

## A Study to Assess the Impact of Moderate/Significant Infiltrations on the Standardized Uptake Values of Target Lesions

Informed Consent Form to Participate in Research

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### **INTRODUCTION**

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because there was an issue during the injection of your PET/CT radiotracer. Because the injection of the radiotracer may be important to the quality of the image and the numbers the PET/CT scan provides your doctor, you have been invited to repeat your PET/CT scan at no cost to you to provide you the highest quality care. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

### **WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to understand how the initial injection impacted your first PET/CT scan. The research will involve returning for a follow up PET/CT scan within the next 7 days. Today, and when you return for the follow up scan, we will ask you to answer a few questions that will only take about 15 extra minutes of your time.

### **HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Up to 20 people at this research site will take part in this study.

### **WHAT IS INVOLVED IN THE STUDY?**

Today and when you return for the second PET/CT scan, you will be asked some questions about what you ate and drank, your medications, and activity level before the scan. The research team will also collect information on your PET/CT scan to see how much the first injection affected your scan. You will be given instructions on how to prepare for your follow up PET/CT scan, which will take place within the next 7 days. If you return for any additional routine PET/CT scans, we will collect information as part of the study, but this does not require any additional time from you.

If you take part in this study, you will have an additional PET/CT scan within the next 7 days.

We will send copies of your test results to your personal physician who ordered the first test.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study from now up to the time you complete your follow up PET/CT scan (up to 7 days).

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. If you decide not to return for the follow up PET/CT scan you may not have accurate information about your PET/CT scan results.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects include a small risk from exposure to radiation from the additional PET/CT scan.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. This research study involves exposure to radiation from one additional PET/CT. The amount of radiation that you will receive from this procedure is equivalent to a uniform whole body dose of 1.65 rem. This is equal to 33% of the yearly radiation exposure limit allowed for a radiation worker (5 rem). To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of

childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study include the possibility of getting more accurate information on your follow up PET/CT scan. This information may help your doctor with your treatment plan.

### **WHAT OTHER CHOICES ARE THERE?**

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. This is not a treatment study. Your alternative is to not participate in this study.

### **WHAT ARE THE COSTS?**

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

### **WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

## WILL YOU BE PAID FOR PARTICIPATING?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. If you decide to participate in the study, we will offer you a \$20 gift card to help with transportation costs.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Lucerno Dynamics. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

***Lucerno Dynamics*** shall reimburse for reasonable and necessary medical expenses (the “Covered Expenses”) incurred by research subjects for medical care, including hospitalization, in the treatment of adverse reactions arising from study drugs, devices, intervention, procedures and tests following their administration or use in accordance with the protocol, which expenses were not caused by negligence or misconduct of any person in the employment of Wake Forest University Health Sciences or to your own failure to follow instructions. Lucerno Dynamics is not responsible for expenses that are due to pre-existing medical conditions or underlying disease.

If you are injured, the sponsor may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the sponsor is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Shane Masters at [REDACTED].

## What About My Health Information?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected

Health Information. The information we will collect for this research study includes:

- Age
- Gender
- Height
- Weight
- Medication list
- Diet for the day before the scan
- Exercise for the day before the scan
- Injection quality data
- PET and CT images

Note that most of this information is routine for anyone getting a PET/CT scan.

Protected Health Information collected from you during this study will be placed in your medical record, and will be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

- 1) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.
- 2) Representatives from government agencies such as the US Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Masters that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

**Shane C. Masters, MD, PhD**



However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

A description of this clinical trial will be available on <http://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.

Laboratory test results and other medical reports created as a result of your participation in the research study will be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

### **WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?**

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, you failed to follow instructions for the follow up PET/CT scan, or the study is stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

### **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of a research-related injury, contact the study investigators, Dr. Shane Masters or Dr. A. William Blackstock at [REDACTED].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [REDACTED].

You will be given a copy of this signed consent form.

### **SIGNATURES**

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): \_\_\_\_\_

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**Adult Consent Form**

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm

Person Obtaining Consent (Printed): \_\_\_\_\_

Person Obtaining Consent: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm