

Participant Information Sheet/Consent Form
Interventional Study – Adult providing own consent

Title	Effect of Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA): A Randomized, Double-Blind, Placebo-Controlled Trial
Short Title	Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA)
HREC Number	009/24
Project Sponsor	The University of Melbourne, Parkville, Victoria, 3010
Coordinating Principal Investigator	Professor Michelle Dowsey
Principal Investigator	Professor Phong Tran
Associate Investigators	Libby Spiers, Truc Minh Ngo, Eugenie Ng, Angela Cochrane, Francesca Sasanelli, Jeremy Abetz, Saad Alkassab, Marc Macaluso
Location	Western Health

Part 1 What does my participation involve?

1 Introduction

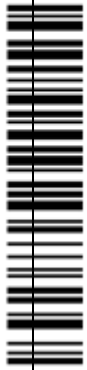
You are invited to take part in this research project. This is because you have both osteoarthritis (OA) of the knee and excess weight, and have been deemed eligible to undergo knee replacement surgery with Western Health. This research project aims to determine whether undergoing medication assisted weight-loss prior to knee replacement, will delay or avoid your need for knee replacement surgery.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the tests and treatments that will be completed during study participation. Knowing what is involved will help you decide if you want to take part in this study.

Please read this information carefully and ask the study doctor questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor/GP.

It is desirable that your local doctor/GP be advised of your decision to participate in this research project. If you have a local doctor/GP, we strongly recommend that you inform them of your participation in this research project.

Participation in this research is voluntary. If you do not wish to take part, you don't have to. If you decide you do not want to take part, it will not affect the treatment and care you get at Western



Health. You will receive the best possible care whether or not you take part in this research project.

If you decide you want to take part in the research project, you will be asked to sign the consent section of this document. By signing it you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to have the tests and treatments that are described; and
- Consent to the use of your personal and health information as described.

It is important to understand that consenting to take part does not mean you will definitely be able to be in the research project as there are certain study eligibility criteria that need to be met.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Current guidelines recommend weight loss for people with both knee OA and excess weight. We define excess weight by a measure called the body mass index or BMI. If your BMI reaches 30kg/m² or above, this is also known as obesity. Studies have shown that weight loss can improve the pain caused by knee OA when you have excess weight. This can also lead people to be less likely to want to undergo a knee replacement. Current weight loss treatments include diet and exercise which can be difficult for people with knee OA, or weight loss surgery which has strict criteria.

Medication-assisted weight loss treatments may allow patients with excess weight to lose weight and avoid knee replacement surgery, without undergoing more invasive and less widely accessible treatments such as weight loss surgery.

The purpose of this study is to see whether medication assisted weight loss, combined with diet and physical activity recommendations, will reduce/delay your likelihood of undergoing a knee replacement. The study also aims to see if medication-assisted weight loss leads to other improvements in your OA symptoms, such as knee pain, function, and knee stiffness.

This study will do this by testing the weight loss drug, tirzepatide that is given by subcutaneous weekly injection under the skin, together with diet and lifestyle advice given by a dietitian. You will be randomised to either receive a weekly tirzepatide injection or a weekly placebo injection. Comparing the tirzepatide medication to a placebo substance is called a 'placebo-controlled trial' and is the 'gold standard' way of testing how effective a medication is.

This study is "blinded", which means that you and your study doctor will not know whether you have received the weight-loss medication or the placebo. However, if needed for a medical emergency, your study doctor can quickly find out what you received.

Medications, drugs, and devices have to be approved by the Australia Federal Government and tirzepatide is currently approved in Australia to treat chronic weight management in adults with a BMI \geq 30kg/m².

This research has been initiated by Professor Michelle Dowsey.

This investigator-initiated trial is being sponsored by The University of Melbourne. The pharmaceutical company Eli Lilly has provided part of the funding to the University of Melbourne to conduct this project.

3 What does participation in this research involve?

All people who have been deemed eligible for knee replacement surgery to treat osteoarthritis at our Orthopaedic Clinic who also have excess weight, will be offered to participate in this research study. Before you begin the research project, you will be given detailed information about the study medication, the tests, and procedures to be carried out, and any other relevant information by research staff. You are encouraged to ask questions until you fully understand the nature of and requirements of the research project.

