

Vein Puncture

You could experience bruising, pain, and rarely infection at the vein puncture site for the blood draw. Care will be taken to minimize these risks.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about how best to treat men who have a rising PSA after surgery to remove their prostate. The study results may be used to help others in the future.

Will you be paid for your time and effort?

We will compensate you $100.00 for travel expenses to Emory for the PET scan.**What are your other options?**

If you choose not to join this study, you can get care outside of this study.
Your other choices may include:

- Getting treatment or care for your cancer without being in a study; this could include the following options (any of which could involve getting the conventional radiotracer [fluciclovine] off study), either alone or in combination with each other:
  - External beam radiation therapy (typically, to the prostate bed)
  - External beam radiotherapy plus hormone therapy
  - Hormone therapy
  - Taking part in another study
  - Getting no treatment (With this choice, your tumor could continue to grow and your disease could spread)

Talk to your doctor about your choices before you decide if you will take part in this study.

How will your private information be protected?

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.

Emory, Saint Joseph's Hospital, or Grady Health System will keep any research records that it creates private to the extent that this is required to do so by law. 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.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory, Saint Joseph's Hospital, and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory, Saint Joseph's Hospital, and Grady Health System received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in

this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory, Saint Joseph's Hospital, and Grady Health System from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory, Saint Joseph's Hospital, and Grady Health System or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, Saint Joseph's Hospital, and Grady Health System, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory, Saint Joseph's Hospital, and Grady Health System. We will not share the link between the study code and your identity.

Medical Record

If you have been an Emory, Saint Joseph's Hospital, and Grady Health System patient before, then you already have an Emory, Saint Joseph's Hospital, and Grady Health System medical record. If you have never been an Emory, Saint Joseph's Hospital, and Grady Health System patient, you do not have one. An Emory, Saint Joseph's Hospital, and Grady Health System medical record will be made for you if an Emory Atlanta, Saint Joseph's Hospital, and Grady Health System 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, Saint Joseph's Hospital, and Grady Health System medical record you have now or any time during the study.

Emory, Saint Joseph's Hospital, and Grady Health System 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, Saint Joseph's Hospital, and Grady Health System 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. For this study, those items include:

- Fluciclovine PET scan or GaPSMA PET scan

Tests and procedures done at non-Emory, Saint Joseph's Hospital, and Grady Health System places may not become part of your Emory, Saint Joseph's Hospital, and Grady Health System 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

The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this study, you should contact Dr. Schuster, Phone: [redacted] or Dr. Ashesh B. Jani, [redacted] if you are being treated at the Emory Clinic. At Saint Joseph's Hospital contact Dr. Bruce Hershatter at [redacted]. At Grady Healthcare contact Dr. Joseph Shelton at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory, Saint Joseph's Hospital, and Grady Health System will help you to get medical treatment. Emory, Saint Joseph's Hospital, and Grady Health System and the study sponsor has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. "Negligence" is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study drug or a study procedure, the sponsor will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory, Saint Joseph's Hospital, and Grady Health System employee.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study.

You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

Costs

The sponsor will pay for certain items or services associated with the study.
The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory, Saint Joseph's Hospital, and Grady Health System will submit claims to your insurance for items and services that the sponsor does not cover. Emory, Saint Joseph's Hospital, and Grady Health System 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, Saint Joseph's Hospital, and Grady Health System 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, Saint Joseph's Hospital, and Grady Health System 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 last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

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 this study.

PHI that will be Used/Disclosed:

The PHI that we will use and/or disclose (share) for the research study includes

- Entire medical record.
- Results of exams, procedures and tests you have before and during the study including pathology results, laboratory results, and radiology results.
- Fluciclovine or GaPSMA PET scan results.

Purposes for which your PHI will be Used/Disclosed:

We will use and disclose 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. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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 use 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, Saint Joseph's Hospital, and/or Grady Health System 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. David Schuster 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.
- Telix Pharmaceuticals (US) Inc. (Kyzeo Imaging LLC) is a supporter of this study. Your PHI may be shared with Telix for regulatory purposes.
- Your PHI may also be shared with Blue Earth Diagnostics Ltd., manufacturer of fluciclovine, for regulatory purposes such as modifying FDA approval of fluciclovine.
- The research team and the Sponsor may use and disclose your PHI in case of adverse events to the manufacturer of fluciclovine, Blue Earth Diagnostics Ltd, and the manufacturer of the GaPSMA, Telix Pharmaceuticals (US) Inc. (Kyzeo Imaging LLC).
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory, Saint Joseph's Hospital, and/or Grady Health System offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.

  - Research monitors and reviewer.
  - Accreditation agencies.
- 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.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact the study coordinator. Call Dr. David Schuster or Dr. Ashesh Jani, if you have been harmed from being in this study. Call Dr. David Schuster if you have questions concerning the risk of radiation their telephone numbers are:

Dr. Ashesh B. Jani: [redacted]
Dr. David Schuster: [redacted]
Bridget Fielder, RN (Study Coordinator): [redacted]

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**