PARTICIPANT INFORMATION SHEET AND CONSENT FORM
(Part G: Participants with Obesity – Combination Treatment)

Short Title:	Study to Evaluate Single and Multiple Doses, and a Tablet Formulation of TLC-6740 in Healthy Participants and Participants With Obesity and With or Without Diabetes
Protocol Number:	6740-CL-101
Sponsor:	OrsoBio, Inc. 101 Jefferson Drive Menlo Park, CA, 94025 USA
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Phone Number:	Auckland: 0800 STUDIES (0800 788 3437) Christchurch: 0800 862 278
Ethics Number:	2023 FULL 15237

This is the first time that TLC-6740 will be studied in humans with obesity and in combination treatment with a Glucagon-like peptide-1 (GLP-1) medication.
You may get a health benefit from the drugs used in this study; but there are risks of you having a drug reaction, injury, or illness.

You are invited to take part in a clinical research study. This study will test an investigational drug, named TLC-6740. TLC-6740 is an investigational product because it has not been approved by the New Zealand MedSafe or other drug regulatory authorities.

There are multiple parts to this study, and you are being asked to take part in Part G. This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. We expect this will take about 30-60 minutes. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

Please make sure you have read and understood all the pages of this document including the consent form.

1 WHY ARE WE DOING THE STUDY?

1.1 Purpose

TLC-6740 is being developed for the treatment of obesity and insulin resistance. The rate of obesity and insulin resistance has been rapidly increasing with approximately 13% of adults worldwide currently classified as obese, including 1 in 3 adults in New Zealand. Being overweight or obese is one of the leading causes of insulin resistance.

Obesity results from an imbalance between the amount of energy, or calories, consumed, and the amount of energy utilized by the body. Over time, excess or unused caloric intake is stored in the form of adipose tissue, or fat. Mitochondria sit within cells in the liver and other tissues throughout the body and through the processing of glucose (sugar) or fat, serve to generate the energy the body needs to function. Adjusting how the mitochondria process sugar or fat to produce energy may allow for increased burning of excess fat and provide a new method for treating obesity.

Insulin resistance is when your body doesn't respond well to the hormone insulin. Insulin is responsible for helping your cells absorb and use glucose (sugar) for energy and helps maintain normal blood sugar levels. When your cells are not as sensitive to insulin or are resistant to insulin, your body tries to produce more insulin to keep your blood sugar at a normal level, however it is difficult for your body to maintain these increased levels. Over time, this can lead to higher blood sugar, which can progress to the development of type 2 diabetes and other health problems associated with diabetes.

TLC-6740 works by increasing energy burning in cells throughout the body, primarily in the liver. Over time, a moderate increase in the rate of energy burning throughout the body may shift the balance of energy intake and use to a state of energy (calorie) deficit, potentially leading to weight loss. In the liver specifically, cells that accumulate increased amounts of lipid, or fat, do not function normally (e.g. respond poorly to insulin), with effects that impact the entire body. It is believed that by moderately increasing the amount of energy burning in cells throughout the body, especially in the liver, that this excess fat may be reduced, leading to improved function of these cells, including improved response to insulin, resulting in improved control of glucose (sugar) and lipids (fats) in your blood.

Given the above, TLC-6740 may be an effective treatment for obesity, insulin resistance, diabetes, fatty liver diseases, lipid disorders, and other diseases that result from the accumulation of fat over time in the liver and other tissues.

This study will investigate the effects of a single dose oral suspension (Parts A and C), multiple doses oral suspension (Parts B and C), a tablet formulation with food effect (Part D), the effect of different drug-drug interactions (DDI) (Part E) of TLC-6740 in healthy participants, multiple doses of TLC-6740 in people with obesity (Part F), and multiple doses of TLC-6740 combined with tirzepatide in people with obesity (Part G).

Tirzepatide is a once-weekly injectable peptide (protein-based) medication approved under the trade name Mounjaro for type 2 diabetes and Zepbound for obesity (weight management) in the U.S., EU, UK, Canada, and Australia. It works by mimicking two natural gut hormones, GLP-1 and GIP, which help control blood sugar, slow digestion, and reduce appetite. By acting like these hormones, tirzepatide helps the pancreas release insulin when needed to lower blood sugars, prevents too much sugar being released

from the liver, and makes people feel hungry less, and when they do eat, feel fuller earlier and for longer, leading to lower food intake and over time, weight loss. Since it is a peptide (protein), it is usually an injected medication. Many people experience significant weight loss and better blood sugar control because tirzepatide lowers both how much people eat, and when they do eat, how the body handles sugar after eating, making it an effective treatment for patient with obesity, with or without insulin resistance or diabetes.

You are being asked to participate in Part G.

The purpose of Part G of this study is to:

- Evaluate how safe and well tolerated TLC-6740 is when given in combination with tirzepatide, in people with obesity.
- Evaluate the levels of TLC-6740 in the blood over time, following multiple doses and when given in combination with tirzepatide
- Evaluate if TLC-6740 when combined with tirzepatide has an effect on metabolic parameters, including body weight and levels of fat and sugar in the blood

1.2 Study Design

Approximately 506 healthy participants and people with obesity will take part in this study including approximately 100 participants with obesity in Part G. Part G of this study requires a Screening visit to confirm eligibility and six scheduled clinic visits at NZCR research unit.

In Part G, all participants receive tirzepatide.

Part G includes Cohorts 26 and 27, which are randomised, blinded, and placebo-controlled cohorts:

- Randomised means that the study treatment (TLC-6740) you take (active study drug or placebo) will be assigned randomly (by chance).

- Blinded means that neither you nor your study doctor will know whether you will be receiving TLC-6740 or placebo (a substance that looks like TLC-6740 but contains no active medication). In an emergency, the study doctor can find out what you are receiving.

Based on your screening results, you will be assigned to one of two cohorts. Your physician or study staff will inform you which Cohort you will be assigned.

