# INFORMED CONSENT DOCUMENT

## ERP RT-060 - Intrinsic Dosimetry for Radioembolization utilizing PET-CT Imaging Data: A Prospective Registry Study

**Principal Investigator: Joshua Meyer, MD**

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You should discuss your decision with your friends and family. You will also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this research study because you have liver-dominant or liver-only metastatic disease from any primary histology or you are a patient with primary hepatocellular or biliary cancer and your doctor is planning on treating you with radioembolization (delivery of radioactive spheres to the liver).

The sponsor of this study is Fox Chase Cancer Center.

### Why is this research study being done?

The purpose of this research study is to determine the relationship if any, between the radiation dose delivered with radioembolization to 70% of the total amount of your liver disease, which will be determined by an after-treatment PET-CT, and local control of your liver disease at 6 months.

We do not expect you will benefit from this research study. We can use what we learn from this research study to help other people with the same disease.

### How many people will take part in this research study?

About **43** people will take part in this research study.

### What will happen if you take part in this research study?

Before you begin the research study…

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

## BLOOD TESTS

**5 ml (cc) = 1 teaspoon, 10 ml = 2 teaspoons**

- Blood counts: purple top tube (5 ml or about 1 teaspoon)
- Blood pregnancy (10ml or about 2 teaspoons), if you are a woman of child bearing potential.
- Chemistry: red top tube (10 ml or about 2 teaspoons)
- Coagulation studies: blue top tube (3 ml or about ½ teaspoon)

## IMAGING EXAMS

- A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body
- A MRI scan uses a magnetic field and radio waves to take pictures of the inside of your body

During the research study…

You will need to have the following exams, tests or procedures. These exams, tests or procedures may be a part of regular cancer care and may be done even if you do not join the research study.

### Pretreatment

Staging Angiogram – A mapping of the blood vessels going to your liver in order to ensure that the radioactive spheres will be injected only to the region of the liver containing your cancer.

Coil Embolization – Any blood vessels leading away from the liver toward a region that should not receive radiation will be clogged off using coil embolization. This will prevent radioactive spheres from being delivered to unintended areas such as small intestine or stomach.

Tc-99m test injection – A tiny test dose of radiation will be delivered at the end of the staging angiogram in order to ensure that the amount of radiation exposure to the lungs is safe.

SPECT scan: A SPECT Scan is a single-photon emission computerized tomography (SPECT) scan lets your doctor analyze the function of some of your internal organs. A SPECT scan is a type of nuclear imaging test, which means it uses a radioactive substance and a special camera to create 3-D pictures.

A 3 Phase Liver CT simulation must before Day 0 (Treatment Initiation Day). This simulation may occur before or after the staging angiogram, coil embolization, Tc-99m test injection, and planar and SPECT imaging of the participant's liver.

You will receive radioembolization in this research study. The radioembolization is standard of care treatment. You may need a second treatment with radioembolization, this will be up to your study doctor. The visits discussed below refer to your first

radioembolization treatment only. You will need to repeat these tests or procedures if you are going to have a second embolization.

**Visit 1**

Visit 1 will take place after the pretreatment visits, and will be referred to as Day 0, the day of radioembolization. Visit 1 will include the following procedures:

- PET/CT is an imaging technology that combines two imaging modalities (PET and CT images) into one image
    - PET stands for "positron emission tomography," and CT stands for "computed tomography." This combination allows doctors to see the location and function of cells within the body
    - A PET scan produces 3-D images to see how your cells work. It requires an injection of a radioactive material into a vein. Pictures will be taken of your body with a special donut shaped camera as you lie very still on a table
    - A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body as you lie on the same table that moves slowly through the donut shaped camera
- Radioembolization – This will be the injection of the treatment dose of radioactive spheres to treat your liver cancer.
- PET-CT performed just after the radioembolization in order to measure radioembolization dose.

**Visit 2**

Visit 2 will take place on Day 1. A small group of patients will be required to have the visit 2 PET/CT.

**Follow-up**

Follow-up visits will occur after treatment and will be scheduled at 1 week, 1 month, and then every 3 months for one year, every 6 months for 1 year and then annually for 3 years or until local disease progression or death. Study follow-up visits may be with any investigator.

**BLOOD TESTS**

**5 ml (cc) = 1 teaspoon, 10 ml = 2 teaspoons**

- Blood counts: purple top tube (5 ml)
- Chemistry: red top tube (10 ml)

Beginning with your first 3 month visit (3-months after you treatment), you will need to have either a CT Scan or PET/CT Scan prior visit day. The type of scan will be at the discretion of your study doctor, but it is encouraged to the same type consistently over time.

## Study Chart

You will receive radioembolization in this research study. The radioembolization is standard of care treatment. You may need a second treatment with radioembolization, this will be up to your study doctor. The visits discussed below refer to your first radioembolization treatment only however. You may need to repeat these tests if you are going to have a second embolication. Your study doctor will let you know which if any of these test will be required if you need a second embolization.

You will have other procedures in the days leading up to your radioembolization, the day of your radioembolization and in follow up after your radioembolization.

