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

PARTICIPANT INFORMATION SHEET
Single Ascending Dose

A Study to Evaluate ORKA-002 in Healthy Volunteers Following a Single Dose.

Formal Study title:	Phase 1, First-in-human, Double-blind, Placebo controlled, Single Dose Escalation Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of ORKA-002 in Healthy Participants
Protocol number:	ORKA-002-211
Sponsor:	Oruka Therapeutics, Inc. 855 Oak Grove Ave Ste 100 Menlo Park, California 94025-4429
Lead Study Doctor:	Dr Chris Wynne
Study Site:	**New Zealand Clinical Research (NZCR)** 264 Antigua Street, Christchurch, New Zealand
Contact phone number:	0800 862 278
Ethics committee ref.:	**2025 FULL 22321**

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 form.
- 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.

This is the first study of ORKA-002 in humans.

1 INTRODUCTION

You are invited to take part in a clinical research study. This study will test an investigational medication, named ORKA-002, designed to potentially treat plaque psoriasis.

Psoriasis is an autoimmune chronic (long-term) inflammatory condition with skin lesions. Autoimmune means the immune system attacks the body's own cells. The skin lesions are red, raised patches of skin with silvery, white scales that can appear anywhere on the body. These patches can be itchy and sometimes painful. The severity of the psoriasis condition can impact the quality of life of people who have it. In NZ, about 90,000 people are living with this condition.

ORKA-002 is a monoclonal antibody (a medicine that mimics the body's natural antibodies that protect your body from unknown substances) that targets Interleukin-17 (IL-17). IL-17 is an immune messenger considered to play an important role in psoriasis. IL-17 signals the immune system, which increases inflammation in the skin. This results in skin lesions and the symptoms of psoriasis (itchiness and pain in the patches). It is hoped that by reducing the IL-17 signalling, ORKA-002 may reduce inflammation and improve skin lesions and symptoms of psoriasis.

ORKA-002 is investigational, which means that it is not approved for general use by the New Zealand Health Authority. Investigational items must be tested in studies like this one before they can be approved for use.

2 WHAT IS THE AIM OF THIS STUDY?

This study will investigate single ascending doses (SAD) of ORKA-002 in healthy participants.

This study aims to see:

- How safe and well tolerated ORKA-002 is in healthy participants.
- How a single dose of ORKA-002 is processed and cleared by the body.
- How the body responds to a single dose of ORKA-002.
- The body's immune response to ORKA-002.

3 WHAT TYPE OF STUDY IS THIS?

This is a randomised, placebo, double blinded study.

Placebo-controlled	This means the study uses a placebo to compare against the active ORKA-002. A placebo looks the same but does not contain active ORKA-002.
Randomised	This means you will be assigned to receive either ORKA-002 or placebo randomly (by chance). You will not be able to choose which group you are in.
Blinded	This means that you and the study team do not know which product you are getting, but the study doctor can find out, if needed in an emergency. You cannot find out which product you received after the study has ended.

4 HOW IS THIS STUDY DESIGNED?

Study Sites	This study is being run in New Zealand only.	**Number of Participants**	Approximately 24 people will be enrolled from New Zealand.
Time in the Study	You will be in this study for about 56 weeks/1 year and 1 month (including screening, dosing and follow up).	**4 nights in-clinic**	You will stay in-clinic at the NZCR site for 4 nights.
13 Study Visits	You will have scheduled 13 follow up study visits. You may be asked to come for extra visits if needed.		

5 HOW WILL I RECEIVE THE STUDY MEDICATION?

Every person in the study will receive a single dose of ORKA-002 or placebo. Each dose will be given as an injection under the skin on the abdomen, thighs or upper arm (subcutaneous injection). You may have multiple injections to achieve the dose.