Cohort	Study Design
26	If you are assigned to Cohort 26, you will be randomly assigned into one of two treatment groups: • **Group A** = 30 participants to receive 180 mg of TLC-6740 AND tirzepatide • **Group B** = 20 participants to receive 0 mg of TLC-6740 (will receive placebo) AND tirzepatide
27	If you are assigned to Cohort 27, you will be randomly assigned into one of two treatment groups: • **Group A** = 30 participants to receive up to 270 mg of TLC-6740+ tirzepatide • **Group B** = 20 participants to receive 0 mg of TLC-6740 (will receive placebo) + tirzepatide

After the Day 1 visit, you will take the **oral study drug at approximately the same time each day** at home. Each dose includes one tablet from Bottle A and one tablet from Bottle B daily, for a total of 2 tablets per day. Each dose should be taken by mouth, with a full glass of water (at least 240 mL).

At the Week 2, 4, 8, and 12 visits, you will take oral study drug at your clinic visit. Do not take oral study drug before coming in for these visits.

Blood samples and other tests to measure study drug levels and effects on the body will be collected at specific time points during the study, your safety will be monitored, and any changes in your health will be recorded.

1.3 Nature and Sources of Funding of the Study

This research project is being conducted and funded by OrsoBio, Inc. and locally sponsored in New Zealand by Avance Clinical Pty Ltd., a Contract Research Organisation (CRO) which help conduct and monitor the study in New Zealand.

By taking part in this research study, you agree that data generated from your assessments throughout the study, will be provided to the Sponsor. The knowledge gained from this data may lead to new discoveries, which would assist them in obtaining approval for a new drug and benefit the sponsor financially. There would be no financial benefit to you from these discoveries.

NZCR will receive a payment from OrsoBio, Inc. for undertaking this research project.

If you were referred to this trial by your GP, your GP may receive a payment from the sponsor. Whilst it is important for you to be informed of this, this should not impact your decision to participate in this trial. Your decision to participate in this study is voluntary and you may decide to withdraw your consent at any time without penalty to you or any party involved.

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

1.4 Approval by Ethics Committee.

This study has been reviewed by an independent group of people called a Health and Disability Ethics Committee (HDEC). The ethical aspects of this research project have been approved by the **Northern B Ethics Committee**.

A description of this clinical study will be available on http://www.ClinicalTrials.gov. 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 website at any time.

2 WHAT WOULD YOUR PARTICIPATION INVOLVE?

Participation in this study will last up to approximately 18 weeks (126 days), including a screening, treatment, and follow-up period. If you wish to participate in this study, you will be asked to sign this consent form before any study assessments can be performed.

The details of the study and tests performed are discussed and shown below. During the screening period, assessments will be done to check whether the study is suitable for you. The day you have your first dose of TLC-6740 is called Day 1 and all other days are counted back or forward from this day.

The results of the screening assessments will determine whether or not you can take part in the study. However, even if all your results are normal, you may not be guaranteed a place. This will mean you will be asked to come to the clinic and undergo the tests and procedures to determine your eligibility for the study until the point that we have enrolled enough eligible participants, at which point screening activities will stop.

2.1 Tests and Procedures

Questions about your health:
The study doctor will ask you questions about your health, medical history, medication history, and social history (e.g. alcohol consumption, smoking history, physical activity etc) to determine whether you are eligible for the study.

Physical Examination:
During the study, the doctor will perform a physical examination to check your health. Your height and weight will also be measured to calculate that your Body Mass Index (BMI) is within range for the study, as well as body circumference measurements.

Electrocardiogram (ECG):
An ECG measures the electrical activity of your heart, using 12 wires attached to your chest and limbs with sticky pads.

Vital Signs:
Vital signs include recordings of your pulse, blood pressure, breathing rate, and temperature.

Blood and Urine Samples:
At clinic visits, blood samples are taken by direct vein puncture. Blood and urine samples collected during the study may be used:

- To monitor your safety (blood cells, clotting, chemistry, fats, liver function, kidney function, insulin levels, thyroid, blood sugars, blood fats)
- To check whether you may be pregnant (for people of childbearing potential only), or to confirm post-menopausal status (in people who are post-menopausal only)
- To screen for recreational drugs such as cannabis, methamphetamine, and opiates.
- To screen for specific infections (HIV, Hepatitis B, Hepatitis C)
- To measure the amount of TLC-6740 in the blood
- To measure the body's response to TLC-6740

Indirect Calorimetry Assessments:
At select recruiting sites in Part G, participants will complete an Indirect Calorimetry assessment at 3 times during the study. **During your Screening visit, you will be notified by site staff if your completion of this assessment will be required.**

The Indirect Calorimetry assessment will be performed at the University of Auckland, Human Nutrition Unit (18 Carrick Place, Mount Eden, Auckland 1024). The Indirect Calorimetry assessment will be performed using the COSMED Q-NRG® device, also referred to as a metabolic cart. The COSMED Q-NRG is a safe, non-invasive device cleared by the United States Food and Drug Administration.

During the Indirect Calorimetry assessment, as shown in the image below, you will wear a transparent, ventilated, open-circuit hood over your head, mouth, and nose. During the assessment you will be asked to relax quietly in a comfortable position and to breathe normally.

Over 30-45 minutes, the rates and amounts of oxygen you breathe in and carbon dioxide you breath out will be measured. Using these measurements, the device will calculate your resting energy expenditure, which is the amount of energy your body is using to maintain its normal functions and activity levels.

To measure your body composition, which is an estimate of the different body tissue types (lean muscle mass, body fat), you will be asked to stand on a bioimpedance scale for 1-2 minutes just before you start the above assessment. For scheduling reasons, this may be moved to the end of the assessment at the discretion of the site staff.

You will have three Indirect Calorimetry assessments (one in the week prior to Day 1, one just before or after Day 28, and one in the week before Day 84).

