Please let the study team know if you need an interpreter.

PARTICIPANT INFORMATION SHEET

A Study to Evaluate Pain Tolerance Effects of Suzetrigine in Healthy Male Adults

Formal Study title:	A Randomized, Double-Blind, Placebo-Controlled Crossover Study to Evaluate the Pharmacodynamic Effects of Suzetrigine in Healthy Male Adults
Protocol number:	LTG-OBS-103
Sponsor:	Latigo Biotherapeutics, Inc. 1300 Rancho Conejo Boulevard, Suite 305 Thousand Oaks, California 91362, USA
Lead Study Doctor:	Dr Hamish Prosser
Study Site:	New Zealand Clinical Research (NZCR) Main Building: 264 Antigua Street, Christchurch, New Zealand Satellite Site: Level 4/108 The Terrace, Wellington 6011, New Zealand
Contact phone number:	0800 862 278
Ethics committee ref.:	2025 FULL 22547

Taking part in this research is your choice. You do not have to take part.
If you choose not to take part or withdraw from the study, you do not have to give a reason.

- You will be given time to decide whether you want to take part in this study.
- The study team will discuss the study with you and answer any questions you have before you decide.
- You may talk to family, whānau, friends, or healthcare providers before you decide.
- If you have private medical insurance, you may wish to check whether this study will impact your cover.
- If you decide to take part, you will be asked to sign the Consent Form. You will also be given a copy of this information sheet and the signed consent.
- If you change your mind about taking part, you can withdraw from the study at any time by telling the study team.
- There will be no direct benefit to you from taking part in this study, and there may be risks of injury or illness.

1 INTRODUCTION

One in five New Zealanders live with persistent pain, making it hard to sleep, work and enjoy life. Current pain therapies are limited and may increase risk of abuse or dependence. There is a large unmet need for new, more effective pain therapies to be available to people who need them.

The aim of this study is to evaluate the pain relief effect using a cold pressor test in healthy biological males by comparing an FDA approved pain medication called suzetrigine (marketed under JOURNAX™ in the USA) and comparing this to a placebo (a substance that looks like suzetrigine but contains no active medication).

The results of this study will help facilitate the design of studies with investigational pain medications.

Suzetrigine is investigational, which means that it is not approved for general use by Medsafe, however, it has been approved by the FDA for use in the USA.

Suzetrigine has been studied in 3 clinical studies involving over 1000 participants.

2 WHAT TYPE OF STUDY IS THIS?

This is a placebo-controlled, randomised, crossover, blinded study.

Placebo-controlled	This means the study uses a placebo to compare against the active suzetrigine. A placebo looks the same does not contain active suzetrigine.
Randomised	This means that the order you will receive suzetrigine and placebo will be assigned randomly (by chance). You will not be able to choose which group you are in.
Crossover	This means that all participants in this part of the study will receive both active study medication (suzetrigine) and placebo, but the order that you receive them will differ between participants.
Blinded	This means that you and the study team don't know which product you are getting, but the study doctor can find out if needed in an emergency.

3 HOW IS THIS STUDY DESIGNED?

Study Sites	This study is being run in New Zealand only.	**Number of Participants**	About 20 people will take part.
Time on Study	You will be in this study for up to 43 days (including screening, dosing and follow up)	**In-clinic Stays**	You will stay in-clinic at the NZCR facility twice for 1-night each time (2-nights total)

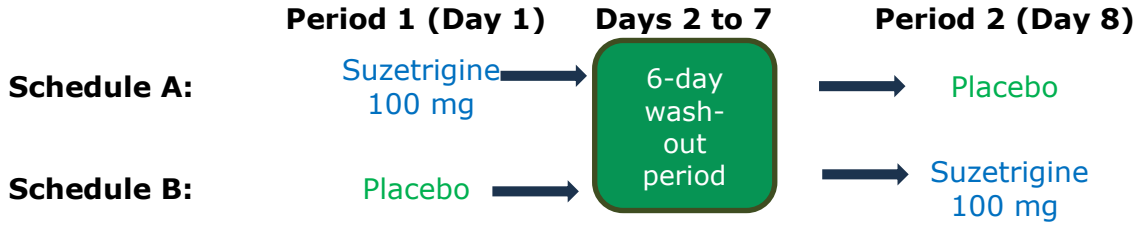
Follow Up Phone call	You will have 1 follow up safety phone call.