This research project is a randomised, double-blinded, placebo-controlled trial:

- **“Randomised”** means that the experimental treatment group that you will be assigned to (either the tirzepatide medication or placebo) will be a random draw process, where a computer decides which study treatment you will receive. Sometimes we do not know which treatment is best for treating a condition, to find out we need to compare different treatments. We place people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).
- **“Double-blinded”** means that that you, the participant, and the study doctor, will not know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.
- A **“Placebo”** is a medication with no active ingredients, it looks like the real thing but is not.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Study Treatment:

Overall, the study will recruit 352 participants across several hospitals. You will be randomised into one of two equally sized groups, the tirzepatide or the placebo group, which will be decided by a computer. You will also receive lifestyle modification counselling, including both dietary and physical activity recommendations from a dietitian. You will be given the active medication or placebo medication to take as a sub-cutaneous injection once a week for 72 weeks.

The study involves two phases, the dose escalation phase, and the maintenance phase. The “dose escalation phase” will last for 20 weeks, and the “maintenance phase” will continue for a further 52 weeks, with total treatment lasting for 72 weeks.

- (i) **Dose escalation phase:** during this phase you will be given the medication as a subcutaneous injection, starting at a dose of 2.5mg, to be given once a week for 4 weeks. If everything is going well, the dose will be increased by 2.5mg every four weeks until the target dose of 15mg is achieved or you reach a lower dose of 5mg or 10mg, at the end of 20 weeks.

- (ii) **Maintenance Phase:** At the end of the “dose escalation phase”, 20 weeks, whichever dose you have achieved, you will stay on, and continue with weekly subcutaneous injections at that dose, for the remaining 52 weeks.

MANDATORY TESTS AND PROCEDURES DURING THE STUDY

Participation in this project means that you must follow some instructions. Your safety and the quality of the data that will be collected depend on this. If you do not think you can follow these instructions, you should reconsider your decision to participate.

- Sign and date the informed consent form, which indicates that you authorise the study team to use and disclose protected health information.
- Provide information about your medical conditions, your current medications, and the ones you have been on previously. Also allow your study doctor or staff to review your previous medical records and records created during the project.
- Provide all the information as required by the study doctor or staff to determine your eligibility to participate in the project.
- Provide blood samples that will be analysed during the screening visits to find out if you are able to participate in the study.
- Attend and complete the scheduled visits and tests or procedures as planned and follow the study doctor’s or staff’s instructions.
- Agree to the contact schedule with the study team, including ongoing contacts for checking on how you are going with the study medications and if you have any issues.
- You must quickly inform us of any new or worsening health problems, even if you think they are not caused by the study injections.
- You must also inform us if you are receiving any other medical treatments or alternative therapies.
- The study medication will be administered once a week as a subcutaneous injection, which is an injection, via needle, into the fatty tissue, just under the skin. You will be taught how to do this safely.
- You will be given 4 weeks supply of the medication at the beginning, with the initial dose of 2.5mg. At the end of every 4 weeks, you will be assessed by the doctor to determine suitability of progressing to the next dose. At the end of the dose-escalation phase, you will be given 12-weeks supply of the medication following each visit with the study doctor.
- Have samples of your blood taken as required by the study schedule. See Table 1. If any of the results from your safety laboratory tests are out of the normal range, or you feel unwell, you may be asked to provide additional samples for more testing

- Complete the participant diary as instructed by your study doctor, dietician and/or study staff, so we can monitor how you are feeling whilst taking the medication.
- Complete questionnaires asking about the impact your knee pain has on your daily function, your work productivity, mental well-being and quality of life. See Table 1
- Have some information about you collected from your medical records, including, prescription medications, Medicare data where available, and your age, gender, postcode, and cultural background.

If you participate in this study, we prefer any plans for knee replacement surgery be deferred (placed on hold), whilst you are receiving the first phase of the weight-loss medication (20 weeks). However, you are welcome to discuss scheduling surgery at any time, based on your preferences, needs and fitness for surgery. Every 12 weeks, during the maintenance phase, from week 20 to week 72, you will be asked whether you would still like to defer your knee replacement surgery.

Study Summary:

Screening:

You will be approached by a member of the research team either in the orthopaedic clinic or over the phone, after you have been seen by the surgeon about your knee replacement surgery, and you will be provided with an explanation about the study. You will be given this Participant Information and Consent Form, and the opportunity to read it and ask any questions. You will also be encouraged to discuss the study with friends, family, and your local doctor. If you would like to be assessed to be a part of this research project, you will need to attend two screening visits.

