ELM PARK, DUBLIN 4

Conway Institute of Bimolecular and Biomedical Research, University College Dublin, Belfield, Dublin 4

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: **Food preference following Bariatric Surgery**

NAME OF PRINCIPAL INVESTIGATOR:

Prof Carel le Roux MB MSc FRCP FRCPath PhD

Research Investigator

Dr Loai Shakerdi

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

Adults who are over weight and obese are at increased risk of developing associated health complications compared to patients who are of normal weight. An effective treatment of obesity is bariatric surgery. It has been shown to reduce blood pressure and improve diabetes in addition to its weight lowering effects. Among patients who have had bariatric surgery we see that their total food intake is reduced compared to before the operation. This will contribute to the weight loss as well. However we would like to understand more about why food intake changes by following up people over time that have undergone surgery and assessing their natural gut hormone response to food intake.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you will be undergoing bariatric surgery.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment in any way. Furthermore your doctor may decide to withdraw you from this study if, he/she feels it is in your best interest.

If you agree to participate you will be invited to attend for a screening visit where any questions you have will be addressed and you will be asked consent to the study. In addition we will ask you to fill out a questionnaire regarding your food preferences. The study will be conducted at the Clinical Research Centre at St Vincent's University Hospital, Elm Park, Dublin 4.

There will be a total of **5 visits** to the research centre over a period of 2 years. On each occasion you will be asked to attend having fasted from the night before. The visit will commence at 10.30am. At each visit the research team conducting the study will meet you. They will complete a questionnaire with you, complete measurements of your weight, height and abdominal circumference. In addition you will have a blood test, this will measure hormones produced by your gut that may be altered by surgery and food. This will take 60-90 minutes to complete. Following this you will be presented with a buffet meal containing foods of your liking and advised to eat until you feel "comfortably full". Once again a blood test will be taken after the meal and you are free to leave. The entire visit will take **approximately 4 hours** to complete. The total amount of blood taken at each test is 10ml (approximately 1 tablespoons).

On two of the study visits an additional step is required. Before commencing the meal you will be given an injection under the skin of a medication called Octreotide or Saline (salty water). We would like to see the effect these treatments have on the blood tests taken after your meal. Octreotide is a medication that is well-tolerated and safe to use. Only one dose of Octreotide is required during the study. These visits will take place at 12 months after your surgery.

The visits will take place 1 month prior to your operation, 3, 12 and 24 months after the surgery. At 12 months participants will be asked to attend on two occasions one week apart for testing.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not directly benefit from participation in the study however the information obtained from the study may help improve our understanding of the how bariatric surgery in adult's works. This is not intended to replace routine medical assessments with your GP or specialist.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There may be some discomfort associated with blood sampling as the needle is inserted into the vein. Sometimes there may be bruising after the blood sample is taken and very rarely inflammation around the site of entry of the needle. Every effort will be made to minimize risks. You will be monitored for any side effects to the drug therapy given as part of the study.

You may feel some stinging or burning where we give the injection of saline (salty water) and octreotide, but this usually only lasts a minute or so. We usually give these injections beneath the skin on the abdomen or shoulder as it causes least discomfort.

Octreotide is a medication that resembles a natural hormone. It can be given as an injection. It temporarily prevents release of other hormones from the gut after you have a meal. It is commonly used in hospitals and considered a safe medicine. Some people experience minor side effects such as nausea or abdominal discomfort after receiving this injection, but if this happens it is usually transient. The medication is completely eliminated from your body within about 8 hours, but some people may have loose bowel motions the next day. Serious side effects are extremely rare, and the research team will ask you about any medical problems that would make this medication unsafe for you to take.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way.

CONFIDENTIALITY

Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone.

COMPENSATION

Your doctors are adequately insured by virtue of their participation in the clinical indemnity scheme.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is funded by a grant from the Health Research Board.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Participants will not be paid for participation in this study

WILL MY EXPENSES BE COVERED FOR TAKING PART IN THIS STUDY?

Reasonable travel expenses will be reimbursed

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS

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PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO ☐
- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: _____