3 dose groups (cohorts) are planned for the study. Your dose of ORKA-002 will depend on which group you are enrolled into. The group you are assigned to will depend on when you join the study. Details for the dosing groups are as follows:

Cohort	Dose of ORKA-002 or Placebo	Frequency
1	Less than or equal to 160 mg	1 dose on Day 1 via subcutaneous injection(s)
2	Less than or equal to 320 mg	
3	Less than or equal to 640 mg	

In each dose group, two people will be dosed first (one will receive ORKA-002, and one will receive placebo). The rest of the group will be dosed only if there are no safety concerns after 48 hours of monitoring. In the rest of each dose group, 5 people will receive ORKA-002 and 1 will receive placebo. This is called *sentinel dosing.*

- If you are in a sentinel dose group, you will have a 1 in 2 chance of receiving ORKA-002 or placebo
- If you are not in a sentinel group, you will have a 5 in 6 chance of receiving ORKA-002 and a 1 in 6 chance of receiving placebo.

Dose groups will be enrolled in order. You will be told which dose group you will be in. You will also be told if any changes are made to the planned dose for your group.

6 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 aged 18 – 65 years, inclusive.
✓	Have a BMI (Body Mass Index) between 18.0 kg/m^2 – 32.0 kg/m^2
✓	Have no tattoos or skin conditions (e.g. scarring or rashes) in the injection area (abdomen, thigh or upper arm) – check with the study team if you are unsure.

You cannot take part in this study if you:	
✗	Are pregnant or breastfeeding or plan to become pregnant for the duration of the study
✗	Have poor vein access, which makes it difficult to draw blood from your veins
✗	Have taken any prescription and non-prescription medication (excluding contraceptives started at least 4 weeks prior to screening paracetamol used per label or routine supplements or vitamins) within 2 days prior to dosing. Vitamins and supplements may be allowed to be used while on the study per label. If you are unsure, please speak with the study doctor for further clarification.
✗	Have a history of drug or harmful alcohol use (defined as an average of more than 10 standard drinks per week) within 2 years prior to screening.
✗	History or current frequent tobacco/nicotine usage (defined as more than 5 cigarettes per day or equivalent amount of nicotine while vaping) within 2 years prior to screening.
✗	Current positive test at screening for HIV, Hepatitis B or C infection or Tuberculosis. Evidence of resolved infection may be allowed. Please speak with the study doctor if you are unsure.
✗	Are diagnosed with or suspected to have, are or have a history of immunodeficiency or autoimmune diseases or undergoing anticancer chemotherapy or radiotherapy or have received corticosteroid treatment (e.g. Symbicort (inhaled corticosteroid), prednisone, non-topical hydrocortisone, etc.) in the last 120 days prior to dosing (Day-1). If you are unsure, please speak with the study doctor for further clarification.

✗	Are suspected to have, are diagnosed with, or have a history of inflammatory bowel disease (ulcerative colitis or Crohn's disease), or if you have a first degree relative (parents, siblings, children) with inflammatory bowel disease (Crohn's disease or ulcerative colitis)
✗	Have a history of cancer (except non-melanoma skin cancers, or cancers that have been curatively treated greater than 5 years before screening without evidence or recurrence).
✗	Have a history of a significant medical problem, for example, heart, high blood pressure, kidney, liver conditions, mental health problem or severe allergy (for example, anaphylaxis). History of some minor disease (e.g. mild child asthma, migraines, or gallbladder removal) may be acceptable. If you are unsure, please speak with the study doctor for further clarification.
✗	Donated or lost more than 450 mL of blood within 12 weeks prior to Screening or donated plasma within 1 month prior to dosing (Day 1).
✗	Have history of chronic conditions e.g. diabetes, liver conditions, skin conditions (e.g. psoriasis).
✗	Had a fever (i.e. temperature greater than 38.0ºC) within 7 days of dosing (Day 1).
✗	Have received a vaccination within 14 days prior to dosing (Day 1).
✗	Have had a previous sensitivity to a biologic medication If you are unsure, please speak with the study doctor for further clarification.
✗	Have participated in a clinical trial within 30 days prior to dosing (Day 1).

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. There are other criteria you must meet to be eligible for the study. The study team will discuss all of them with you to make sure you are able to take part.

7 WHAT WILL TAKING PART IN THE STUDY INVOLVE?

The day you have your dose of ORKA-002 (or placebo) is called Day 1 and all other days are counted back or forward from this.