Screening and Randomisation Visits:

Screening Visit 1:

You will need to attend this visit while fasted, which means you should not eat or drink anything other than water in the 8-hours prior to arriving nor consume alcohol in the 24-hours prior to arriving. At the first visit, a study nurse and doctor will discuss the trial with you and will answer any questions you may have. If you wish to participate you will sign this consent form. During this visit blood, and other tests will be arranged for you, and you will undergo a health assessment to determine if this project is suitable for you.

You will be required to fast for your second screening bloods, and are able to have these at approved collection centres in your local community. A doctor will discuss these results with you at visit 2.

You will not be eligible to participate in the study if you do not meet the entry requirements for the project.

Visit 2 Randomisation:

You will also need to be fasted when attending this visit. If you have enrolled in the study and meet all eligibility criteria, you will be accepted into the study and will be randomised into to either the tirzepatide medication group or the placebo medication group. During this visit the following will occur:

- Your knee replacement surgery will be deferred (placed on hold).
- You will receive study medication and training on how to inject it by the study nurse.
- You will be contacted by the dietitian and be given a food diary.
- You will undergo a standard health assessment including your height and weight.
- You will be required to complete questionnaires assessing your pain and function, mental well being and general health.

*Please refer to Table 1

Visit Plan Summary:

- You will have to come fasted to the Western Health 12 times, to see the Nurse and Doctor to see how you are progressing, and to answer any questions or queries you may have.
- You will have 8 nurse telephone scheduled visits throughout the study, to help monitor how you are feeling or to answer any questions or concerns you may have.
- You will receive 11 dietitian visits throughout the study, they will all be by telehealth / telephone, and they will provide you with dietary and lifestyle recommendations.

Table 1: Visit structure and participant timelines

	Screening		Dose escalation phase					Maintenance phase													
	1		2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Visit Number																					
Weeks of Treatment			0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68	72
In-Person Visit	X		X	X	X	X	X	X	X			X			X			X			X
Telephone Visit										X	X		X	X		X	X		X	X	
Screening Visit	X																				
Fasting Visit	X	X	X	X	X	X	X	X	X			X			X			X			X
Informed Consent	X																				
Enrolment & Randomisation			X																		
Surgery placed on hold			X																		
Doctor Visit	X		X	X	X	X	X	X	X			X			X			X			X
Nurse Visit	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dietitian Visit			X	X	X	X	X	X	X			X			X			X			X
Clinical Assessment	X		X	X	X	X	X	X	X			X			X			X			X
Blood Tests	X	X*																			X

Injection Training			X																		
Collection of new medication			X	X	X	X	X	X	X			X			X			X			
Study Diary			X	X	X	X	X	X	X			X			X			X			X
Questionnaires	X		X			X			X			X			X			X			X
X-Ray	X																				
Patient offered to be scheduled for surgical review									X			X			X			X			X

* Second non-consecutive fasting pathology can be taken in approved community collection centres

Additional tests

Your study doctor may request additional procedures or tests be performed to assess how you are doing during the research project. In addition, unplanned blood samples may be necessary for safety reasons. Your study doctor will discuss this with you at the time.

Additional Costs:

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge. As an acknowledgement for your time and travel associated with the research project visits, you will receive a \$50 Coles gift voucher for each in person follow-up visit and \$25 Coles gift voucher for each telehealth visit.

Data Safety Monitoring:

The data from this study will be reviewed by a group called the Data Safety Monitoring Board (DSMB). There are rules for whether the study is allowed to continue or in the event of safety concerns when it would be stopped.

4 What do I have to do?

By taking part in this research project, you have to be willing to attend all scheduled visits and follow the health recommendation of the research team and healthcare providers that are outlined in the “Mandatory Tests and Procedures” list. You should consider the length of the study and the time involved and ensure you are able to commit to participation for the length of the project.

5 Other relevant information about the research project

This study will be conducted at several hospitals throughout Victoria. This project involves researchers from several organisations working together and includes researchers from The University of Melbourne.

The active phase of the research project will last for 72 weeks, and passive follow-up via data linkage, which will not require you to attend any appointments or answer any questionnaires, will take up to 10 years.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide that you want to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide that you would like to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or relationship with those treating you or your relationship with {site}

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Your study doctor will discuss these options with you before you decide whether or not you can take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. Your participation in this research may benefit you by reducing your knee pain, helping you lose weight, and possibly help you to avoid knee replacement surgery. We hope that your participation in this research will help inform improvements in the treatment of people with knee OA in the future.

9 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or you are worried about them, talk with your study nurse and doctor. The study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study doctor immediately about any new or unusual symptoms that you may have.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop or pause your treatment. The study doctor will discuss the best way of managing any side effects with you. Since everyone is different, it is not possible to predict what side effects, if any, you may experience.