4 HOW WILL I BE GIVEN STUDY MEDICATION?

Every person in the study will receive a single dose of both 100 mg suzetrigine and placebo. Each dose will be given by mouth, with a glass of water.

You will be randomised to either Schedule A or Schedule B to receive one dose assignment on Day 1 (period 1) and one dose assignment on Day 8 (period 2). You will not be told which study schedule you will be on. You will be told if any changes are made to the planned dose for your group.

You will be assigned to either Schedule A or B:



Before and after receiving suzetrigine or placebo, you will have your pain tolerance assessed using cold pressor tests (which will be explained further in Section 7).

5 WHO CAN TAKE PART IN THE STUDY?

To take part in this study you must:	
✓	Be able to give informed consent and follow the study procedures.
✓	Be a biological male aged 18 – 55 years, inclusive.
✓	Have a BMI (Body Mass Index) between 18.0 kg/m^2 – 32.0 kg/m^2

You cannot take part in this study if you:	
✗	Have a history of a significant medical problem, mental health problem or severe allergy.
✗	Have taken any prescription medication within at least 14 days prior to Day 1; have used over-the-counter medications, herbal medications, or vitamin supplements within at least 7 days prior to Day 1; have used antibiotics or systemic steroids (e.g. prednisone) within at least 28 days prior to Day 1; or have received a vaccination within 14 days prior to Day 1.
✗	Are unable to take oral medications or have a medical condition which may impact gastrointestinal absorption.
✗	Have received an investigational medication or device, or participated in a drug study within at least 28 days prior to Day 1, or participated in a

	clinical study with a monoclonal antibody or biologic medication within at least 180 days (6 months) prior to Day 1.
✕	Have a history of alcohol abuse, and/or have used any illicit drugs (e.g. cocaine, PCP, ecstasy etc.) within 6 months of Screening, or have had any past/current history of dependence on recreational drugs (e.g. marijuana) or used them within at least 28 days prior to Day 1. You must pass a drug test at your Screening visit and on Day 1 and Day 8.
✕	Have lost or donated more than 500mL of blood within 3 months prior to Day 1
✕	Have used any nicotine or nicotine containing products (including vaping products) within 14 days prior to Day 1.
✕	Have any pain conditions, including but not limited to chronic pain conditions, any current pain condition requiring pain relief during the study.
✕	Have any hand/arm/skin conditions including but not limited to eczema/psoriasis/dermatitis affecting hand or arm, peripheral vascular disease, sickle cell disease, skin grafts, injuries to the hand or arm, neurological or musculoskeletal conditions affecting hand or arm, and/or Raynaud's disease.
✕	Have human immunodeficiency virus (HIV), or test positive at screening.

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. There may be reasons for excluding you that we may not able to divulge as it may impact the integrity of the study.

6 WHAT WILL TAKING PART IN THE STUDY INVOLVE?

The day you have your first dose of the study medication is called Day 1 and all other days are counted back or forward from this.

Screening (up to 28 days)

Before you can enroll into the study, the study doctor will take you through this information form first and ensure you understand what is involved. This will be done either in-person or over a video call, this may be done in a group. You will then have the opportunity to ask the study doctor questions 1-on-1 (or with a support person). If you decide to take part, you will be asked to sign the consent section at the end of this form.

The study team will then check whether you meet all the criteria to take part. This is called Screening.

- Screening must be done within 28 days of Day 1
- It may be done on a single day or over several days.
- You will be told if you can take part once all your results have been checked.

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. We may screen more participants than we need and so you may be asked to be a reserve. This will mean you will be asked to come to the clinic and undergo the tests and procedures until the point that

we have enrolled enough eligible participants. You will then be discharged and where possible we will try to include you in a later group.