Screening (up to 28 days prior to Day 1)

Before any study procedures can be done, the study doctor will take you through this information form first and ensure you understand what is involved. 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 to your dose of the study medication (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 and Follow-Up (365 days)

On Day -1 (the day prior to dosing), you will check in the NZCR unit where the study doctor will confirm your eligibility. On Day 1, (if you are eligible) you will receive your dose of ORKA-002 or placebo. You will have regular tests and procedures to monitor your safety and to measure the study objectives until you check out of the clinic on Day 4.

You will attend 13 scheduled follow-up visits. During your in-clinic stay and 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.

Early withdrawal visit

If you decide you want to withdraw from the study, please let us know. The study team will ask you to come in for a final visit to do some final health checks, if possible.

8 STUDY ASSESSMENTS

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

Eligibility check
We will check that you qualify 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.

Height and weight
We will check your height and weight to calculate your body mass index (BMI). Height will only be measured at screening.

Physical Examination:
A study doctor will examine you. This may include checks of your heart and lungs, blood vessels, brain and nerves, arms and legs, skin, neck and glands. You are welcome to ask for a chaperone during the exam. At some visits you will have only a brief physical exam.

Injection Site Evaluation

On Day 1, after your dose of ORKA-002 or placebo, study staff will check the site of your injection.

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

Pregnancy tests:
If you can get pregnant, you will have blood/urine pregnancy tests during the study.

Blood Samples
At clinic visits, blood samples are taken by direct vein puncture. On the day you receive your dose, a cannula (thin plastic tube) will be inserted into a vein in your arm to take blood samples. If your cannula stops working, direct vein punctures will be used. **You will have several blood samples collected on Day 1**. Blood samples will be collected to:

- Monitor your safety (blood cells, clotting, chemistry, fats, liver function, kidney function)
- Screen for specific infections (HIV, Hepatitis B, Hepatitis C, Tuberculosis)
- (if applicable) To confirm whether you are post-menopausal.
- Measure the amount of ORKA-002 in the blood (pharmacokinetics)
- See whether you develop antibodies to ORKA-002. Antibodies are proteins that recognise foreign substances in the body, so that the immune system can fight them off. If a person develops antibodies against a medication, the antibodies can sometimes stop the medication from working or cause reactions if the medication is given again.
- To measure the biological effects of ORKA-002 in your body. This might include effects on the immune system and other proteins or chemicals.

Urine safety tests
We will collect urine samples for similar reasons to blood samples.

Alcohol Breath Test 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 measure the presence of alcohol on your breath.
- You will also be screened for recreational drugs such as cannabis, methamphetamine, and opiates (which will be a urine test). You will also be tested for nicotine in your system.

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.

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.

8.1 Table 1: Study Schedule

Study Visit	Screening	**In-Clinic Stay**					**Follow-Up**								
Study Day	**-28 to -2**	**-1**	**1**	**2**	**3**	**4**	**8**	**15 & 22**	**29**	**43 & 57**	**85**	**113 & 141**	**169**	**253 & 337**	**365 EOS/ EW [a]**
Visit length	~3 hrs	4-night stay					~2 hrs								~3 hrs
Clinic Visit	X						X	X	X	X	X	X	X	X	X
Informed Consent	X														
Eligibility check	X	X													
History & Demographics	X														
Admission to the unit		X													
Discharge from the unit						X									
Physical Exam	X[b]	X		X	X	X	X	X	X	X	X	X	X	X	X
Injection Site Evaluation			X												
Vital Signs	X	X	X[c]	X	X	X	X	X	X	X	X	X	X	X	X
ECG	X	X	X[c]			X	X		X		X		X		X
Height & Weight	X[d]	X													X
ORKA-002 or Placebo Administration			X												
Blood Tests	X	X	X[e]	X	X	X	X	X	X	X	X	X	X	X	X
Urine Safety Tests	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Alcohol Breath and Urine Drug Test	X	X													
Pregnancy test	X[f]	X					X	X	X	X	X	X	X	X	X

Health & Medication Check	X

[a] EOS = End of Study EW = Early Withdrawal (if you withdraw from the study early, you will have these assessments at your EW visit).
[b] A full physical examination will be done during Screening. The rest of the visits, an abbreviated physical exam may be done.
[c] You will have frequent blood tests, vital sign checks, injection site evaluations, and ECGs done on Day 1.
[d] Height will only be done at Screening.
[e] Several bloods will be taken on Day 1.
[f] A pregnancy blood test will be done during Screening. The rest of the pregnancy tests will be a urine pregnancy test.