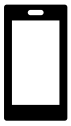
You will be asked to fast **overnight for at least 10 hours prior to the scheduled Indirect Calorimetry assessment time** (no food or drinks, except water), for at least 10 hours prior to the scheduled assessment time. To minimize the effect of dietary factors on the Indirect Calorimetry measurements, the fasting requirement may be extended to 12 hours and/or a meal may be provided to you to eat for dinner the evening prior to your assessment(s).

In the 24 hours prior to each Indirect Calorimetry assessment:

- Do not consume any alcohol
- Do not exceed your normal daily caffeine intake (e.g., 2 coffee per day)
- Do not participate in any moderate or strenuous physical activity (e.g., weightlifting, jogging or running, cycling, swimming)
- Do not walk or bicycle to the assessment location the day of your assessment. You should travel by car or bus to the assessment location.

Data Collection:
Data collected from the COSMED Q-NRG device will be uploaded directly into secure cloud storage at University of Auckland. This data will be deidentified (meaning that there will be no personal identifiable data in the data set). You will be identified by a code only.

Dosing Diary:
You will be asked to complete a Dosing Diary in which you will note down whether you took your once daily dose of oral medication (Days 1-84) and your weekly dose of tirzepatide (Doses 1-12), including the date and time you took the dose. You are required to update the Dosing Diary every day, Day 1 through Day 84.



DAILY EATS® Questionnaire:
Every day starting on Day 1 through the Follow Up visit, you will be asked to respond to a set of 5 questions regarding your hunger, appetite (desire to eat), cravings and satiety (comfortably full). The questions are the same every day. You will be instructed on how to complete the questionnaire on your personal device, such as a mobile or tablet device. You will be given a paper copy of questionnaire as a backup in case you are unable to access the electronic version. You should bring your paper copy to your next visit.

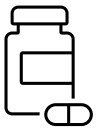
See Section 9 for more details on the application.

Tirzepatide Administration At Home

You will administer your first dose of tirzepatide at clinic on Day 1. After the Day 1 visit, every participant will administer tirzepatide once a week at home, 11 more times, for a total of 12 doses of tirzepatide. Tirzepatide will be provided as a pre-filled injectable pen (KwikPen®). Each pen holds 4 total doses of either 2.5 or 5 mg of tirzepatide. You will be given a new tirzepatide pen at Day 1, Week 4 and Week 8 visits.

For your first 4 doses, you will use the same pen to inject 4 total doses of 2.5 mg of tirzepatide. If you are tolerating the medication well, starting with the 5th dose, you will be given a new pen and administer a dose of 5 mg once weekly and continue on this dose through to your 12th and final dose.

Each dose of tirzepatide should be administered on the same day of the week at approximately the same time of day (e.g. Mondays). Please speak with study staff if you have any questions.



Pill Count
On days where you are not dosing on site, you will be provided with tablets (TLC-6740 or placebo) to be taken at home. You will be asked to bring your tablets to each clinic visit for study staff to perform a pill count. You will be reminded of this prior to each visit.

Lifestyle Counselling
On Day 1, study staff will counsel you regarding general lifestyle measures for weight management.

Study Schedule

Period	Screening	On Treatment Visits					Follow-Up Visit	
Study Day	**Day -28 to -1**	**Day 1**	**Week 2**	**Week 4**	**Week 8**	**Week 12**	**Week 14 EOS[a]**	**Early Withdrawal**
Clinic visit	X	X	X	X	X	X	X	X
Questions about your health	X	X	X	X	X	X	X	X
Physical Exam[1]	X	X	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X	X	X
ECG	X	X	X	X		X	X	X
BMI (Height & Weight) and other body measurements	X	X	X	X	X	X	X	X
TLC-6740 or Placebo Administration in clinic[2]		X	X	X	X	X		
Tirzepatide Administration [6]		X	X	X	X	X		
Fasting for clinic visit[3]	X	X	X	X	X	X	X	X
Blood Sampling	X	X	X	X	X	X	X	X
Urine Sampling	X	X		X		X		X
Indirect Calorimetry Assessment[7]		X		X		X		X

Period	Screening	On Treatment Visits					Follow-Up Visit	
Study Day	**Day -28 to -1**	**Day 1**	**Week 2**	**Week 4**	**Week 8**	**Week 12**	**Week 14 EOS[a]**	**Early Withdrawal**
Dosing Diary Review[4]			X	X	X	X		X
Daily Eats Questionnaire[5]		X	X	X	X	X	X	X
Lifestyle Counselling		X						

[a] EOS = End of Study

[1] You will have a complete physical examination at Screening. At other time points, you will have a shorter physical examination based on any symptoms you report.

[2] At the Day 1 visit, you will take your oral study drug and tirzepatide in the clinic. At your Week 2, Week 4, Week 8, and Week 12 visits, you will also take your oral study medication at your clinic visit. Do not take your oral study medication at home before coming in for these visits. Study staff will remind you of this prior.

[3] For all visits, you are required to be fasting for at least 10 hours beforehand, which means no food or drink, except water. Study staff will remind you of this prior.

[4] If you still need to finish taking medication after your Week 12 clinic visit, you will bring back your oral study medication bottles and daily dosing diary to your Follow-Up visit.

[5] You will complete DAILY EATS questionnaire each day on your device from Day 1 through the day of your Follow-Up visit.

[6] You will continue your tirzepatide weekly dosing at home. You need to administer tirzepatide on the same day of the week at approximately the same time of day. On Day 1, you will receive your tirzepatide supplies.

[7] The Indirect Calorimetry assessments are applicable to selected sites only.

2.2 Who Can Take Part in this Study?

To take part in this study you must:

- Be able to give informed consent and follow the study procedures.
- Be aged 18 – 70 years, inclusive.
- Have a BMI (Body Mass Index) between 30-50kg/m^2.
- Have a history of at least one unsuccessful attempt to lose weight via lifestyle changes (e.g. reduced calorie diets, increasing exercise etc.)