Dosing/Washout Periods and Follow Up (11 days)

- **Dosing Period 1 (Day 1):** On Day 1, you will check-in to the NZCR unit in the morning where the study doctor will confirm your eligibility and your baseline pain tolerance using the cold pressor test. If you are eligible, you will be randomised to receive Suzetrigine or placebo. You will have tests and procedures to monitor your safety and to measure the study objectives. You will be discharged from the clinic approximately 24 hours after dosing on Day 2.
- **Washout Period (6 days):** You will have a 6-day wash-out period (from Day 2 to Day 7) between Dosing Period's 1 2.
- **Dosing Period 2 (Day 8):** On Day 8, you will check-in to the NZCR unit again in the morning and repeat the same assessments that are outlined for Dosing Period 1. You will receive your dose of Suzetrigine or placebo (whichever you did not receive in Dosing Period 1). You will be discharged from the clinic approximately 24 hours after dosing (on Day 9).

You will then have a follow-up safety phone call on Day 11.

At each visit you will have some of the assessments listed on the next page. Table 1 gives a summary of what will happen at each visit.

You may be asked to come to extra visits if the study team thinks this is needed for safety or other reasons.

If your study doctor identifies any significant abnormal results during the study, they will tell your GP.

7 STUDY ASSESSMENTS

Informed consent
You will read and sign an informed consent form before you take part.

Eligibility check
We will check that you meet all the required criteria for the study.

History and demographics
We will review your medical history, medications and lifestyle choices (e.g. alcohol use, smoking, physical exercise etc.) relevant to the study and record your age, gender, and ethnicity.

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

Physical Examination:
A study doctor will examine you. This may include checks of your heart and lungs, abdomen, nervous system, skin, mouth/throat and glands. Your height and weight will also be measured to calculate that your Body Mass Index (BMI) is within range for the study. You are welcome to ask for a chaperone during the exam.
On Day 8, you will have a shorter symptom-directed physical examination.

Electrocardiogram (ECG):
An ECG is a device that is used to monitor the electrical activity of your heart. This is done by applying small adhesive pads to your skin which peel off easily afterwards.

Blood Samples
At your screening visit, blood samples are taken by direct vein puncture. Blood samples will be collected to:

- To monitor your safety (including blood cell counts, clotting, electrolytes, fats, liver function, kidney function)
- To screen for HIV infection

Urine Safety Tests
We will collect urine samples for safety analysis at screening

Alcohol Breath Testing (ABT) and Drugs of Abuse Testing (DOA)

- You will be screened for the presence of alcohol via a breathalyser. You will blow into the mouthpiece for a few seconds to identify the presence of alcohol on your breath.
- You will also be screened for recreational drugs such as cannabis, methamphetamine, and opiates using a urine test.

Health and Medication check
We will ask you about any changes in your health and any changes to your medications. This includes prescription and over-the-counter medications, herbal or homeopathic remedies, and nutritional supplements.

Phone call
The study team will call you to check on your health before you leave the study.

COVID-19 testing – You may have COVID-19 testing done at Screening, Day 1 and Day 8 (if required).

Cold Pressor Test (CPT)
You will complete cold pressor tests to assess your pain tolerance baseline, and after suzetrigine and placebo. You will place your non-dominant hand in a warm water bath (approximately 35°C), you will then transfer your hand into a separate cold-water bath (approximately 1°C) and keep it in there for as long as tolerable. You will have this test done three times on the day of Screening, two times prior to dosing on Day 1 and Day 8, and 5 times post-dose on Day 1 and Day 8.

In the event that an assessment is not performed on the day outlined within the Study Schedule below, the assessment may be performed at your next study visit.

Table 1: Study Schedule

Study Visit	Screening	Dosing Period #1	Discharge #1	Washout period	Dosing Period #2	Discharge #2	Follow up Phone call
Study Day	**-28 to -1**	**1**	**2**	**3 to 7**	**8**	**9**	**11 (EOS)**
Visit length	**~2 hrs**	**~26 hrs (overnight)**			**~26 hrs (overnight)**		**~30 mins**
Informed Consent	X						
Eligibility check	X	X					
History & Demographics	X						
Clinic visit	X	Overnight stay			Overnight stay		
Phone Call [1]							X
Physical Exam [2]	X	X			X	X	
Vital Signs	X	X			X	X	
ECG	X						
Dose Administration		X			X		
Blood Tests	X						
Urine Safety Tests	X						
Health & Medication Check	X	X			X	X	X

Urine Drug Test and Alcohol Breath Test	X	X			X		
CPT	X	X	X		X	X	
COVID-19 Testing (if required)	X	X			X		

EOS: End of Study. ECG: Electrocardiogram. CPT: Cold Pressor Test

[1] During the safety phone call, the study nurse will ask you questions about your health.