9 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.
✓	Agree to be compliant with all meal requirements on this study. When you are an inpatient with us, we will provide you with all of your meals. In certain cases, we may be able to cater for dietary requirements, please discuss this with the study team before joining the study.

You should not:	
✗	You will not take any prescription or non-prescription medication (excluding contraceptives, paracetamol) within 2 days prior to dosing and during the inpatient stay. Vitamins, supplements, are allowed to be used while on the study as long as you have been on a stable dose within 1 month prior to dosing and the remainder of the study. If you are unsure, please speak with the study doctor for further clarification
✗	Regularly smoke or use any nicotine containing products (defined as more than 5 cigarettes or equivalent in vaping, per day) within 48 hours before admission, until Day 15 of the study. You will not be able to smoke or vape at all during your inpatient stay. You must not smoke more than 5 cigarettes/day (or the equivalent) for the remainder of the study. Some smoking cessation products (e.g. nicotine gum, patches etc.) may be allowed at the study doctors discretion while in patient – please discuss with them if you think you may require this.
✗	Regularly consume alcohol (defined as drinking an average of more than 10 drinks per week) for at least 48 hours prior to admission (Day-1) and until Day 15 of the study. You must pass an alcohol breath test at screening and Day -1.
✗	You must abstain from illicit drug use for at least 48 hours prior to admission and while you are on the study. You must pass a urine drug screen at screening and Day -1.
✗	You must refrain from strenuous exercise for at least 48 hours prior to dosing (Day 1).
✗	You must not donate blood for at least 12 weeks prior to screening. You must not donate plasma 1 month prior to screening.
✗	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.

10 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 plaque psoriasis.

11 WHAT ARE THE POSSIBLE RISKS OF THE STUDY?

You may experience some side effects from ORKA-002. 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 ORKA-002

This is the first time that ORKA-002 is being tested in humans and as such there is no human experience available to identify all of the risks of ORKA-002.

Animal studies have been done with ORKA-002 to try and predict what type of side effects might occur in people. However, animal studies do not always predict human responses to medications. When ORKA-002 was given to animals at doses higher than the doses that will be given in this study, no adverse (harmful) side effects were seen. There have been no signs of changes in the animal's normal body functions, including heart, eyes, lungs, brain, or nerve functions, in tests done with much higher doses of ORKA-002 given 3 times over a 5-week period. In addition, no clinically relevant findings were noted in blood counts.

The doses planned for this study in people are much lower than any of the doses given to animals (~20 times less than the amounts given to animals). The study will begin with low doses of ORKA-002 that will be gradually increased if the medication is well tolerated. However, as noted above, animal studies do not always predict human response to medications. Among side effects that could occur, some could be life-threatening.

ORKA-002 belongs to a class of drugs (IL17A inhibitors- Cosentyx® [secukinumab] and Taltz® [ixekizumab] and IL17A/F- inhibitors (Bimzelx® [bimekizumab-bkzk]), which have been thoroughly studied in humans with plaque psoriasis and psoriatic arthritis and are approved by regulatory authorities and available across the world. Secukinumab is approved for use in New Zealand. The side effect profile of these drugs is well known in patients with plaque psoriasis and psoriatic arthritis; IL-17A and IL-17A/F inhibitors are generally safe and well tolerated. Given that ORKA-002 shares the same way of working in the body as bimekizumab, it is anticipated to have similar side effects to bimekizumab (Bimzelx®).