You cannot take part in this study if you:

- Are pregnant or breastfeeding.
- Have had a change in body weight of over 5 kg within 3 months (90 days) before Screening.
- Have had previous or planned (during the study) obesity treatment with surgery or a weight-loss device (e.g. gastric sleeve surgery)
- Had type 2 diabetes diagnosed at any time in the past or at Screening
- Drink more than 21 units (males) or 14 units (females) of alcohol per week, and/or have current drug or alcohol abuse. One unit is approximately one beer, one glass of wine, or one "shot" of liquor.
- Ongoing cannabinoid use
- Have a history of a significant medical problem, mental health problem or severe allergy, including but not limited to:
    - Have a medical history of gallstones (cholelithiasis) or gallstone associated disease (e.g., cholecystitis, choledocholithiasis, or pancreatitis) unless the gallbladder has been removed since this diagnosis (cholecystectomy)
    - Liver disease (other than metabolic dysfunction-associated steatotic liver disease (MASLD) or metabolic dysfunction-associated steatohepatitis (MASH)), including but not limited to alcoholic liver disease, autoimmune disorders involving the liver, cirrhosis.
    - Heart disease or blood vessel issues (e.g. unstable angina, heart attacks, strokes/mini-strokes, or symptomatic congestive heart failure, placement of de-fibrillator)
    - Any abnormality in gut (stomach or intestine) motility or stomach emptying (gastroparesis, gastric outlet obstruction) or taking medications that affect either gut motility or stomach emptying
    - Uncontrolled thyroid disease (e.g. hypo- or hyper-thyroidism)
    - Have any disease or surgery which could affect absorption of medication
    - Severe peptic ulcers, acid reflux or other gastric problems
    - Cancer within the last 5 years (except some non-melanoma skin cancers or cervical carcinomas which have been removed)
    - Medullary thyroid carcinoma or multiple endocrine neoplasia syndrome, type 2 (MEN 2), any personal history or family (first degree relative)
    - Psychiatric hospital admission or emergency room visit (for psychiatric diagnosis) in the last 2 years, or any prior suicide attempt
- Have received an investigational medication in a clinical study within 28 days of planned study medication dosing.
- Have taken any medication or therapy for the indication of weight loss within 90 days of Screening, including prescription or over-the-counter. Certain medications may be okay, please speak with the study doctor to check if any medications you are taking are not allowed.
- Have received a COVID-19 or a "live" vaccination within 14 days of planned dosing.

If you think that any of the above applies to you, or you have one of the conditions described, please discuss these with your study doctor for more thorough assessment to see if you can take part in this

study or not. Additionally, there are other criteria that you will need to meet in order to be eligible for the study, but the study doctor will discuss this with you at your screening visit.

2.3 Study Instructions

It is important that you follow the instructions you are given and attend all scheduled clinic visits. It is also possible that the study doctor may schedule extra visits or tests for you, if considered necessary. In the event that an assessment is not performed on the day outlined within the Schedule of Activities within this document, the assessment may be performed at your next study visit.

You will be given a Participant Identification Card if you participate in this study, stating the name of the study and the study doctor's contact information. This card should be carried with you at all times so that you can contact the study doctor at any time and so you can show it to any other doctor, dentist, or pharmacist that you might visit while in this study.

At each visit, the study staff will ask you questions about your health and the medications you are currently taking. You should always report any changes in your health, unusual feelings, or symptoms to the study staff. It is also important that you do not start, stop, or make changes to any of the medications you are currently taking without first discussing this with your study doctor.

Please inform the study doctor or staff if you decide to stop having the TLC-6740 or Tirzepatide for any reason. If you stop receiving the investigational medicine or Tirzepatide for any reason (either your choice or on the advice of your study doctor) your study doctor will ask you to continue to attend the unit for follow-up assessments. If you decide to stop participating in the study for any reason your study doctor will discuss treatment choices with you.

Restrictions and Other Study Requirements:

- You must refrain use of cannabis or cannabinoid containing compounds during the study through until your final follow up visit.
- You must avoid consuming any food or drinks containing grapefruit or Seville orange juice from 72 hours prior to your first dose (Day 1) and during the study through follow up visit.
- You must record your study drug dosing, including daily oral study medication and weekly tirzepatide injections in the provided dosing diary. At each visit from Week 2 until Week 12, and the Follow-up visit (if necessary), you will have your diary checked for compliance.

3 WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

You do not have to take part in this research project to receive treatment for obesity. Other options are available. Your study doctor will discuss the risks and benefits of these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor. If you were referred to NZCR by your GP, they won't be able to provide independent medical advice regarding the trial as they will receive financial compensation.

4 WHAT ARE THE POSSIBLE BENEFITS, COSTS AND RISKS TO YOU PARTICIPATING?

4.1 Benefits

This study is not designed to provide you with specific therapeutic benefits. Your condition may improve, remain the same, or worsen during the study. Individual responses will vary, however given that the established clinical benefits of tirzepatide (lipid lowering, weight loss), it is expected the majority of participants may experience similar benefits after 12 weeks of treatment. As

4.2 Reimbursement and Costs

All tests required to be done for this study will be paid for by OrsoBio, Inc. and there will be no cost for you to participate in this study.

You will be reimbursed the sum of $4,300 (before tax) following the final study visit**.** If you are required to participate in the metabolic cart (or Indirect Calorimetry) assessment, you will receive additional amount of $300 ($4,600 before tax) for your participation. Your study team will let you know during screening if you are required to participate in metabolic cart (or Indirect Calorimetry). However, the timing of reimbursement is flexible and can be adjusted to suit your needs – please discuss this with study staff if you have any concerns regarding your reimbursement. **We are required to deduct withholding tax at the applicable rate you have declared in the IR330C form**. You will be responsible for any other tax obligations (e.g., ACC). If you are GST registered, it may be possible for you to submit a GST invoice. Contact paymentforms@nzcr.co.nz if you would like to discuss this further.