[2] A full physical exam will be done at Screening, a physical exam based on your symptoms will be done on Day 8

8 WHAT ARE MY RESPONSIBILITIES DURING THE STUDY?

You should:	
✓	Follow the instructions you are given and attend all scheduled clinic visits.
✓	Carry your participant ID card at all times. 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 is so 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.
✓	Report any changes to your health, unusual feelings or symptoms, to the study team.
✓	During your in-clinic stays on Day 1 and Day 8, we will provide you with all of your meals. By signing this document, you are agreeing that you will be compliant with all meal requirements for this study. In certain cases, we may be able to cater for dietary requirements, please discuss this with the study team before joining the study.

You must not:	
✗	Smoke, vape or use any nicotine containing products for at least 14 days prior to Day 1, and during the study.
✗	Consume any caffeine or xanthine containing products (i.e., coffee, tea, chocolate, soda) for at least 48 hours prior to dosing Day 1, and Day 8.
✗	Consume any alcohol for at least 48 hours prior to Day 1, and during the study.
✗	Consume any food or drink containing grapefruit or Seville oranges for at least 14 days prior to Day 1, and during the study.
✗	Eat or drink anything (other than water) for at least 10 hours prior to Day 1, and Day 8.
✗	Donate blood for 3 months prior to Day 1 and during the study.
✗	Bring in prohibited items, including food, drinks, vapes/cigarettes, alcohol and prohibited medication. By signing this consent form, you agree to have your bags checked at admission. Any prohibited items will be removed and returned to you on discharge from the unit.

9 WHAT ARE THE POSSIBLE BENEFITS DURING THE STUDY?

This study is not designed to provide you with any therapeutic benefits. The information from this study might help to develop better treatments in the future for acute and chronic pain.

10 WHAT ARE THE POSSIBLE RISKS OF THE STUDY?

You may experience some side effects from Suzetrigine. You will be monitored for risks and side effects while you are in the study.

You should contact us if you experience any changes in your health.

Your GP or other healthcare professionals may be contacted if we have concerns about your health, including your mental health. We will discuss this with you prior to contacting other parties, unless believed to be contrary to your best interests.

Risks of Suzetrigine

The FDA have approved suzetrigine for use in the USA, but it has yet to be approved in NZ and still considered investigational.

The following adverse events have been associated with suzetrigine in clinical studies:

- Side effects seen in more than 1 in 100 people:
  - Itch
  - Muscle spasms
  - Increased enzymes that indicate muscle inflammation
  - Rash

The following adverse events were seen, but may or may not be associated with suzetrigine (similar numbers were seen in people also taking placebo):

- Nausea and vomiting (seen in 1 in 5 people taking suzetrigine)
- Decreased kidney function (seen in 2-3 in 100 people taking suzetrigine)

Allergic Reactions

If you are allergic to anything, tell us before you join the study. As with other medications suzetrigine may cause an immune or allergic reaction.

Some symptoms of allergic reactions are listed below. Tell the study doctor or nurse straight away if you have any of these symptoms. If not treated promptly, an allergic reaction could become life-threatening:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

If you have a skin reaction or other adverse event, the study doctor may take a photograph to document the event.

Life-threatening or fatal allergic reactions can occur. However, severe reactions are very rare. If you have a severe allergic reaction after leaving the study site, seek treatment immediately by dialing 111 or going to an Emergency Department.

Unknown risks

Although suzetrigine has been studied in over 1000 people in clinical trials and approved for use by the FDA in the USA, there is always a risk of some unexpected serious, life-threatening side effects occurring following the administration of a relatively new medication. You will be monitored closely for any side effects and undergo treatment if they occur.

New Information

If new information becomes available about suzetrigine, 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 continue in the research project, you may be asked to sign an updated consent form.