In plaque psoriasis patients who receive multiple doses of bimekizumab in clinical studies comparing bimekizumab against a placebo, the expected side effects are:

Less serious side effects and most common:

Upper respiratory tract infections (15 out of 100 participants in clinical trials):

- Sore throat
- Stuffy nose

Skin (1 to 9 out of 100 participants in clinical trials):

- Fungal infections (oral thrush or infections in the mouth, throat, skin, nails, feet or genitals)
- Pain, swelling or redness at the injection site
- Small red bumps on the skin
- Acne
- Herpes Simplex Infections (cold sores in or around the mouth)

General (1 to 3 out of 100 participants in clinical trials):

- Headache, feeling tired (malaise), stomach flu (gastroenteritis)

More serious side effects and less common:

Signs of a serious infection (1 to 9 out of 1000 participants in clinical trials):

- Fever
- Flu-like symptoms
- Night sweats
- Feeling tired or short of breath
- Cough that won't go away
- Warm, red painful skin
- Painful skin rash with small red blisters

Inflammatory bowel disease, very rare (1 to 2 out of 1,000 participants in clinical trials):

- New cases of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- Flare up of existing inflammatory bowel disease (ulcerative colitis or Crohn's disease)

Very serious side effects: very rare (not observed in any participants in clinical trials):

- Difficulty breathing or swallowing
- Swelling of face, lips, tongue or throat
- Severe itching of skin, with a red rash or raised bumps

There is a risk that you could develop antibodies against ORKA-002. Developing antibodies to ORKA-002 could neutralise the effect of the medication, which means it may not work if you used it for treatment purposes in the future. It could also cause an allergic reaction if you have future doses of ORKA-002.

Allergic Reactions

If you are allergic to anything, tell us before you join the study. As with other medications, ORKA-002 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 dialling 111 or going to an Emergency Department.

Unknown risks
Because ORKA-002 has never been tested in humans / has limited exposure in humans, there is always a risk of some unexpected serious, life-threatening side effects occurring following the administration of a new experimental treatment. It is unknown whether some unexpected serious or life-threatening side effect could occur with ORKA-002. You will be monitored closely for them and treated if they occur.

You could have an unwanted reaction when ORKA-002 is taken with another medication.

New Information

If new information becomes available about ORKA-002, 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.

Assessment Risks

Some of the study assessments have known risks. These are listed in Appendix 1.

12 REPRODUCTIVE RISKS AND CONTRACEPTION

Being in this study may result in risks to a foetus or baby. If you are pregnant or breast-feeding, you will not be able to take part.

You must not get pregnant, or get a partner pregnant, during this study.

- If you could become pregnant, or your partner could become pregnant to you, and you are sexually active, you and your partner must use effective contraception during the study.

- We will discuss effective contraception options with you, and how long they must be used for. **Details are in Appendix 3 of this information sheet.**

You must agree not to donate sperm or eggs, from screening until the end of study (EoS) visit.

You are responsible for informing your sexual partner(s) of the possible risks.

If a pregnancy occurs, you must report this to us as soon as possible. You or your partner will be asked to give consent for pregnancy information and the infant's information to be collected for monitoring purposes.

13 WILL ANY COSTS BE REIMBURSED?

There are no costs associated with taking part in this study. Study-specific costs will be paid for by Oruka Therapeutics, Inc. You will still have to pay for your non-study related medical care.

You will receive a reimbursement of $14,000 (before tax) following the final study visit. 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. This is subject to tax. Further information about the reimbursement will be included in appendix 2.

You will be reimbursed separately for travel expenses associated with the study (if you use 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. 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 either; admit to the unit on Day -1 just for the day (**day reserve**) or admit to the unit on Day -1 and stay overnight (**night reserve**). If you are a reserve, and you are not required to be dosed, you will be reimbursed for your time and inconvenience (day reserve = $150 or night reserve = $350). This is subject to tax.

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

14 WHAT IF SOMETHING GOES WRONG?

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

Oruka Therapeutics, Inc. 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.

15 WHAT WILL HAPPEN TO MY SAMPLES?

- Blood and urine will be collected from you during the study.
- About 372 mL of blood will be collected in total. To compare, a standard blood donation is 470 mL.
- Some samples will be sent to the local laboratory in New Zealand and will be identified with your name and date of birth.
- Other samples will be identified using your study ID code only and will be sent to laboratories in the USA (Florida, North Carolina, Massachusetts and New York). We can give you the names and addresses of the laboratories if you wish.

