Participant Information and Consent Form

Title of research project: Region-specific Adipose Tissues and Liver Changes Associated with Semaglutide Treatment in Chronic Kidney Disease Patients

Protocol: U1111-1328-1600

Principal Investigator: Dr. PR
Co-Investigator: Dr. LDM
Research/Study Coordinator: Dr. MR

Why am I being asked to take part in this research study?

You are being asked to participate in this research study because you have diabetes mellitus. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part in it. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. You will be given a copy of this form for your records. Participation in this study is voluntary.

What is the reason for doing the study?

Obesity is considered a global pandemic and is associated with various diseases and metabolic complications, such as type 2 diabetes mellitus, high blood pressure, cholesterol disorders, cancer, cardiovascular disease, and kidney disease. Obesity can affect the kidneys in two main ways: indirectly, through mechanisms related to diabetes and high blood pressure, and directly, through complex proteins called "adipokines," which are produced by fat cells (also known as adipocytes).

Many of these adipokines are secreted by adipocytes under normal conditions, as they contribute to maintaining immune defenses and energy production. However, in obesity these adipokines acquire harmful properties and produce chronic inflammation in the heart, blood

vessels, the pancreas (that regulates blood sugar levels), and the kidneys leading to a deterioration in liver and kidney function.

In recent years, novel drugs have been developed, such as glucagon-like peptide-1 receptor agonists (GLP-1Ras), like Semaglutide also known as Ozempic. These medications lower blood sugar levels, induce weight loss, and improve kidney and liver function. However, little is known about their specific effects on fat (adipose) tissue. Therefore, studies in patients receiving these drugs could tell us how they affect chronic inflammation, fat accumulation around internal organs, and they affect heart, liver, and kidney function.

We are asking patients who attend the diabetes clinics associated with the University of Alberta to join the study.

What will I be asked to do?

If you agree to join the study, you will be asked to have a magnetic resonance imaging **(MRI)** scan to evaluate the fat around the heart, liver and kidneys.

When you arrive for your imaging tests, if you agree to be in this study, you will first sign this consent form. You will have the MRI examination done on the same day.

The MRI imaging study will be performed in the ABACUS Research Center on the lower level in the Mazankowski Alberta Heart Institute (part of the University Hospital). You will need to change into a hospital gown and lie on the scanner table. You will be asked to hold your breath 2 times, each breath-hold takes about 10 seconds. This part of the procedure takes about 5 minutes. There is no injection or IV.

Study personnel will also ask you questions about your medical history. Other information collected will include medications, recent tests your doctor may have ordered, and basic information such as age, weight, height. These questions are like what would be asked for a routine MRI or other scans.

Possible Side Effects and/or Risks

The risks and discomforts you may experience related to your participation in this study are like those you would experience related to a usual imaging scan.

For this MRI scan you will not receive ionizing radiation like in other test such as computer tomography (CT).

What are the benefits to me?

There is no definite benefit to you from taking part in this study.

If we find any important diagnostic information about you from the MRI scan, we will contact your hospital clinician and family doctor with this new information.

What happens if I am injured because of this research?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form, you are not releasing the investigator(s) and/or institution(s) from their legal and professional responsibilities.

Do I have to take part in the study?

Your participation in this study is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. You are under no pressure to take part and may withdraw from the study at any time without having to explain why. You have the right to withdraw any of your data from the database so that it is not included in the study.

Will I be paid to be in the research?

You will not be paid to participate in this research study. We will be happy to give you a pre-paid parking voucher for the East Parkade for the day you attend your imaging test.

Will my information be kept private?

All records relating to this study will be kept confidential. Your name will not be disclosed outside the research group. Any report published as a result of this study will not identify you by name. Sometimes, by law, we may have to release your information with your name and so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

In addition to the investigator(s), the Health Research Board or University of Alberta may have access to your personal health records to monitor the research and verify the accuracy of study data.

By signing this consent form, you are giving permission to the study doctor/staff to collect, use and disclose information about you from your personal health records as described above. Study data will be kept for a minimum of 25 years. Even if you withdraw from the study, the images that were obtained of you for study purposes will not be destroyed.

What if I have questions?

If you have any questions about the research now or later, please contact:

Principal Investigator: Dr. PR
Co-Investigator: Dr. LDM
Research/Study Coordinator: Dr. MR

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

Thank you for taking the time to read this information.

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Please circle your answers to the following questions:

1. Do you understand that you have been asked to volunteer in a research study? **yes / no**

2. Have you read the information sheet and understand you will receive a copy? **yes / no**

3. Do you understand the benefits and risks involved with taking part in this study? **yes / no**

4. Have you had opportunity to ask questions & discuss this study to your satisfaction? **yes / no**

5. Do you understand you are free to refuse to participate & you may withdraw from the study at any time? (You do not have to give a reason) **yes / no**

6. Has the issue of confidentiality been explained to you? **yes / no**

7. I agree to take part in this study? **yes / no**

This study was explained to me by: _____

_____	_____	_____
Signature of patient	Printed name	Date
_____	_____	_____
Signature of witness	Printed name	Date

I believe that the patient signing this form understands what is involved in the study and voluntarily agrees to participate:

_____	_____	_____
Signature of Investigator or designee	Printed name	Date

A SIGNED COPY OF THIS INFORMATION SHEET AND CONSENT MUST BE GIVEN TO THE RESEARCH PARTICIPANT