Risks or Side Effects of Study Procedures

Blood Sample Collection:
Risks include bruising, swelling, itch, and 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.

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.

Cold Pressor Tests (CPT):
The CPT is designed to measure your pain tolerance and cause discomfort. You can remove your arm from the water at any time, and any discomfort will dissipate quickly.

11 REPRODUCTIVE RISKS AND CONTRACEPTION

The information on effects of suzetrigine if passed on through semen are limited, 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, or who is pregnant) it is very important that you use contraception during this study. You must use at least a male condom, from your first dose of the medication through until at least 3 months after your last dose.

If a pregnancy occurs, you must report this to the study doctor as soon as possible.

You must also agree not to donate sperm, from first dosing until at least 3 months after your last dose of the study medicine.

12 WILL ANY COSTS BE REIMBURSED?

There are no costs associated with taking part in this study.

Study-specific costs will be paid for by Latigo Biotherapeutics, Inc. ("Latigo" or "Sponsor") You will still have to pay for any non-study related medical care.

You will receive a reimbursement of $2,800 following the final study visit for participating in this study. This is subject to tax. Further information about the reimbursement will be included in appendix 1.

You will be reimbursed separately for travel expenses associated with the study (if you use personal transport), or you can use an uber or taxi for your study visits, which can be arranged and paid for by NZCR if you live in the metropolitan area. Please discuss arranging study transport with the site study staff. If you live outside this area, we will discuss your travel costs individually. This reimbursement is not subject to tax.

In order to meet dosing requirements, additional (reserve) participants may be admitted to the unit. If you are invited to attend the study as a reserve, you will be asked to admit to the unit on

Day 1 just for the day (day reserve). If you are a reserve, and you are not required to be dosed, you will be reimbursed $250 for your time.

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

13 WHAT IF SOMETHING GOES WRONG?

As this research study is being conducted for a commercial sponsor, Latigo, you won't be eligible for ACC in the event of a study related injury.

Latigo has confirmed to the approving Health and Disability Ethics Committee that appropriate insurance for injury is in place.

You should be aware that:

- Sponsor insurance may not provide ACC equivalent compensation.
- There are limitations on compensation availability.
- Compensation is not provided on a no-fault basis. The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the researchers, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you.

You will need to apply to the sponsor and/or its insurers for compensation, but approval is not guaranteed. You are entitled to take action through the Courts for compensation.

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.

14 WHAT WILL HAPPEN TO MY SAMPLES?

- Blood and urine will be collected from you during the study.
- About 25 mL of blood will be collected in total. To compare, a standard blood donation is 470 mL.
- All samples will be sent to the local laboratory in New Zealand and will be identified with your name and date of birth. Before the results of these tests are sent to the Sponsor, your identifiable information will be removed and replaced with a code.
- Your samples will be kept for up to 3 months at the local New Zealand laboratory. They will then be destroyed using standard practices.
- If you wish karakia to be performed at the time of sample collection, please let the study staff know and they can arrange this.
- If you withdraw from the study, samples previously collected will still be used, unless you ask for the samples to be destroyed. Results from samples that have already been tested will be used for the study.

You will be tested for HIV, and COVID-19. By signing this consent form, you agree to these tests. A positive result for HIV does not necessarily mean you have the disease. If you test positive for HIV, the study doctors will provide initial counselling, medical advice, and help arrange follow-up tests. HIV and COVID-19 are legally notifiable diseases, meaning health authorities must be informed of new cases.

Are There Any Cultural Considerations?

You may hold sacred and shared values about your tissue samples and/or data originating from this tissue 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 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.

NZCR is committed to meeting their Te Tiriti o Waitangi obligations by ongoing training to understand what our responsibilities are.

15 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. Information such as your name, sex, age, race/ethnicity, address and phone number will be recorded 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, except your sex, race/ethnicity and age/year of birth.

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.