- Your samples will be kept for up to 15 years. 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. However, due to your 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 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.

The required blood tests include screening for HIV, Hepatitis B and C, and Tuberculosis (TB). By signing this consent form, you agree to these tests. A positive result does not necessarily mean you have the disease. If you test positive for HIV or Hepatitis B/C, the study doctors will provide initial counselling, medical advice, and help arrange follow-up tests. HIV, newly diagnosed Hepatitis B/C, and TB 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.

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

16 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?	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 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 ORKA-002 or plaque psoriasis or psoriatic arthritis, 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.

17 COULD THE STUDY END EARLIER THAN PLANNED FOR ME?

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

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.

18 CAN I FIND OUT THE RESULTS OF THE STUDY?

Information relating to this study, such as a summary of results, will be available at, e.g. http://www.ClinicalTrials.gov .

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.

19 WHO IS FUNDING THE STUDY?

This study is being funded and conducted by Oruka Therapeutics, Inc., and locally sponsored in New Zealand by Calyx Bioconsulting Limited. The study will be monitored / overseen by Molecule2Market, a Contract Research Organisation (CRO), which help conduct and monitor the study in New Zealand.

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

NZCR will receive payment from Oruka Therapeutics, Inc. for conducting this research. The study team members will only receive their ordinary wages for conducting this research.

20 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).

21 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 Chris Wynne, Principal Investigator
Phone: 0800 862 278
Email: milford.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 – PROCEDURE RISKS AND DISCOMFORTS

Blood Sample Collection & Cannulas:
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.

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.

APPENDIX 2 – 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 (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 reimbursement will be made after you complete the study to cover your time and inconvenience, however, the payment schedule can be flexible to suit your needs. Please discuss with the study team about changing your payment schedule if needed.

- 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.

APPENDIX 3 – CONTRACEPTION REQUIREMENTS

For participants who could become pregnant:

You must use two forms of contraception with one of the methods of contraception listed below, from admission (Day-1) until the end of the study (EoS visit that is 52 weeks after your dose of study drug). If you are on a hormonal form of contraception, it must be used for at least 4 weeks before admission (Day-1) through until the EoS visit:

A highly effective method (less than 1 pregnancy/100 women using the method for one year):

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

OR an effective method (5-10 pregnancies per 100 women using the method for one year):

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

You and your partner must also use a barrier form of contraception, from your admission until your end of study (EoS) visit. Barrier methods of contraception include:

- Male condoms
- Female condoms
- Female 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 investigational medicine (from at least Day -1 until the end of study) is considered an acceptable form of contraception if this is in line with your preferred and usual lifestyle.

For participants who could get a partner pregnant

The effects of ORKA-002 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.**

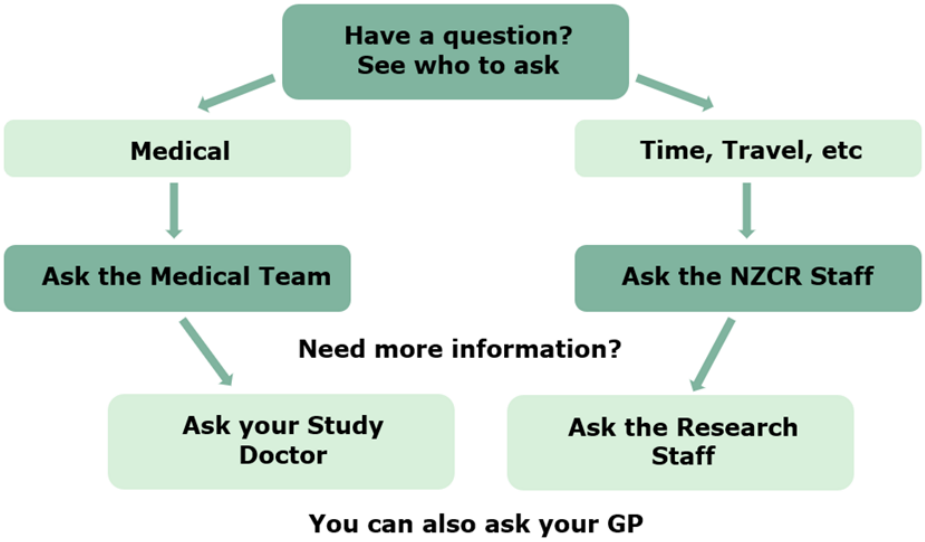
You and your sexual partner must use 1 of the contraception options listed above, from at least admission (Day-1) until the end of study (EoS) visit.