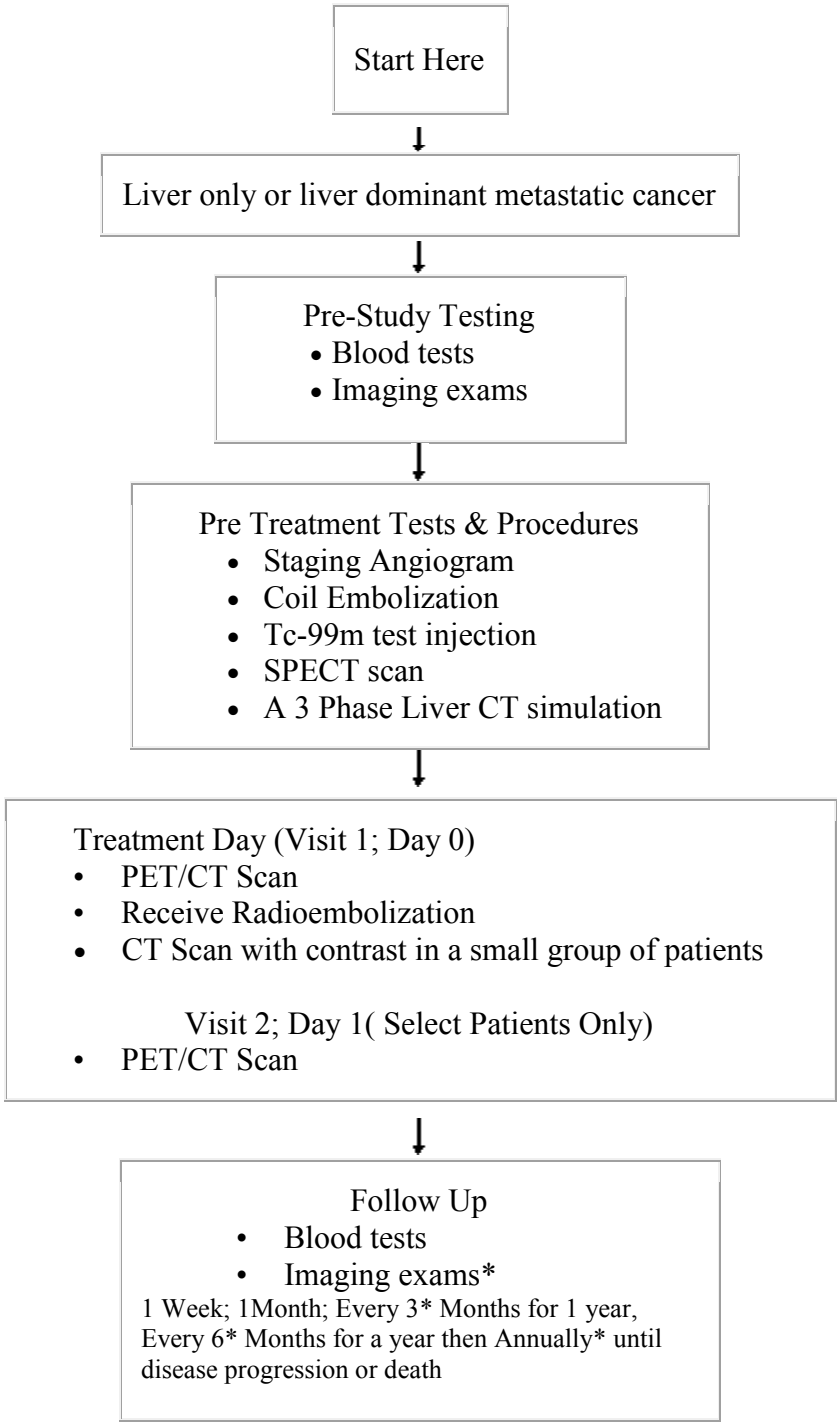
The chart below shows what will happen to you during this clinical trial as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

| **Day** | **What you do…** |
|---|---|
| Before starting study | **BLOOD TESTS**<br>**5 ml (cc) = 1 teaspoon, 10 ml = 2 teaspoons**<br>• Blood counts: purple top tube (5 ml)<br>  • Blood pregnancy (2 teaspoons), if you are a woman of child bearing potential.<br>• Chemistry: red top tube (10 ml)<br>• Coagulation studies (3 ml)<br><br>**IMAGING EXAMS**<br>• A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body<br>• A MRI scan uses a magnetic field and radio waves to take pictures of the inside of your body<br>• PET/CT is an imaging technology that combines two imaging modalities (PET and CT images) into one image<br>  o PET stands for “positron emission tomography,” and CT stands for “computed tomography.” This combination allows doctors to see the location and function of cells within the body<br>  o A PET scan produces 3-D images to see how your cells work. It requires an injection of a radioactive material into a vein. Pictures will be taken of your body with a special donut shaped camera as you lie very still on a table<br>  o A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body as you lie on the same table that moves slowly through the donut shaped camera |
| Pretreatment | • Staging Angiogram<br>• Coagulation studies (if more than 4 weeks since the last lab test) |

