The attached document is the informed consent form included for the following study:

Title: Patterns and Prevalence of FDG Extravasation in PET/CT Scans (Lucerno device)

ClinicalTrials.gov NCT03041090

Document Date: January 30, 2017

SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	**Patterns and Prevalence of FDG extravasation in PET/CT scan**

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	26741
	First Name / Last Name		
Principal Investigator (PI)	Medhat Osman, MD	**Contact Phone #**	314-577-8047
	First Name / Last Name Credentials		
Title of Project:	Patterns and Prevalence of FDG extravasation in PET/CT scans		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Medhat Osman because you are scheduled for a standard of care PET/CT exam at SSM Saint Louis University Hospital.

This consent document may contain words that you do not understand. Please ask the research study doctor or research staff to explain anything that you do not understand.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

PET/CT scans play a vital role in imaging for the brain, heart, and in many types of cancer. When physicians read the images, they often obtain a value, called a Standard Uptake Value (SUV) from the images. It has been determined that SUV values can be influenced by the patient's height and weight and also by the amount of radioactive tracer given to a patient.

For a PET/CT scan, the radioactive tracer is injected into a vein (usually in the hand, elbow, or lower arm). If the tracer does not all go into the vein and some leaks out into the surrounding tissues, the tracer will possibly not distribute correctly in the body. It is suspected that leaking tracer could affect the SUV values and thus alter a physician's ability to read the scan accurately.

This study hopes to look at the prevalence and pattern of tracer leaking around the injection site through the use of a non-invasive device made by Lucerno Dynamics, the study sponsor. This device has four passive sensors with the ability to detect radioactive counts from the PET tracers that will be placed on separate sites of the body to measure if the radioactive PET/CT tracer is distributing as planned.

Saint Louis University aims to enroll 250 subjects into this study.

2. WHAT AM I BEING ASKED TO DO?

If you choose to participate in this study, it should only add less than 5 minutes to the total time you are here for your PET/CT exam. Once the technologist has asked all the questions to confirm your PET/CT exam, the study procedures will begin. The Lucerno device sensors will be placed on the skin in four separate locations: over the injection site, the same site on the opposite arm, over the subclavian area, and over the liver (right side of the abdomen below the rib cage). These detectors have the ability to count the radioactive tracer as it circulates through your body and see if the tracer is distributing the way we think it should or if any remains at the injection site. After the dye is injected, it normally needs to circulate for a minimum of 60 minutes before imaging. The dectors will be placed at the time you are given the dye and remain in place for the whole circulation time. If the camera bed (imaging couch that you lie upon to take PET/CT pictures) is available, you may be asked to spend the uptake period resting comfortably on the camera bed. This would allow us to take pictures of the injection site to compare to the counts the sensors are getting. If the camera bed is not available, the detectors will placed in the same way, they will just count the dye while you sit in a reclining chair and no comparison pictures will be obtained.

After the 60 minute uptake period, the four sensors will be removed and you will proceed on with the normal PET/CT procedure your doctor ordered. Once the standard of care PET/CT scan is complete, you will be asked to complete a short questionnaire about how comfortable it was to wear the detectors for the circulation period. Your standard of care PET/CT scan will be reviewed by a physician and a report will be sent to the doctor who ordered it, which is where you find out the results of the scan.

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

Your normal PET/CT scan process can take up to 2 hours. Your participation in this study will only be for the day of your PET/CT exam and will only add an additional 5 minutes or less to the total time of your scan. If you come back for repeated PET/CT exams, you may be asked to repeat this research study and you can participate every time you are scheduled for a PET/CT exam. The research team expects it will take approximately 3 years to recruit the expected 250 patients, analyze the data, and publish our results.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study. One risk is discomfort from the detector's adhesive pads when they are removed and discomfort while lying on the imaging table during the circulation period. If side effects or discomforts occur, Dr. Medhat Osman and his research team will try to help these by making you as comfortable as possible while the detectors are on and being sure to remove the adhesive pads to your comfort. There is also a risk of allergic type skin reactions to the adhesives on the sensors. Study team members will monitor you while they are in place and remove them should you mention any signs of reaction such as redness, itchiness, burning, etc.. There is also a risk of loss of confidentiality with participation in this study. Our team works very hard to protect your private health information and only key

members will be able to access your identified data and any information shared outside the team will be coded, and thus not able to be traced back to you. The final risk is that of distress while filling out the questionnaire at the end of the study asking your comfort of wearing the detector devices. The study staff will be nearby and should you feel distressed, study team members will be available to answer questions or if necessary, discontinue research procedures.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You will not directly benefit from this research study. Your condition may get better, stay the same, or worsen. Even though you may not receive any immediate benefit, other people getting PET/CT scans may benefit in the future because of what the researchers learn from this research study.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study without affecting your PET/CT exam or your ordering doctor's ability to get the results. The only alternative to participating in the research study is to choose not to participate.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published but your name or identity will not be revealed and your record will remain private. In order to protect your information, Dr. Medhat Osman will never release any identifying information and will group the data with all the other participants so you cannot be identified.

Your research record will contain identifiers such as your date of birth, date of exam, name, and gender. Dr. Osman and his study team will keep your research record protected by keeping any paper documents behind two locked doors. Any identifiable data that is electronic will be held on a secure server behind a firewall that is only accessible by study team members.

Information collected for this research study will be shared with other researchers and our industry partner for this study, Lucerno Dynamics. Lucerno Dynamics is the financial sponsor of our study and the group that provided the sensors for the study. Some of the information we capture will be shared with them, but it will be provided in a coded format (we keep any identified information at SLU and give them information only a study code – no name, date of birth, medical record number, etc. is shared). Lucerno Dynamics will only receive coded PET pictures the coded radiative counts from the detectors and coded questionnaire data.

The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research) and other University officials

may review your research study records. State laws or court orders may also require that information from your research records be released.

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.

8. WHAT ARE THE COSTS AND PAYMENTS?

Because this research involves standard treatment (PET/CT exam) and follow-up tests for the disease or condition being studied, insurance carriers ordinarily cover the costs. You should check with your insurance company to verify that they cover standard of care procedures. You will be responsible for any costs not covered by your health insurance company.

The Lucerno sensor device is provided by Lucerno Dynamics and the use of the device will not be billed to insurance or cause you to incur any additional costs.

You will not be receiving an incentive or payment for participation in this research study.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call Dr. Medhat Osman at 314-977-8163. For after-hours concerns, please call the hospital operator at 314-577-8000 and ask them to page the Nuclear Medicine Resident on call.

If you have any questions about your rights as a research participant or if you believe you have suffered an injury as a result of taking part in the research, you may contact the Chairperson of the Saint Louis University Institutional Review Board (314-977-7744), who

will discuss your questions with you or will be able to refer you to someone else who will review the matter with you, identify other resources that may be available to you, and provide further information as how to proceed.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

In this research study, a valuable mechanism to uncover the occurrence and behavior of radioactive tracer leaking into surrounding tissues may be developed. Should the Lucerno ID device from Lucerno Dynamics be developed resulting from the sensor counts obtained from this research, there are no present plans to share any monies obtained from the sale of the product with you.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. I have been asked if I wish to speak directly to the researcher or research study doctor responsible for this research study. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent
I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____ _____
Consent Signature of Research Participant (18 and over) Date

_____
Print Name of Participant

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #: 26741
Approved: 02-10-17
Expires: 02-15-18
Board #: 1
Saint Louis University

I certify that I have explained to the above individual(s) the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the subject/patient has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	