The payment will be made after you complete the study, to cover your time and inconvenience. If you are receiving a benefit or allowance, your usual payments may be affected. Your tax statement will state that you were paid from your dosing day through to your final study visit.

To be able to receive reimbursement as part of this study, you must be eligible to work in NZ (e.g. as a NZ resident, NZ citizen, or with the appropriate work visa) for the entire duration of the study. If you are no longer eligible to work in NZ during the study, you will be withdrawn from the study and your reimbursement will be a pro-rata of the total amount.

If you leave the study of your own choice or are released from the study for non-medical reasons, you will receive a partial reimbursement (a pro-rata reimbursement) according to how far you contributed to the study. Full reimbursement requires completion of all visits according to study requirements. If you are withdrawn from the study for medical reasons, having received trial medication, you will receive reimbursement in full.

You will be reimbursed separately for travel and parking (if you use your personal transport) or you can use uber or taxi for your study visits, which can be arranged and paid for by NZCR if you live in the metropolitan area. If you live outside this area, we will discuss your travel costs individually.

If you complete the screening visit assessments and are found not eligible for the study, you will not receive any reimbursement.

4.3 Possible Risks and Disadvantages?

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. There may also be unknown side effects from taking TLC-6740 alone or with other drugs you may be taking. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

What are the Risks or Side Effects of TLC-6740?

This study is the first time that TLC-6740 is being tested in humans and as such there is limited human experience available to identify all of the potential risks of TLC-6740.

Animal studies have been done with TLC-6740 to try and predict what type of side effects might occur in people. However, animal studies do not always predict human responses to drugs. When TLC-6740

was given to animals at doses higher than the doses that will be given in this study, the below effects were observed:

- Increased body temperature
- Increased liver and muscle enzymes
- Decreased body weight

The doses planned for this study in people are lower than any of the doses given to animals. Importantly, animal studies do not always predict human response to drugs. Among side effects that could occur, some could be life-threatening.

The doses of TLC-6740 planned to be tested in Part G were previously evaluated in healthy volunteers treated with TLC-6740 at that dose or greater for 10 days and were well tolerated.

As with other drugs, TLC-6740 may cause an immune reaction or allergic reaction. Symptoms may include rash, flushing, itching, sneezing or runny nose, abdominal pain, diarrhea, swelling of face, tongue or throat, dizziness, lightheaded or fainting, trouble breathing, irregular or racing heart rate, and seizures. These reactions can be life-threatening / fatal. If you have a skin reaction or other adverse event, the study doctor may take a photograph to document the event.

What are the Risks or Side Effects of Study Procedures?

Blood Sample Collection:
Risks include bruises, swelling with itching, and slight bleeding. The area may become inflamed. In rare cases, it may result in a blood clot, an infection or nerve damage. As needles can cause pain, you may feel light-headed or faint.

Tirzepatide Injection
Important risks associated with tirzepatide include mild to moderate gastrointestinal distress, including decreased appetite, nausea, diarrhea, and vomiting. These symptoms are usually experienced during the first 4-6 weeks of treatment and usually decrease in severity and/or resolve completely as your body adjusts to the effects of tirzepatide. Participants that experience these symptoms find that small changes to eating behaviors, including eating smaller, more frequent meals and staying hydrated are helpful in managing symptoms. If dietary modifications are not helpful, other options including the temporary use of medications may be recommended by your study doctor. While these effects are expected and usually temporary, **it is important to report any change in your health, including any new symptom to your study doctor.**

In addition to the above, with tirzepatide there is the potential risk of injection site reactions, which may include pain, bruising, redness, bleeding, or swelling. There is a smaller risk of infection, blood clot formation, or nerve damage at the injection site(s). Some participants may feel lightheaded or faint when administering an injection.

Occurrence of any AE of special interest for tirzepatide may require collection of additional safety information and should be immediately reported to your study doctor. Tirzepatide AEs of special interest include inflammation of the pancreas (pancreatitis), severe gastrointestinal reactions such as gastroparesis or bowel obstruction, acute gallbladder disease (including gallstones or gallbladder inflammation or infection), acute kidney injury, severe low blood sugar (hypoglycemia), changes in thyroid cells including potential thyroid cancers, major depressive disorder or suicidal thoughts or behaviors, and any serious allergic reaction to tirzepatide.

ECG Tests:
Sometimes the sticky pads used to attach the ECG leads can cause skin irritation (redness / itchiness).

Physical Examination:
During this examination you may be asked to remove some items of clothing so a full examination can be done. You can request a chaperone to be with you at the time of the physical examination, please ask one of our research nurses.

Indirect Calorimetry Assessments:
The COSMED Q-NRG device is a safe, non-invasive device which prevents rebreathing of previously exhaled air and all hoods and masks are sterilised as per strict cleaning and disinfection protocols. In the case you experience mild claustrophobia, at the discretion of the site staff, modifications may be made to your testing environment to attempt to make you more comfortable. If despite these attempts you are unable to complete the assessment, the assessment will be stopped.

Bioimpedance is a safe, non-invasive of method of measuring body composition. For a short period, bioimpedance scales send a weak electrical current through the body which most people do not feel, however people who are highly sensitive might experience mild tingling or discomfort. Rarely, the sensors on the scale can cause mild skin irritation to the feet.

There are no additional risks to participating in the Indirect Calorimetry assessments.

4.4Contraception

Reproductive Risks for Sexually Active Participants of Child-Bearing Potential

The effects of TLC-6740 in pregnancy and breastfeeding are unknown, but there is a risk it may cause birth defects or foetal deaths, and/or be passed on in breast milk. If you are pregnant or breastfeeding, you cannot take part in this study.