Identifiable information – *this information traces directly to you.*	
Examples?	*e.g. information carrying your name, initials, birthdate, contact details, or NHI number; photographs (if required) for adverse reactions; laboratory results.*
How is it stored?	• Paper: under restricted access at NZCR until the end of the study, then at a secure storage facility. • Electronic: on secure NZCR servers (in New Zealand and Australia)
Who has access?	• NZCR study staff and health services that do your study assessments • Your GP / usual doctor • Local laboratory staff to process and report your screening and safety tests • Study monitors, to make sure data is collected properly • Study auditors (see below) • Representatives from the Sponsor if you make a compensation claim for study-related injury. Identifiable information is required to assess your claim • The Medical Officer of Health (only if you have a positive test result for a notifiable disease)

	• Ethics committee, regulatory authorities, and sponsor/CRO representatives if the study or site is audited
How long is it kept?	It is kept a secure storage facility for at least 15 years

De-identified (Coded) information – *this information is labelled only with your unique study ID*	
Examples?	*All your information that is loaded into the study database. This may also include photographs (if required) for adverse reactions that has been de-identified.*
How is it stored?	• On a secure electronic server that complies with New Zealand and Australia and/or international data security guidelines.
Who has access?	• The research team, Sponsor and other companies working with or for the Sponsor • Regulatory or other governmental agencies worldwide.
How long is it kept?	For at least 25 years

Anonymised information – *cannot be traced back to you*	
Examples?	*Information that has had the unique ID code removed.*
How is it stored?	• On a secure sponsor-managed overseas database
Who has access?	• Access is not restricted
How long is it kept?	Indefinitely

Extra information about my data

The lead study doctor may need to share your identifiable information 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.

Audits: The study may be audited. Audits make sure studies are being carried out properly. Auditors need access to your identifiable study data and relevant health records to do this. Audits may be done by the Sponsor, NZ or overseas regulatory agencies, or the approving Ethics Committee.

Data Access: You have the right to request access to information about you held by the research team, including the results of tests and procedures. 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.

Study Withdrawal: You can ask the study team to stop collecting information about you at any time. This will end your participation in the study. Information collected up until this point will continue to be used, to protect the quality of the study.

Data Storage: After the study, your identifiable data will be stored for at least 15 years in a secure storage facility. Your coded and anonymised data will be stored indefinitely on secure electronic servers. All storage will comply with local and/or international data security guidelines.

Future Research Using Your Information
Your coded information may be used indefinitely for future research on pain medications or pain disorders, including studies conducted overseas. It may be shared widely with other researchers or companies and combined with data from other studies.

You will not receive reports or updates on research involving your information.

If you withdraw consent, it may be difficult or impossible to retrieve your information once shared.

Data Risks
Although efforts will be made to protect your privacy, absolute confidentiality cannot be guaranteed. There is a risk that people may access or use your information in ways that you may not be acceptable to you.

Data sent overseas will be governed by overseas laws. These may not give as much protection as New Zealand laws.

Māori Data
Māori data is a potential taonga. Māori data sovereignty permits Māori organisations to access coded Māori data, to support Māori development aspirations.

16 COULD THE STUDY END EARLIER THAN PLANNED FOR ME?

If you wish to withdraw from the study, please let us know. We may ask you to complete some end-of-study assessments if you withdraw early, if you are willing to.

We may withdraw you from the study if we believe it is not in your best interests to continue. We will discuss any withdrawal decisions with you and provide health care advice where appropriate. Other reasons that you may be withdrawn from the study are:

- You need treatment that is not allowed in this study.
- You did not follow the instructions for the study.
- The study is stopped
- You have a serious reaction or illness or injury that is not related to the study.

17 CAN I FIND OUT THE RESULTS OF THE STUDY?

Information relating to this study, will be available at http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

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.

18 WHO IS FUNDING THE STUDY?

This study is being funded and conducted by Latigo and locally sponsored in New Zealand by NZCR.

Data and samples that lead to discoveries and inventions, or the development of a commercial product, will be owned by Latigo. You will not have rights to ownership or benefit financially.

NZCR will receive payment from Latigo for conducting this research. The study team members will only receive their ordinary wages for conducting this research.

19 WHO HAS APPROVED THIS STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central HDEC has approved this study.

The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT).