Local Injection Site and Blood Draw Risks (Uncommon, occurs in between 1 in 100 and 1 in 1000 people).

Having a drug injected or blood (or tissue sample) taken may cause some discomfort, bruising, rash, itching, pain, minor infection, or bleeding. If this happens, it can be easily treated.

Tirzepatide Medication Side Effects:

	Very common ≥10%	Common ≥1% and <10%	Uncommon ≥0.1% and <1%	Rare ≥0.01% and <0.1%	Very Rare <0.01%
Gastrointestinal Disorders					
Nausea/feeling sick	X				
Diarrhoea	X				
Stomach pain		X			
Vomiting		X			
Reflux or heart burn		X			
Constipation		X			
Bloating (feeling full)		X			
Burping		X			
Wind/Gas		X			
Gallbladder pain			X		
Acute Pancreatitis			X		
General					
Tiredness/Fatigue		X			
Injection site reaction		X			
Allergic Reactions		X			
Metallic taste in mouth			X		
Low blood sugar					X
Hair Loss		X			
Dizziness		X			
Serious Allergic Reaction				X	

Diarrhoea: diarrhoea, frequent bowel movements

Stomach Pain: abdominal pain, abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, gastrointestinal pain

Constipation: constipation, faeces hard

Tiredness/Fatigue: fatigue, asthenia, malaise, lethargy

^a Excessive diarrhoea and vomiting may lead to dehydration, which could cause a deterioration in kidney function, including decreased kidney function.

Other Risks:

- (1) Tirzepatide is known to slow down stomach emptying. If you are having surgery, you need to inform your doctors you are taking this medication so they can follow their hospital guidelines regarding your anaesthetic and stopping this medication before any planned surgery.
- (2) Pancreatitis is inflammation of the pancreas and can potentially be a serious complication. The pancreas is an organ that sits behind the stomach and helps to digest food and control blood sugars. Although uncommon pancreatitis can occur suddenly, symptoms include pain in the upper stomach that can travel through to your back, tenderness when touching your stomach, fever, rapid pulse rate and vomiting. You should see a doctor if you develop

sudden stomach pain that does not improve, and if you are unable to sit still or find a comfortable position.

- (3) Acute Kidney Failure: because a known risk of this drug is gastrointestinal symptoms of vomiting and diarrhoea that could lead to dehydration, you should try to maintain a good level of hydration over the course of the trial. Be aware that in severe cases of dehydration acute kidney failure can occur.
- (4) Diabetic Retinopathy: an eye condition that can cause vision loss and blindness in people which have diabetes. Although we are excluding people with diabetes, if you are to develop diabetes over the course of this trial, you should be aware of this risk.
- (5) If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my information and test samples?

We will store the information we collect about you on a secure, password protected computer file which will only be accessible by the researchers. We will keep this information for at least 15 years following publication of the research findings, which is consistent with the National Health and Medical Research Council (NHMRC) Statement Guidelines on Research Practice. As recommended by the NHMRC Open Access Policy, non-identifiable data can be made available to appropriately qualified researchers, to be used in future related research (with appropriate ethical approval in place) upon reasonable request to the research team.

Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law. The Coordinating Researcher (Professor Michelle Dowsey) will have ongoing custody of these data. Your privacy will be protected when data is made available by making the data non-identifiable.

Your urine and blood samples taken for screening assessment will be analysed by your Western Health pathology laboratory. These will also be used for screening purposes for your knee replacement surgery.

The blood samples collected during this study for screening and for the assessment of your health status will be processed by the Western Health central pathology laboratory. These samples will be destroyed after they have been analysed, as per Western Health central pathology laboratory policy and procedures.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If it is decided that you can continue in the research project, you will be asked to sign an updated consent form.

Also, upon receiving new information, your study doctor might consider it to be in your best interests to be withdrawn from the research project. If this happens, the doctor will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture, or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor will also explain to you which treatments and/or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

If you do withdraw during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw, will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug being shown not to be effective
- The drug being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

15 What happens when the research project ends?

When you have finished the study, we will tell you which study group you were assigned.

At the completion of this research project, you will continue to receive the standard care at Western Health.

At the end of this research project, you will no longer receive the study drug and there could be a risk of weight gain. You should speak to your GP for follow-up care.