If you are sexually active and of child-bearing potential (able to become pregnant), it is very important that you do not become pregnant during this study. A person of child-bearing potential is any pre-menopausal person who may become pregnant. If you are unsure if this applies to you, please check with the study doctor before you start the study treatment. **You must use one of the methods of contraception listed below**, from at least screening until at least 30 days after your last dose:

A highly effective method (less than 1 pregnancy per 100 people using the method for one year) e.g.:

- Implant contraceptive (e.g., Jadelle®)
- Intra-uterine device (IUD) containing either copper or levonorgestrel (e.g., Mirena®)
- Sterilisation (e.g., vasectomy, bilateral tubal ligation ('clipping or tying tubes' or hysterectomy)

OR an effective method (5-10 pregnancies per 100 people using the method for one year) e.g.:

- Injectable contraceptive (e.g., Depo Provera)
- Oral Contraceptive Pill (combined hormonal pill or progestogen-only 'mini-pill')

You and your partner must ALSO use a barrier form of contraception, from screening through until 30 days after your last dose. Barrier methods of contraception include:

- Condoms (external or internal)
- Diaphragm ('cap')

Please note that barrier methods alone are not highly effective methods of birth control.

Total abstinence from heterosexual intercourse during the entire period of risk associated with the study drug (from screening until at least 30 days after your last dose) is considered an acceptable form of contraception if this is in line with your preferred and usual lifestyle.

If you are unsure which method of birth control you are using (or want to start using) and whether it is acceptable for this study, please ask the study doctor for more information.

You must also agree to not donate eggs, from dosing until at least 90 days after your last dose of study drug.

If you do become pregnant during the study, you must tell the study doctor as soon as possible. If you do become pregnant you will be asked to sign a separate consent form, to allow the Sponsor to collect information about your pregnancy and the outcome of your pregnancy.

Reproductive Risks for Sperm in Sexually Active Participants

The effects of TLC-6740 if passed on through semen are unknown, but there is a risk it may cause birth defects or foetal deaths. **You are responsible for informing your sexual partner of these possible risks.**

If you are sexually active and have any partner who is of child-bearing potential (meaning a partner who may become pregnant) it is very important that you use contraception during this study. You and your partner must use one of the contraception options listed above for participants of child-bearing potential, from dosing until at least 90 days after your last dose.

You and your partner must also use a barrier method of contraception, from your dose of study drug until 90 days after your last dose. Barrier methods of contraception include:

- Condoms (external or internal)
- Diaphragm ('cap')

Please note that barrier methods alone are not highly effective methods of contraception.

Total abstinence from heterosexual intercourse during the entire period of risk associated with the study drug (from dosing until at least 90 days after your last dose) is considered an acceptable form of contraception if this is in line with your preferred and usual lifestyle.

If a pregnancy occurs, you must report this to the study doctor as soon as possible. Your partner will be asked to give consent for their information and their infant's information to be collected for monitoring purposes.

You must also agree not to donate sperm, from dosing until at least 90 days after your last dose of the study drug.

5 WHAT WOULD HAPPEN IF YOU WERE INJURED IN THE STUDY?

As this research study is for the principal benefit of its commercial sponsor OrsoBio, Inc. if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, OrsoBio Inc., has satisfied the **Northern B** Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

The sponsor has voluntarily committed to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the investigators, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you.

An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

6 WHAT WILL HAPPEN TO MY TEST SAMPLES?

Blood and urine samples will be collected throughout the study. These samples will be used for various tests. Some of the samples will be used for regular routine blood counts and blood chemistry, to monitor your general health. Some of these routine samples may be sent to Canterbury Health Laboratories (if you are in Christchurch) or Awanui or LabPlus laboratories (if you are in Auckland or Hamilton)for testing and destroyed after 3 months by internationally accepted means.

All other study samples (safety, PK, PD, and biomarkers) will be sent to central laboratories; Inotiv Laboratory in West Lafayette, Indiana, USA, and SciSafe in East Windsor, New Jersey, and Sonic Clinical Trials located in Australia and Bengaluru, India for testing and destroyed after 3 years by internationally accepted means.

The maximum amount of blood collected from each participant during the study will be up to approximately 200mL. For comparison, a standard blood donation at a blood collection centre, is about 470mL. Samples collected by NZCR will be identified by your study number, year of birth, initials, and sex, to allow study doctors to quickly respond to any abnormal results. Before the results of these tests are sent to the Sponsor, your identifiable information will be removed and replaced with a code.

The proposed blood tests include a screening test for HIV and for viral Hepatitis B and C. Signing the consent form means that you agree to have this testing performed. It is important to understand that a positive screening test does not necessarily mean you have the disease. Should you receive a positive screening result for HIV or either Hepatitis B or C, then the study doctors will provide initial counselling

and medical advice and will assist in arranging any follow up tests that you require. HIV, Acute (newly diagnosed) and Hepatitis B and C are all 'notifiable diseases', which means that it is required by law to notify government health authorities of any new cases.

6.1 Are There Any Cultural Considerations?

You may hold sacred and shared values about your tissue samples and/or data originating from this tissue. In line with this we include data sovereignty principles in our practices and in our data management plan. These principles are in place to ensure that the data generated from this research is protected (**whanaungatanga** – relationships) and may benefit Māori now and into the future. More information on data can be found in Section 7.3 including what happens to your data, **kaitiakitanga** (protectors/guardianship) and how this impacts **whakapapa** (whānau, hapu, iwi). NZCR also honour **Kotahitanga** (working together) and ensure that participants are not discriminated based on beliefs.

If you wish karakia to be performed at t the time of sample collection, please let the study staff know and they can arrange this. However, due to samples being sent to countries outside of New Zealand, a karakia will not be able to be performed at the time of your sample disposal.

If you would like to take part in this study you may want to talk to your whānau about it as the study will impact on their whakapapa (that is any tissue and data we gather from you will potentially include information about your whanau, hapū and iwi. If you are involved in any hapū and iwi events and have access to people who understand the impact of this research on your whakapapa you may be able to contact them as well.

