# Theranostic Low Dose Y90 Microspheres for Personalized Y90 Radioembolization Dosimetry Planning

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# You Are Being Asked to Be in a Research Study

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 30 people who are being studied at Emory.

## Why is this study being done?

This study is being done to answer the question: How accurate is a low dose Y90 Sir- Spheres microspheres during therapy planning to determine the amount of blood that flows between the liver and the lung and obtain an accurate estimation of distribution of Y90 in the tumor(s), liver and lung. You are being asked to be in this research study because you have been diagnosed with HCC (Hepatocellular Carcinoma) and were found to be a good candidate for Y90 radioembolization by multidisciplinary tumor board.

## Do you have to be in the study?

It is your decision to be part of 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 make your decision, you should take time to learn about the study.

## What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 6 months and 5 study visits. The researchers will ask you to do the following: Have an additional y90 therapy planning with low dose Y90 Sir-Spheres microspheres for research purposes, in addition to the standard of care therapy planning, both will be done on the same day. You will be asked to come back for a PET scan of chest and abdomen the next day and will return for 3 standard of care clinic follow up visits. All the extra studies/procedures will be paid for by the study sponsored by SIRTEX Medical Ltd.

## How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question to ensure maximizing dose delivered to the tumor(s) while minimizing dose to normal liver and lungs.

## What are the risks or discomforts I should know about before making a decision?

The study will take additional time and commitment. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, Pain is the most common side effect, other rare sides effects are nausea, vomiting and fever,

loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

**Alternatives to Joining This Study**
Since this is not a treatment study, the alternative is not to participate.

**Costs**
You WILL NOT have to pay for some of the additional study procedures, in particular those that are not covered by your medical insurance.
The study team can help you work out how much you might have to pay. There is more information in the cost section below.

**What Should I 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 (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

**Emory University**
**Consent to be a Research Subject / HIPAA Authorization**

**Title**: Theranostic Low Dose Y90 Microspheres for Personalized Y90 Radioembolization Dosimetry Planning

**Principal Investigator:** [redacted]

**Study-Supporter:** Radiologic Society of North America Research and Education Foundation and SIRTEX Medical Ltd.

## Introduction

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

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

This study is partially supported by Sirtex Medical. Dr. Kokabi serves as a consultant to Sirtex Medical and receives compensation for his services. The terms of this agreement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

## What is the purpose of this study?

The purpose of this study is to effectively determine the amount of blood that flows between the liver and the lung using low dose Y90 Sir-spheres for therapy planning on patients diagnosed with HCC and undergoing Y90 treatment as well as obtaining an accurate estimation of dose distribution of Y90 Sir-Spheres microspheres in the tumor(s), liver and lungs. This is to ensure maximizing tumor response while minimizing side effects of radiation to the normal liver and the lungs.

## What will I be asked to do?

You are being asked to participate in this study because you have been diagnosed with HCC (Hepatocellular Carcinoma).

Your Dr. would like to treat your HCC with Radioembolization (Ytrrium90) which was determined as the most appropriate treatment for you by tumor board consisting doctors from many different specialties. Y90 is a minimally invasive procedure that combines embolization and radiation therapy to treat liver cancer.
Tiny beads filled with radioactive isotope Y-90 are placed inside the blood vessel that provide blood supply to the tumor. this will block the blood flow to the tumor cells while providing a high radiation dose without harming healthy normal tissue
The total duration of your participation will be 6 months.
As part of this study you will be asked to stay extra time during your therapy planning day and have 2 Positron Emission Tomography (PET) scans either on the same day or the day after the planning and therapy respectively. Each PET/CT scan is like a prolonged CT scan taking approximately 30 minutes where you lay flat on a bed and the activity in your liver is captures by the machine. This also includes a low-dose CT scan. You will come for 3 follow up clinic visits, which are the standards of care and part of your scheduled post treatment follow up clinic visits.

In order to plan for procedure your Dr. needs to plan the treatment and map the arteries that will be used to access the tumor and deliver the Y90 beads. You will have a conventional therapy planning as part of your treatment, and if you agree to participate in this study, another mapping using very low dose Y90 will be used only for research purposes right after the standard of care mapping is completed. In addition, you will have an additional 1 Single photon emission computed tomography (SPECT)/CT for research purposes on the day of the mapping and a PET/CT scan the next day. Each SPECT/CT which the standard of care is similar to the PET/CT described above. After the actual therapy, we will have the standard of care SPECT/CT. You will get a second additional PET/CT the next day after the therapy.

The entire planning and therapy will happen over the course of **1 week**. You will have your standard of care and Y90 mapping on Monday (~8AM to 4PM), first PET/CT on Tuesday morning (~1 hour), therapy on Thursday (~8 AM to Noon), and second additional PET/CT on Friday morning (~1 hour). The mapping day (Monday) is the most involved and includes standard of care angiography and SPECT/CT (~8AM to noon), additional angiography and SPECT/CT for the purpose of the research (~noon to 4pm). Therefore, overall, you will commit to an additional ~6 hours for all the additional imaging involved in this study (excluding travel time for the 2 additional PET/CT's).

