Participant Information Sheet / Consent Form

Study title:	A Clinical Trial on Safety and Effectiveness of CBT-001 in Patients With Pterygium		
Sponsor:	Cloudbreak Therapeutics, LLC		
Locality:	Auckland Eye Limited, 8 St Marks Road, Remuera, Auckland 1050	**Ethics committee ref.:**	2023 FULL 18325
Principal Investigator:	Dr Dean Corbett	**Contact phone number:**	(09) 529 2480

You are invited to take part in the above-named study because you have pterygium. 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.

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. 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.

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.

This document is 15 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

You are being asked to take part in this research project because you have pterygium, a wedge-shaped thickening of the outer coating of the eye that extends onto the cornea that can become red and irritated. CBT-001 ophthalmic emulsion is the investigational study drug that is being tested in this study. This is the first study of the emulsion formulation in humans, modified from the original solution formulation tested in previous phase of this clinical study. The active medicine in the study drug is a multikinase inhibitor (a medicine that can stop a number of proteins involved in disorders such as pterygium). An investigational drug is one that is currently being tested and has not been approved for use by Regulatory Authorities such as Medsafe in New Zealand and the Food and Drug Administration (FDA) in America. Experimental drugs may be tested in research studies such as this one.

The main purpose of this study is to look at how safe the study drug is and whether it works to treat your pterygium.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you agree to take part in this research project, you will be one of about 600 participants at about 30-35 study sites in United States of America, Australia and New Zealand. This research project is open to male and female participants, aged ≥18 years, who meet all of the requirements.

During the study, one drop of the study drug will be applied to the eye(s) with pterygium twice daily by the participant for 24 months except on the days of scheduled visits. You will be randomised (randomly assigned) to receive either the study drug or placebo (together the study drug and placebo are referred to as the 'study medication'). Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). The placebo looks like the study drug but doesn't have any active medicine in it. This is a double-masked study. This means neither you nor the study doctor knows which study medication you are receiving; however, if there is an emergency, the study doctor can find out the details. You will have a 3 in 4 chance of receiving the study drug. That means for every 4 participants, 3 will receive the study drug and 1 will receive the placebo.

You must be willing to attend all the scheduled visits to the site. Various procedures will be performed each time you visit the site.

The study doctor might need to repeat any of these procedures at times other than those specified below if it is necessary for your safety.

If you choose to take part, you will be asked to attend a screening visit to assess if the study is right for you. If the study is right for you, study medication will be provided to you on Day 1, participation in the study may last for 2 years following your acceptance onto the study at Day 1 (Baseline visit). During your participation in the study, you will need to visit the clinic up to 12 times (including the screening visit).

STUDY PROCEDURES

If you agree to take part in this research project, no research project-related procedures can start until this form is signed and dated.

The study has 2 main periods, a screening period and a treatment period. Detailed information about what will happen in each period is given below.

Screening period (up to 2 weeks)

The screening visit will take about 2-4 hours. During this visit, we will do some tests and procedures to see if you qualify to take part in this research study. The doctor will review the results of these tests and procedures. If you do not qualify, the study doctor will tell you why. If you qualify for the study, the following procedures or questions will occur during the screening visit:

- You will be asked to answer questions about your health, your medical history, surgical history, and any medications you take.
- During your first visit, you will be asked to give personal information, such as your name, date of birth, race, etc.
- The study doctor will give you a physical exam
- The study staff will take some blood about 4.5 ml to do laboratory tests.

- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative for you to be in the study.
- You will be asked to complete an eye symptom questionnaire
- Vital signs including blood pressure, pulse, and temperature.
- You will have eye exams which will include eye drops that make your pupils larger so that the study doctor can perform certain measurements. You will be asked to sit in a chair in-front of multiple machines to have examinations of your eyes performed.
- Photographs of your eye will be taken

Treatment period

The treatment period will consist of up to 12 visits to the study centre Day 1, Week 2, Week 4, Months 3, 6, 9,12,15,18, 18+ 2 Week visit (for participants entering open label part of the study), 21 and 24/exit visit. Each visit will take between 2- 4 hours. The following procedures or questions will occur during these visits:

- You will be asked to answer questions about your medical history and eye history on Day 1.
- You will be asked to answer questions about your health and any medications you take
- The study doctor will give you a physical exam
- The study staff will take some blood about 4.5ml to do laboratory tests (at months 3, 12 and 24/exit visit).
- If you are a female of childbearing potential, you will be asked to have a urine pregnancy test (all visits except week 2).
- You will be asked to complete Eye Symptom, Likelihood to Seek Surgery and Comfort of Eye Drops questionnaires
- Vital signs including blood pressure, pulse, and temperature.
- Eye Exam which will include eye drops that make your pupils larger so that the study doctor can perform certain measurements. You will be asked to sit in a chair in-front of multiple machines to have examinations of your eyes performed.
- Photographs of your eye will be taken
- Study staff will give study drug by placing one drop into each eye with pterygium. At each visit after Day 1, previously dispensed study medication will be collected.