| | |
|---|---|
| | • Coil Embolization<br>• Tc-99m test injection<br>• SPECT scan: A SPECT Scan is a single-photon emission computerized tomography (SPECT) scan lets your doctor analyze the function of some of your internal organs. A SPECT scan is a type of nuclear imaging test, which means it uses a radioactive substance and a special camera to create 3-D pictures.<br>• A 3 Phase Liver CT simulation must before Day 0 (Treatment Initiation Day). This simulation may occur before or after the staging angiogram, coil embolization, Tc-99m test injection, and planar and SPECT imaging of the participant's liver. |
| Day 0 | • PET/CT Scan<br>• Receive Radioembolization<br>• Small group may receive a CT Scan with contrast. |
| Day 1 | • PET/CT – May or May NOT be required, your study doctor will notify you if you are required to have this PET/CT scan. |
| Follow Up | 1 week, 1 month, and then every 3 months for one year, every 6 months for 1 year and then annually for 3 years or until local disease progression or death.<br><br>**BLOOD TESTS**<br>**5 ml (cc) = 1 teaspoon, 10 ml = 2 teaspoons**<br>• Blood counts: purple top tube (5 ml)<br>• Blood pregnancy (2 teaspoons), if you are a woman of child bearing potential.<br>• Chemistry: red top tube (10 ml)<br><br>**IMAGING EXAMS ( At your first 3 month follow up which will be 3 months after you have your treatment, then at all remaining follow up visits.)**<br>• A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body<br>• A MRI scan uses a magnetic field and radio waves to take pictures of the inside of your body<br>• PET/CT is an imaging technology that combines two imaging modalities (PET and CT images) into one image |

**Study Plan**

Another way to find out what will happen to you during the research study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



**How long will you be in the research study?**

You will be asked to be in the study until your cancer gets worse or you die.

**Can you stop being in the research study?**

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping to discuss what followup care and testing could be most helpful for you.

**Can you be removed from this research study?**

The study doctor may stop you from taking part in this research study at any time if he/she believes it is in your best interest; if you do not follow the research study rules; or if the research study is stopped.

**What side effects or risks can you expect from being in the research study?**

You may have side effects while on the research study. Everyone taking part in the research study will be watched carefully for any side effects. However, doctors 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. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the research study.

**Radiation Risk for Diagnostic Imaging**

- It is unlikely that there will be any harmful effects from the radiation exposure you will receive from participating in this study.
- At high levels of exposure, scientists agree that radiation can cause cancer.
- At low exposure levels most scientists agree that the risk, if any, is very low. You will have low levels of radiation exposure with diagnostic imaging procedures.

**Blood Draw Risks**

- Fainting
- Bleeding
- Bruising at the place on your arm where the blood was drawn or needle inserted
- Pain
- Swelling
- Infection (rare)

**Reproductive Risks**

- Radiation treatments may make you sterile (unable to have children).
- This study may affect a baby, before or after the baby is born.
- You should not become pregnant or father a baby while on this research study because the procedures in this study could possibly hurt an unborn baby.
- If you are pregnant now or if you are breast-feeding now, you may not take part in this research study.
- If you become pregnant while you are on the research study, you may not continue to take part in the research study.

**For women who can become pregnant:**

- You should not become pregnant while you are in this study.
- You should not breast-feed your baby while taking drugs for this research study.

**For men:**

- You should not make a woman pregnant while you are in this study.

**For women and men:**

- If you are having sex that could lead to pregnancy, you should use birth control while you are in this study.
- Check with the study doctor about birth control methods and how long to use them. Some methods might not be approved for use in this study.

**Are there benefits to taking part in the study?**

Taking part in this study may not make your health better. We do know that the information from this study will help doctors learn more about radioembolization as a treatment for cancer. This information could help future cancer patients.

**What other choices do you have if you do not take part in this research study?**

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

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

## Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Site name and IRB
- Fox Chase Cancer Center
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

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.

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

## What are the costs?

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

If your insurance will not pay for medicines you may need to help with side effects, you may have to pay for them.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage . You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

## Will you be compensated?

You will not get paid for taking part in this research study. If you are harmed because of the research study, we will provide the medical care to treat that harm. However, you may have to pay for this treatment.

## What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## New findings

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

## Who can answer your questions about the research study?

| If you have questions about: | Please Call: |
|---|---|
| This study | Dr. _____<br>000-000-0000 |
| If you get sick or hurt in this study | Dr. _____<br>000-000-0000 |
| If you have a concern or complaint | |
| Your rights as a research participant while you are on this study or after the study ends | |
| Your bills or health insurance coverage | |

## Where can you get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

- You may also visit the NCI website at http://cancer.gov

- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/
- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

| | | |
|---|---|---|
| **Signature of Participant** | **Print Name of Participant** | **Date** |
| **Signature of Physician Obtaining Consent** | **Print Name of Physician Obtaining Consent** | **Date** |

**By signing this form the Physician obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.**

_____ _____

**Signature of Legally Authorized Representative (LAR)** **Date**

_____

**Print Name of LAR** **Relationship of LAR to Participant**
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under the Commonwealth of Pennsylvania)