There are other ways of accessing cultural support if you need it. There is a contact at the end of this form that you can ring if needed.

Cultural support is different from wanting to know about the study. In this case we can arrange for an investigator to talk to you and your whānau.

New Zealand Clinical Research is committed to meeting their Tiriti obligations by ongoing training to understand what our Tiriti responsibilities are.

7 WHAT ARE THE RIGHTS OF PARTICIPANTS IN THE STUDY?

7.1 Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. This will not affect your routine treatment/medical care which you may otherwise receive, your relationship with NZCR or with those treating you.

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

7.2 New Information

Sometimes during the course of a research project, new information becomes available about the medication 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 you decide to continue in the research project, you may be asked to sign an updated consent form.

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

7.3 Privacy and Confidentiality and Right to Access Information Collected During the Study

What will Happen to my Information?

During this study, the study doctors, researchers, nurses and other NZCR staff will record information about you and your study participation. This includes the results of any study assessments. Your name, address and phone number will be on the demographics page for the study so we can identify you correctly at visits and contact you. This information may be used to obtain health records (detailed below) but is not supplied to anyone overseas.

If needed, **information from your hospital records and your usual doctor (GP) may also be collected**, and your GP will be notified about your participation in the study. You cannot take part in this study if you do not consent to the collection of this information.

Type of information	Where is it stored?	Who can access it?
Identifiable Information – *this information can be traced back to you*		
• Information collected from you • Laboratory results • Photographs if required for any adverse events e.g. skin reactions. • Study Questionnaires and Dosing Diary	• **Paper**: stored securely under restricted access at NZCR. Following study completion paper forms are transferred to a secure site and stored for 15 years, then destroyed • **Electronic**: stored on secure NZCR servers (in New Zealand and Australia).	• NZCR staff • Your GP / usual doctor • Sponsor monitors to ensure the study is run properly and data is collected accurately • Representatives from the Sponsor if you make a compensation claim as a result of study-related injury. Identifiable information is required to assess your claim • Ethics committee, regulatory authorities, and sponsor/CRO representatives if the study or site is audited • Medical Officer of Health for positive test results for a notifiable disease (i.e., Hepatitis B/C) • The study doctor may share your information with other people, in the rare event of a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations
DAILY EATS App Account Registration requires Identifiable Information – *this information can be traced back to you*		

Type of information	Where is it stored?	Who can access it?
• Email Address • Study ID	• **Electronic:** will be stored on a secure platform and will be retained until end of study	• Site staff & Medrio Clinical Data Management System
De-identified (coded) Information – *this information is only labelled with your unique study ID*		
• De-identified information about you (sex, race/ethnicity and age/year of birth) • Study assessment results are uploaded into the study database to be analysed • Laboratory results • Study questionnaires recording in DAILY EATS app and dosing diary • De-identified photographs, if required (as above)	• **Electronic**: will be stored-on a secure platform and will be retained indefinitely. Storage will comply with local and/or international data security guidelines. • **Cloud**: Medrio Clinical Data Management System will retain your data until end of study.	• The Sponsor, for the purposes of this study. • People and companies working with or for the Sponsor, for the purposes of this study. • Regulatory or other governmental agencies worldwide.
Anonymised Information – *this information cannot be traced back to you (code removed)*		
• All de-identified information for which the code has been removed	• **Electronic**: stored on a secure sponsor-managed database	• Access not restricted

Future Research Using Your Information
Your coded information may be used for future research related to TLC-6740 or obesity, insulin resistance, or similar diseases.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information or withdraw consent for its use once your information has been shared for future research.

Security and Storage of Your Information
During the study, your information will be stored on paper forms at NZCR and electronically on secure servers. When the study has finished, paper forms will be transferred to a secure site and stored for at least 15 years, then destroyed. De-identified information in electronic form will remain on a secure platform and will be retained indefinitely. Storage will comply with local and/or international data security guidelines.

Risks
Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. While the risk is currently very small, the chance that someone might access and misuse your information (for example, by making it harder for you to get or keep a job or health insurance) might increase in the future as people find new ways of tracing information.

Your coded information is being sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

Rights to Access Your Information and Results
You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask a study doctor.

8 WHAT WILL HAPPEN AFTER THE STUDY ENDS, OR IF I WANT TO PULL OUT?

8.1 If You Decide to Withdraw

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor. Please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing, such as follow up visits.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

8.2 Why the Study Might be Unexpectedly Stopped

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

- Unacceptable side effects and safety issues
- Poor recruitment
- Poor study conduct

8.3 Will the Study Medication Continue to be Available After the Study Finishes?

TLC-6740 is at an early stage of development. Therefore, after the research finishes, you will not be able to continue to receive TLC-6740. When the research project ends the study doctor may discuss treatment choices with you.

Tirzepatide is not a publicly funded GLP-1 medication here in New Zealand, after the research finishes, you will not be able to continue to receive tirzepatide. When the research project ends, the study doctor will discuss treatment options with you.

8.4 Results

When the research project ends the study data must be analysed, so the results of the study may not be available until about a year after the research finishes. The study doctors and/or Sponsor may decide to discuss or publish the results of the study. This may include publication in journals, presentation at conferences or other professional forums. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you. If you do not wish to receive a summary of the study results when they become available, then please inform NZCR staff.

9 Use of New Technologies

During the study, the use of technology will be a mandatory requirement. Electronic questionnaires called DAILY EATS® Questionnaire will be used. This technology is being used to capture your appetite, hunger, cravings and how full you feel to record any potential changes as a result of this study.