The first dose of the study medication will be given at the office during the Baseline visit (Day 1). Before you leave the clinic, the study staff will show you how to apply the study medication at home. After this visit, you will need to apply one drop of study medication to the eye(s) with pterygium twice daily for 2 years. The first dosing during the waking hours in the morning and the second just prior to bedtime, except on the days of scheduled visits when you will be instructed not to administer your morning dose of study medication before each study visit and the dosing will be conducted at the clinic on visit days.

At all visits you will be given study medication to be used at home. You will need to bring all used and unused study medication to all visits. The last application of study medication is at Month 24.

At the Month 15 visit, if the pterygium grows 2.5 mm in length or more, you will be offered to switch to a higher dose of CBT-001 and continue in the study. If you switch to the higher dose of CBT-001, you will receive the new study drug at Month 18 and be scheduled to return 2

weeks later for a follow up visit. If you choose not to switch to the higher dose, you will be able to continue in the study using the same dose.

If you decide to participate in this research project, the study doctor will inform your General Practitioner (GP).

Blood Sampling
A total of about 18 mL of blood will be taken throughout the course of this research project. Additional blood samples may be taken during the research project if your study doctor considers it necessary for monitoring your health.

WHAT DO I HAVE TO DO?

If you decide to be in this research project, there are certain rules you must follow before, during, and after the research project. Some are listed below, but there could be others that the study doctor will discuss with you:

- You must be able to provide written consent to be in this research project.
- You must tell the study doctor all of the medications that you have been taking for at least 3 months before you take part in the research project and those that will be continued during the study period, including the dose and the reason for taking the medication. This includes vitamins, herbalmedications that do not require a doctor's prescription. Some medications are not allowed. Your study doctor will discuss these with you in detail.
- You must ask your study doctor before you take any new medications during the research project.
- If you decide to take part in this research project, it is very important that you attend each study visit as scheduled, which may last up to 4 hours including the follow-up visit and bring study medication to each visit.
- You must not take part in any other study while taking part in this study. Tell the study doctor immediately if you want to take part in another study while you are taking part in this study. Participating in more than one study at the same time could put your safety at risk and will not be allowed while being part of this study.
- You must follow the instructions you are given by the study doctor and study team at every visit. If you do not follow the instructions, your visit may have to be rescheduled and/or you may not be allowed to continue to participate in this study. If you are unsure about what you are supposed to do, ask the study doctor.
- Only you should take the study drug. It must be kept out of the reach of children. Please also keep the study drug away from people who may not be able to read or understand the label.
- You must return all of the used and unused study drug materials (including empty drug bottles).
- You must not be pregnant or become pregnant or get someone pregnant during this research project (refer to the Pregnancy and Breast-feeding section of this document under 'What are the risks and disadvantage of this study?' for further information regarding this.

If you cannot follow these restrictions, you should not be in this research project.

CAN I HAVE OTHER TREATMENTS DURING THIS RESEARCH PROJECT?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the project team about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. Cost of medications or health care visits due to side effects or symptoms related to this research project will be covered by Sponsor/study insurance.

WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

You do not have to take part in this research project to receive the standard treatment for your pterygium at this study site. Other option is available; this includes surgically removing the pterygium. Your study doctor will discuss this option with you before you decide whether or not to take part in this research project. You can also discuss the options with your GP.

WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

All blood and urine collected from you will be sent to a Central Laboratory located in Singapore for analysis. All blood samples will be destroyed after completion of the analysis (such as blood collected for safety laboratory testing including haematology, chemistry, and coagulation, as well as pregnancy testing if required and urine collected for urinalysis).

You may hold beliefs about sacred and shared values of any tissue samples removed and data originating from the tissue. The cultural issues associated with sending your tissue samples and data overseas and/or storing your tissue and data should be discussed with your family/whanau as appropriate. If you need cultural support this can be provided. Please let us know and we will arrange this for you or you can ring the number at the bottom of the participant information and consent form. Cultural support is different to knowing more about the study treatments. In these cases, we can arrange a primary investigator to come and talk to you and your whānau.

Any laboratory data will be kept confidential by your study doctor; however, if the routine safety tests reveal any unusual findings your study doctor will discuss these with you and your family doctor, if appropriate.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We cannot guarantee or promise that you will receive any benefits from this research; or your participation in the study will improve your personal condition however, the information we get from this research project may help us in the future to treat people with pterygium better. By taking part in this study, you will have close medical monitoring of your health condition by blood, urine tests and other evaluations during clinic visits.

WHAT ARE THE RISKS AND DISADVANTAGES OF THIS STUDY?