The follow-up assessment at 1, 3 and 6 months are part of the standard of care after Y90 radioembolization regardless of whether you opt into the research study. They include obtaining and MRI of the abdomen and standard laboratory blood draws before the clinic visits with an interventional radiologist. During the clinic visit, your Dr. will go over the imaging and lab results with you and examine you to for any signs of side effects.

You can find an overview of the procedures that you will undergo at each study visit on the following table along with a description of the procedures.

| Study Procedures | Screening Visit | Therapy planning/mapping | Y90 sirsphere treatment | 1 month post procedure | 3 months post-procedure | 6 months post-procedure |
|---|---|---|---|---|---|---|
| Informed consent | X | | | | | |
| Entry Criteria | X | | | | | |
| Demographics | X | | | | | |
| Medical/surgical Hx | X | | | | | |
| Blood sampling | X | | | X | X | X |
| Collect list of medications | X | | | | | |
| Vital signs | X | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Physical exam | X | | | | | |
| MRI W & WO contrast | X | | | X | X | X |
| Conventional MAA angiography | | X | | | | |
| Low doseY90 shunt study angiography | | X | | | | |
| SPECT/CT | | X | X | | | |
| PET/CT | | X | X | | | |
| Y90 Treatment | | | X | | | |
| Post Procedure Clinic follow up | | | | X | X | X |

**Who owns my study information and samples?**

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that was already collected may be still be used for this study.

**What are the possible risks and discomforts?**

There may be side effects from the study procedures that are not known at this time. Even though you will be receiving a very low dose of you 90 Sir-Spheres microspheres, the most common risks and discomforts expected in this study are:
Pain
Nausea
Vomiting
Fever
Lethargy
Fatigue

The less common risks and discomforts expected in this study are:
Ulcers in patient's stomach or intestines
Bleeding of the stomach and/or intestines
Hematoma from growing access

Rare but possible risks include:
Lung damage from radiation
Liver damage from radiation
Inflammation of bile ducts

**IV and blood sampling risks**

Risks associated with blood collection or during catheterization include bruising, pain, minor blood loss, or infection. Occasionally people can have allergic reaction to the contrast material (dye). Rarely damage to the blood vessels may happen form insertion of catheters.

**If you are a woman**: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of

birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

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

**Radiation Exposure**
In addition to radiation therapy you may 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 very low compared to the risks from the radiation therapy.

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

**Will I benefit directly from the study?**
You will likely not benefit directly from the study which is intended to develop for future use a more personalized treatment planning than is commonly done in current clinical practice. You will however, have all your planning and therapy in 1 week as apposed to the standard of care which has a lag of 2-3 weeks between the planning and treatment.

**Will I be compensated for my time and effort?**

You will get $50.00 for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $_200_ total, if you complete all study visits.

**What are my other options?**
The current standard of care for Y90 therapy planning with approved imaging agents.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

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

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

**Storing and Sharing your Information**
De-identified data from this study (data that has been stripped of all information that can identify you), This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

**Medical Record**

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory 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 Healthcare medical record you have now or any time during the study.

The results of the 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:

- Low-dose Y90 SPECT/CT
- Low-dose Y90 PET/CT
- Therapy Y90 PET/CT

Also, if you decide to be in this study, it is up to you to let your other health providers know.

**In Case of Injury**

If you believe you have become ill or injured from this research, you should [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 will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. 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.

**Costs**

The study sponsor will pay for certain items and services that you may receive if you take part in this study which are above and beyond the standard of care.

You will have to pay for the items or services for which the study sponsor does not pay which are only the standard of care portion of the treatment. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or

treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and 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 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.

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

These are the expected reasons why the researchers may stop your participation:
They believe it is in your best interest.
You were to object to any future changes that may be made to the study plan
Or for any other reason.

## Authorization to Use and Disclose Protected Health Information

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

**PHI that Will Be Used/Disclosed:**

The PHI that we will use or share for the main research study includes:

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

**Purposes for Which Your PHI Will be Used/Disclosed:**

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

**Use and Disclosure of Your Information That is Required by Law**:

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

**Authorization to Use PHI is Required to Participate**:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, 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 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.
- The research team and the study Supporter 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 offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - 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.

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

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

**Other Items You Should Know about Your Privacy**
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing

records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

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

**Contact Information**

Contact [redacted]

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

Contact the Emory [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant [redacted]

**Consent and Authorization**

***TO BE FILLED OUT BY SUBJECT ONLY***

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

_____

**Name of Subject**

_____ _____

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

_____ _____

**Signature of Legally Authorized Representative** **Date** **Time**

_____

**Authority of Legally Authorized Representative or Relationship to Subject**

***TO BE FILLED OUT BY STUDY TEAM ONLY***

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**Name of Person Conducting Informed Consent Discussion**

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