20 WHO DO I CONTACT FOR MORE INFORMATION?

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

Dr Hamish Prosser, Principal Investigator
Phone: 0800 862 278
Email: ivy.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:

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**

APPENDIX 1 – INFORMATION ABOUT PAYMENT AND TAX OBLIGATIONS

- 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. 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.

- 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.

- 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.

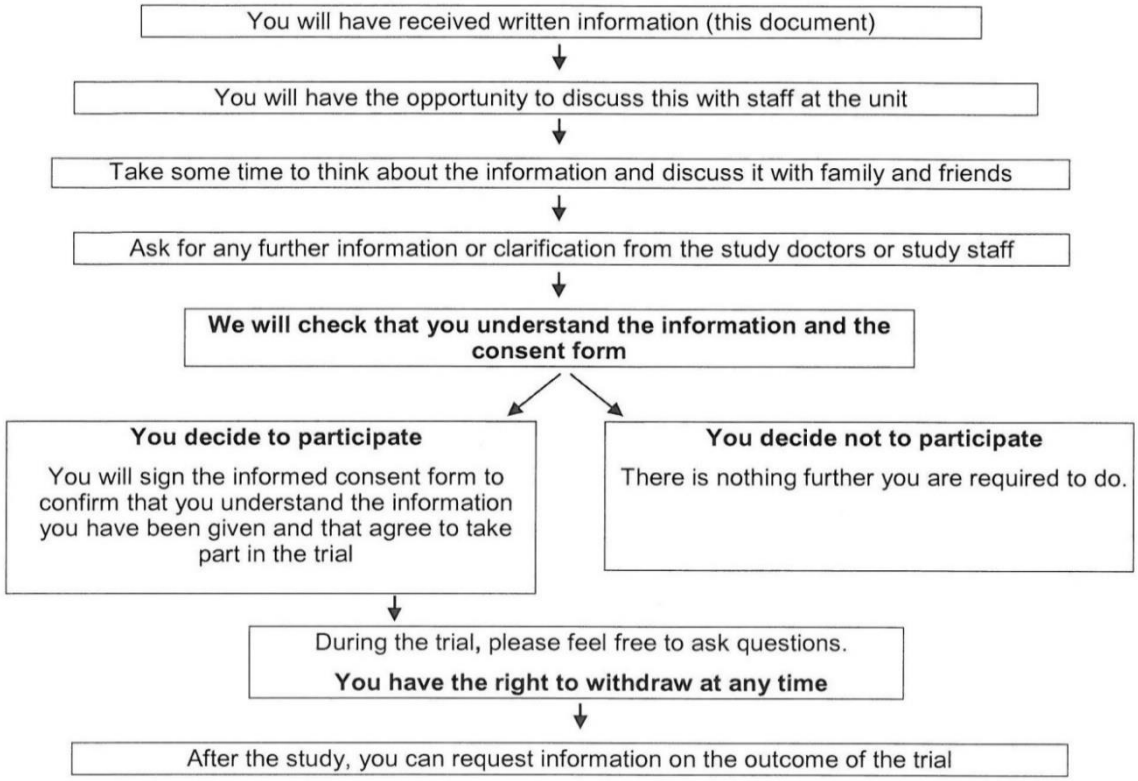
- Full reimbursement requires completion of all visits according to study requirements. If you are withdrawn from the study for medical reasons, having received trial medication, you will receive reimbursement in full.

- 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, due to tax obligations. 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.

WHAT ABOUT ANY OTHER QUESTIONS I MAY HAVE?

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

A Study to Evaluate Pain Tolerance Effects of Suzetrigine in Healthy Male Adults

Protocol number:	LTG-OBS-103
Lead Study Doctor:	Dr Hamish Prosser
Contact phone number:	0800 862 278 (available 24/7)

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

Declaration by participant:

- I have read, or have had read to me, and I understand the Participant Information Sheet.
- 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).
- I consent to my information and samples being sent overseas
- 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 consent to my GP or current provider being informed about my participation in the study and being informed of any significant abnormal results obtained during the study.
- I agree to approved parties including Sponsor or CRO representatives for monitoring and auditing, 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 there may be risks associated with the medication in the event of my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.
- 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.

Declaration 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.

Participant's full name:

Signature:

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

Declaration 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.

Consenter's full name:

Signature:

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