You may have side effects from the drugs or procedures used in this study. Side effects can vary from mild to very serious and may vary from person to person. Everyone taking part in the study will be watched carefully for any side effects. However, Cloudbreak Therapeutics,

LLC, the study doctor, and other doctors do not know all of the side effects that could occur. Your study doctors may give you drugs to help lessen side effects. Many side effects go away soon after you stop what is causing them. In some cases, side effects can be serious and may be long lasting or may never go away. There also is a rare risk of death. You should talk to your study doctor about any side effects you have while taking part in the study.

Risks of* the *study drug

Like all medicines, the study drugs may cause side effects in some, but not all participants. The possible risks from taking part in this study include reversible discoloration of the mucus membrane that covers white of eye and inner eyelid surfaces (conjunctiva) in the treated eye, a temporary burning or stinging sensation or a feeling of discomfort in the treated eye or blurred vision in the treated eye.

In addition to the possible risks as described, there may be other risks involved in receiving this study drug that are not yet known.

If you have any side effects or injuries, or your condition gets worse, tell the study doctor immediately so you can receive appropriate medical care.

Any side effects or other health issues that occur during the study will be followed up by the study doctor.

- Allergic Reactions
  Occasionally, people have allergic reactions (including life-threatening reactions) when taking any medication. Symptoms of any allergic reaction can include: rash, hives, itching and/or trouble breathing, closing of the throat, swelling of the lips, tongue or face, and rarely death. Immediately get emergency medical care if you have any of these symptoms. Stop taking the study drug and let your study doctor know.
  In general, allergic reactions to medicines are more likely to occur in people who already have allergies. If you are allergic to other drugs, foods or things in the environment, such as dust or grass, you should let your study doctor know. Also, if you have asthma, let your study doctor know.
  If you have concerns that you are experiencing an allergic reaction, please call 111 or go to your nearest hospital emergency department.

Risks from* study *procedures

Risks associated with the study procedures are as follows:

- Blood Draws
  Taking blood from a vein (usually in your arm), may cause local pain, bruising, occasional light-headedness, fainting, and very rarely, infection at the site of the blood draw. Please tell the study doctor or study staff if you do not feel well after having your blood drawn.
- **Eye Tests**
  For some eye tests, you will be given eye drops that make your pupils larger so that the study doctor can perform certain measurements. Your eyes may be more sensitive to light for several hours afterwards. It is recommended you bring sunglasses with you to your visit. If you have concerns driving after the visit you should consider arranging for someone to drive you, or alternative transportation.

You will be informed in a timely manner, both verbally and in writing of any new information, findings or changes to the way the research will be done that might influence your willingness to continue to take part in this research project.

Reproductive Risks

The active ingredient in CBT-001 is known to be capable of causing faulty formation in the unborn child when taken orally at high doses. However, the effect of much lower doses of CBT-001 when given in eyedrops, as is the case in this study on the unborn child, or on a

breastfeeding infant, is unknown and may be harmful. 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. You must use one of the methods of contraception listed below, before your *first* dose of study drug 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®)

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 contraceptive pill or progestogen-only 'mini-pill')
- Vaginal contraceptive ring (e.g. NuvaRing®)

You / your partner must also use a barrier form of contraception, from your *first* dose of study drug through until 30 days after your last dose. Barrier methods of contraception include:

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

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

If you do become pregnant during the study, you must tell the study doctor as soon as possible. Information about the pregnancy may be collected through the end of the pregnancy.

Reproductive Risks for Sperm in Sexually Active Participants

The effects of CBT-001 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, until at least 30 days after your last dose.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

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.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Auckland Eye.

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

If you do withdraw your consent during the research project, the study doctor and relevant project team members will not collect additional personal information from you, although

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

If you decide to leave the research project, you are advised to:

- Tell your study doctor
- Return to the study doctor for one more visit
- Return all unused study drug to the study doctor

There is no guarantee that you will continue to receive this study drug when you have finished taking part in the study. The care you receive after the study has ended may involve a different drug or treatment. A decision will be made in consultation between you and your study doctor about the most appropriate treatment and follow-up arrangements for you when this research project ends.

CAN I BE TAKEN OUT OF THE STUDY?

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

- The study drug is shown not to be effective
- Decisions made by the Sponsor or by local regulatory/health authorities
- It is unsafe for you to continue in the study
- You no longer meet the study criteria to continue in the study
- You need a treatment which is not allowed in the study
- You become pregnant or begin breast-feeding,
- You do not consent to continue in the research project after being told of changes in the research that may affect you, or for any other reason.

WHAT IF NEW INFORMATION ARISES DURING THIS RESEARCH PROJECT?

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

WHO PAYS FOR THE STUDY?

There are no costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

This research project is being conducted and sponsored by Cloudbreak Therapeutics, LLC . IQVIA, on behalf of the Sponsor, will be conducting the research project in New Zealand.