The technology is a web-based questionnaire and is a mandatory component of study participation, so we can record how you feel regarding food

- In order to log in, we will need to capture your email address, but this will not be shared beyond the website.
- Your responses to the questionnaire will be identified by your allocated study participant number only.
- The technology has clear privacy guidelines on how data is shared, stored and used. There is a setting which ensures no participant information is shared with anyone beyond the study site team (i.e. not visible to the Sponsor, CRO or system administrators). Further details can be provided if you ask your study team.
- The technology does not share any information with third parties.
- As the technology is web-based, there is security measures inbuilt.
- There are only standard costs associated with using the technology (e.g. wifi / roaming data costs)
- The information you enter is then stored in the cloud, in San Francisco, California, U.S.

10 WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Auckland:
Professor Ed Gane, Principal Investigator
Phone: (09) 373 3474 or 0800STUDIES (08007883437)
Email: azure@nzcr.co.nz

Christchurch:
Dr Jane Kerr, Principal Investigator
Phone: 0800 862 278
Email: azure.christchurch@nzcr.co.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

Māori cultural support is available through:

The Office of the Chief Advisor Tikanga, He Kamaka Waiora, Te Whatu Ora (Health New Zealand) – Waitemata and Auckland

Mobile: 021 0203 1167
Phone: 09 486 8320 ext 43204
Email: hkwresearch@waitematadhb.govt.nz

Waikato:
Te Puna Oranga Māori Health Service, Te Whatu Ora (Health New Zealand) - Waikato

Phone: (07) 8343628
Email: research@waikatodhb.health.nz

Christchurch:

Dr. Matea Gillies
Mobile: 027 4105 025
Email: gillies-lamb@xtra.co.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

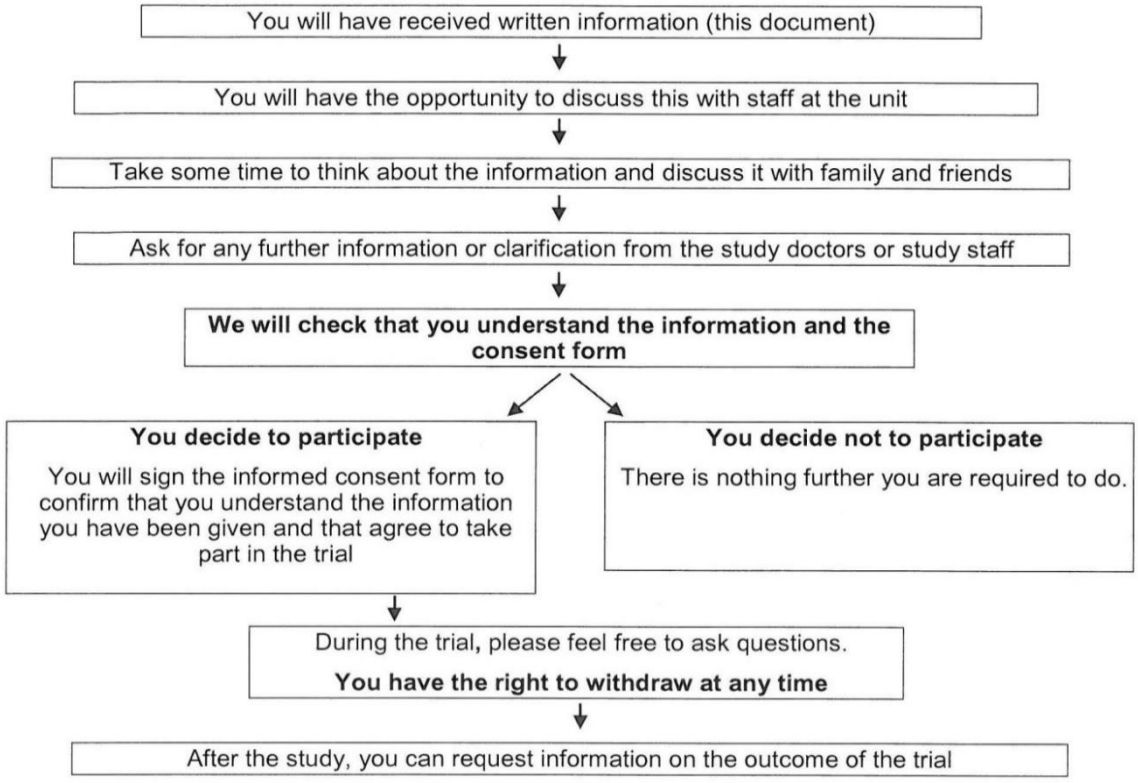
Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

If there is an emergency, please phone **111**

11 WHAT ABOUT ANY OTHER QUESTIONS I MAY HAVE?

12 DO I HAVE TO DECIDE STRAIGHT AWAY?

No, you do not have to decide straight away. You should take some time to consider whether or not to participate, we will be in touch in a week or so to discuss your decision**.** The following steps are useful in helping you reach a decision.



CONSENT FORM
Part G: Participants with Obesity – Combination Treatment

Short Title:	Study to Evaluate Single and Multiple Doses, and a Tablet Formulation of TLC-6740 in Healthy Participants and Participants With Obesity With or Without Diabetes
Protocol Number:	6740-CL-101
Principal Investigator:	Auckland: Professor Ed Gane Christchurch: Dr Jane Kerr

***Please let study staff know if you require an interpreter*.**

Declaration by participant:

- I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I consent to the research staff collecting and processing my information, including information about my health (including information collected from my GP and other Health Providers).
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.
- I agree to my tissue samples being sent overseas, and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.
- I understand that I will receive a summary of the study results and if I do not wish to receive this, I will inform site staff.
- I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.

Statement by Participant I hereby consent to take part in this study. I understand that I will receive a signed copy of this consent form for my records.

_____ (full name)

_____ (signature)

__ __ / __ __ __ / __ __ __ __ (Date DD/MMM/YYYY)

Statement by Consenter (Investigator/designee) I have discussed this study with the above-named participant. The participant appeared to fully understand the information provided about the study.

_____ (full name)

_____ (signature)

_____ (project role)

__ __ / __ __ __ / __ __ __ __ (Date DD/MMM/YYYY)