You and your partner must also use a barrier form of contraception, from your admission (Day-1) through until your end of study (EoS) visit. Barrier methods of contraception include:

- Male condoms
- Female condoms
- Female diaphragm ('cap')

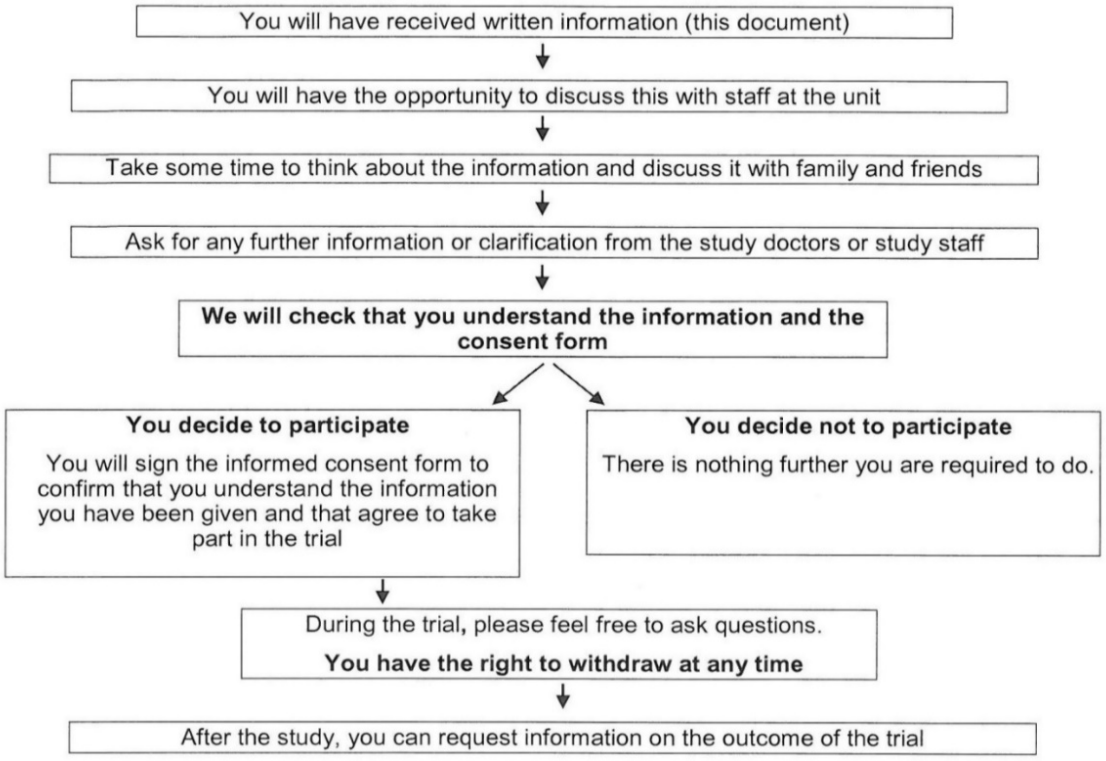
Please note that barrier methods alone are not highly effective methods of contraception.

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
Healthy Volunteer – Single Ascending Dose

A Study to Evaluate ORKA-002 in Healthy Volunteers Following A Single Dose.

Protocol number:	ORKA-002-211
Lead Study Doctor:	Dr Chris Wynne
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.
- I consent to my GP or current provider being informed of any significant abnormal results obtained during the study.
- I agree to an 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 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 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 member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's full name:

Signature:

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