Auckland Eye will receive a payment from the Sponsor for undertaking this research project.No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

WHAT IF SOMETHING GOES WRONG?

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

However, Cloudbreak Therapeutics has satisfied the Southern 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.

Some sponsors voluntarily commit 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.

WHAT ARE MY RIGHTS?

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

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Site staff to complete study assessments
- Your GP will be notified of your participation in this study with your consent.
- Study monitors, to make sure the study is being run properly and that the data collected is accurate.
- The sponsor and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
- The sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct. Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.
- Rarely, it may be necessary for study doctor to share your information with other people – for example, if there is 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.

This research project will also collect information about your race, ethnicity and your date of birth.

The results of this study will be grouped by race and ethnicity. This will help to decide if race and/or ethnicity affect if the study drug works and how safe it is in different populations.

Your year of birth needs to be collected because it is required to check your eligibility to participate in this research project.

If you agree to give this information, your race and ethnicity, and your date of birth will be collected and entered into the same database where the other data about you will be entered, stored, and protected during this research project.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study staff AND/OR any study information sent to the sponsor. Instead, you will be identified by a code. Your study doctor will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information which may be sent and stored overseas:

- The sponsor, for the purposes of this study.
- People and companies working with or for the sponsor, for the purposes of this study (this may include hundreds of people and companies).
- Regulatory or other governmental agencies worldwide.

The information collected about you, will be held by Auckland Eye, the Sponsor, and the Sponsor's authorised representatives. The Sponsor and its authorised representatives will analyse and use the coded information they receive for the purposes of this research project.

Security and Storage of Your Information.

Your identifiable information is held at Auckland Eye during the study. After the study it is transferred to a secure archiving site and stored for at least 15 years then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

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

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Information about your participation in this research project may also be recorded in your health records.

Your medical files may be reviewed at the hospital (or study doctor's office) or remotely (outside of the study centre) in order to check the information and verify the clinical study procedures, while ensuring your privacy is protected.

If your medical files are reviewed remotely, the records will include your participant code but will not include your name or other directly identifiable information, unless these records will be reviewed directly through a secure electronic medical records portal, **or in exceptional circumstances, through a video call/conferencing with the study team.** Whether your medical files are reviewed at the study centre or remotely for the purposes of the study, your records will be kept secure during this process.

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. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may 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 ooverseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you.

Rights to Access Your Information.

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 the results of 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 the study doctor.

You always have the right to access and rectify your data or obtain a copy of your data collected. If your personal data is inaccurate or incomplete or is not being processed in compliance with the applicable regulatory requirements, you may ask for correction or to block your personal data. Please contact the study team member named at the end of this document if you would like to access your information. If you participate in this trial you will not own any of the information collected or produced for the purpose of the trial and you will not be able to request the withdrawal of your information from the trial data.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

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.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Cloudbreak Therapeutics, LLC. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Where possible, your study doctor will advise you of the results of this research project if you wish to know. There may be a very long delay from your entry into the research project until the results are known.

Māori Consultation and Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Dr Helen Wihongi about the collection, ownership, and use of study data.

A description of this clinical trial will be available on 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. You can search this web site at any time.

WHO HAS REVIEWED THE RESEARCH PROJECT?

All research in New Zealand involving humans is 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 Southern Health and Disability Ethics Committee (HDEC). The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT), which is part of Medsafe.

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:

Dr Dean Corbett, M.D, Principal Investigator
Auckland Eye
Phone: 09 529 2480, 021 508 884 (after-hours)
Email: corbettvision@gmail.com

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/

For Māori health support, please contact:

Office of the Chief Advisor Tikanga
Phone: 09 486 8920 ext. 43204
Email: hkwresearch@waitematadhb.govt.nz

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

Phone:	0800 4 ETHICS
Email:	hdecs@health.govt.nz

Participant Consent Form

Study title:	A Clinical Trial on Safety and Effectiveness of CBT-001 in Patients With Pterygium		
Sponsor:	Cloudbreak Therapeutics LLC		
Locality:	Auckland Eye Limited, 8 St Marks Road, Remuera, Auckland 1050	**Ethics committee ref.:**	2023 FULL 18325
Principal Investigator:	Dr Dean Corbett	**Contact phone number:**	(09) 529 2480

If you need an INTERPRETER, please tell us.

Declaration by participant:

- I have read, or have had read to me in my first language, 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, whanau/ 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 personal information (including date of birth, race and ethnicity), including information about my health.
- I consent to my information being sent overseas.
- I agree that if I decide to withdraw and leave the research project, the information and data collected about me up to the point when I withdraw may continue to be used.
- 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.
- 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 blood 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 wish to receive a summary of the results from the study**:** **YES / NO**

Participant Signature of Consent:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

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 name: _____

Signature: _____ Date: _____