It is intended that the results of this study will be presented at conferences and submitted for publication in a peer-reviewed journal. Any presentation or publication will not present any data or health information that can be used to identify you. It is usual for a number of years to elapse before definitive results of this type of study are available.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in with this research project that can identify you will remain confidential. Your information will be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. Additional long-term follow up is planned out to 10 years using health datasets through the Department of Health, Australian Institute of Health and Welfare, and Australian Orthopaedic Association which will provide us with data to see if or when you have had your knee replacement surgery. Further linked data will also be collected, with your consent, from other databases that hold information from the Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, and other Victorian hospital records through the Department of Health (Vic) and Services Australia. Your information will be sent to Services Australia and Department of Health (Vic) for linkage of databases mentioned above. All data received will be stored and analysed in either the Secured Unified Research Environment (through AIHW), Victorian data Access Linkage Trust (through CVDL) or with ethics and data custodian approval, on our secure servers at the University of Melbourne. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

You will also be asked to sign a separate consent form authorising the study to access your Commonwealth health information provided by Services Australia, see the separate Services Australia Participant Information Document and Participant Consent Form. Please note, you can still participate in the study if you choose *not* to sign the Services Australia Consent Form. Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities, the institution relevant to this Participant Information Sheet (HREC of St Vincent's Hospital, Melbourne), or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities.

Members of the research team will meet monthly to discuss the progress of the study to ensure that the study is being conducted appropriately. Progress of the study will be reported to the Department of Surgery, The University of Melbourne and discussed with partner organisations involved in this research.

Information about participation in this research project will be recorded in your health records. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purposes of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and Compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This investigator-initiated trial is being sponsored by The University of Melbourne. A grant by the pharmaceutical company Eli Lilly has provided part of the funding to the University of Melbourne to conduct this project.

No member of the research team will receive a personal financial benefit from their involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital Melbourne.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research 2007 (including all updates)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher Professor Michelle Dowsey on (03) 9231 3955 or any of the following people:

Clinical contact person *Name to be confirmed upon employment*

Name	<i>[To be confirmed upon recruitment of Research Nurse Site Coordinator]</i>
------	--

Position	Research Nurse
Telephone	<i>[To be confirmed upon recruitment of Research Nurse Site Co-ordinator]</i>
Email	<i>[To be confirmed upon recruitment of Research Nurse Site Co-ordinator]</i>

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Mr Bill Karanatsios
Position	Research Program Director, Western Health Office for Research
Telephone	(03) 8395 8073
Email	ethics@wh.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital Melbourne HREC
HREC Executive Officer	HREC Executive Officer
Telephone	03 9231 6970
Email	research.ethics@svhm.org.au

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Dr Kai Yan Mak
Position	Manager – Office for Research
Telephone	03 8395 8070
Email	ethics@wh.org.au



PATIENT LABEL

Consent Form – Person Responsible

Title Effect of Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA): A Randomized, Double-Blind, Placebo-Controlled Trial

Short Title Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA)

HREC Number 009/24

Project Sponsor The University of Melbourne

Coordinating Principal Investigator Professor Michelle Dowsey

Principal Investigator Professor Phong Tran

Associate Investigators Libby Spiers, Truc Minh Ngo, Eugenie Ng, Angela Cochrane, Francesca Sasanelli, Jeremy Abetz, Saad Alkassab, Marc Macaluso

Location Western Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

*Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Person Responsible Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor

I have given a verbal explanation of the research project; its procedures and risks and I believe that the person responsible has understood that explanation.

Name of Study Doctor (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation – Person Responsible

Title Effect of Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA): A Randomized, Double-Blind, Placebo-Controlled Trial

Short Title Subcutaneous Tirzepatide Once-weekly in Patients with Obesity and Knee Osteoarthritis (STOP KNEE-OA)

HREC Number 009/24

Project Sponsor The University of Melbourne

Coordinating Principal Investigator Professor Michelle Dowsey

Principal Investigator Professor Phong Tran

Associate Investigators Libby Spiers, Truc Minh Ngo, Eugenie Ng, Angela Cochrane, Francesca Sasanelli, Jeremy Abetz, Saad Alkassab, Marc Macaluso

Location Western Health

Declaration by Person Responsible

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant’s routine treatment, relationship with those treating them or their relationship with Western Health.

Name of Participant (please print) _____	
Relationship of Person Responsible to Participant _____	
Signature of Person Responsible _____	Date _____

Name of Study Doctor (please print) _____	
Senior Researcher (please print) _____	
Signature _____	Date _____

Note: All parties signing the consent section must date their own signature.