Insert Header with institution's name or institution's letterhead

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

[Insert site name]

Title	A Phase Ib, study of safety and tolerability of Intravitreal Fludrocortisone Acetate (FCA) in Patients with Geographic Atrophy (GA)
Protocol Number	EC-FCA-001
Project Sponsor	Eye Co Pty Ltd
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have a particular type of eye disease known as Geography Atrophy (GA) that is a form of Age-Related Macular Degeneration (AMD). The research project is testing an experimental drug for GA secondary to AMD. The experimental drug is called Fludrocortisone Acetate (FCA).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

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

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive your routine medical care whether or not you take part.

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

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

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

In the sections that follow, the word ‘we’ means the study doctor and other research staff.

2 What is the purpose of this research?

AMD is a disease of the macula, an area in the retina found at the back of the eye. AMD worsens over time and is the leading cause of central vision loss in persons over the age of 50 years in developed countries. In people with AMD, there is loss of central vision over time, there is distortion of images and straight lines, and there is presence of blurry and dark areas in the central vision. The underlying reasons for AMD are complex and the symptoms present in several forms.

In the early and intermediate stages of AMD, there are deposits of drusen (a fatty protein), between the retina and a membrane lining behind the retina, in the eye. As part of the natural course of the disease, something called “geographic atrophy,” or GA develops. GA means a region of the retina where the cells wither away and die. Sometimes, these regions of GA look like a map to the doctor who is examining the retina, hence the term “geographic atrophy.” When this happens, this results in a blind spot in the field of vision.

Because you have GA, you are being asked to participate in a medical research study that involves an injection (shot) of medicine (steroid) called fludrocortisone acetate (injectable suspension) into the eye after careful preparation using a small needle; this is called an intravitreal injection (IVT).

Fludrocortisone acetate is considered an investigational drug to treat GA. “Investigational” means the study drug being tested is not approved by the Therapeutic Goods Administration (TGA) in Australia to treat these conditions. Because this is a research study, fludrocortisone acetate intravitreal injections will be given to you only during this study and not after the study is over.

Fludrocortisone acetate is in a class of drugs called steroids. Fludrocortisone acetate prevents the release of substances in the body that cause inflammation. Fludrocortisone Acetate is already in use treating conditions in which the body does not produce enough of its own steroids, such as Addison’s disease, and salt-losing adrenogenital syndrome.

This study will be conducted in two parts. Part 1 of the study involves 3 participants to assess safety and tolerability of a 1mg dose of FCA. Initially 1 participant will participate in a screening period of up to 14 days and a follow-up period of 28 days. Subsequently 2 participants will be treated with 1mg/0.1mL FCA. These participants will be followed for 4 weeks prior to Part 2.

Part 2 involves 6 participants to assess safety and tolerability of a 2mg/0.1mL dose of FCA subsequent to Part 1. Initially 1 participant will participate in a screening period of up to 14 days and a follow-up period of 28 days. Subsequently 5 participants will be treated with 2mg/0.1mL

FCA. The study can only recruit participants into part 2 once the safety has been assessed by a dedicated review panel.

Participants who meet all necessary requirements will return to the clinic for the administration of a single dose IVT Fludrocortisone Acetate (Day 0).

All participants will return to the clinical site on Day 1 and Day 7 to assess acute safety after the injection. After that, all participants will return for another 6 follow-up visits for 6 months after the injection.

3 What does participation in this research involve?

The study will last approximately 6 months and involve up to 9 clinic visits.

Before the study starts, you will be asked to review and sign this consent form. You will be asked questions about your medical history and any current medications you are taking. This is to ensure that you meet all of the necessary requirements for the study and do not have any conditions that would make participating unsafe for you. Questions asked during a medical history review typically cover current and past medications or therapies, illnesses, conditions or symptoms, and allergies. You will be asked about any new medical events and/or medications at each visit and you will be given several tests to see if you are able to continue participation in this study. Below is the list of tests performed over the period of the study. These will happen at most of the visits, a concise breakdown is provided in the table below.

Study Procedures:

The research study involves the following tests and procedures:

Physical Exam, Vital Signs: Physical examinations, including measurements of weight, height, temperature, blood pressure, heart rate, and respiration rate will be done during the study.

Medical and Medication History: During screening, you will be asked about your past health history and about any medications you may be taking. Besides any conditions in your eyes, you will be also asked about conditions or diseases in other parts of your body and when these were first diagnosed.

Ophthalmic History: During screening, you will be asked questions about conditions and diseases in your eyes and when these were first diagnosed. You will also be asked when you were first diagnosed with AMD. You will also be asked about any medicines or treatments for GA or AMD that you have used and about any medicines or treatments for any other eye diseases or conditions.

Changes in Your Health and Medications: Your study doctor or nurse will ask whether there have been any changes in your general health or medications and if you have seen another doctor or been admitted to the hospital. If you have any concerns between visits, please contact the study staff.

Eye examination and slit-lamp biomicroscopy: This is part of a routine eye exam. The first part of the test is done by examining the outside of your eye. The other part of the exam is done with a microscope with a light attached that allows the study doctor to examine your eye under high magnification. This allows the study doctor to see the front sections of your eye.

Visual Acuity: Be sure to bring your glasses. The study doctor will use special lenses to find your best vision in each eye and ask you to read letters on an eye chart to measure your vision. For Low Luminance Visual Acuity, it will be the same procedure but will be conducted under low light conditions.

Indirect ophthalmoscopy: The study doctor will look at the back of your eyes with a very bright light. Your eyes will be dilated (eye drops will be given to make your pupils large) for this test. Your vision may be blurred for a while after this test. If you were able to drive before the test, you may not be able to do so for several hours afterwards.

Intraocular pressure assessment (IOP): This examination measures the amount of pressure inside your eyes. This test will be done after you have been given a drop of a medicine to numb the front of your eyes so that you won't feel anything. To check the pressure in your eye, a special instrument will come in contact with your eye for a few seconds.

Fluorescein angiography (FA): This test will help the study doctor to see the blood vessels in your eye so that they can be photographed. To do this test, fluorescein (a dye) will be injected into a vein in your arm and it travels throughout your body, including to your eyes. With a special camera and flash, a series of photographs of the back of your eye are taken as the dye passes through it.

Dilated Fundus Exam, Colour Fundus photography (CFP): The study doctor will inspect the back of your eyes including the retina, optic disc and blood vessels. Medicated drops are placed on your eyes to enlarge the pupils and make the back of the eye easier to study. In a dark room, the study doctor will use a beam of light to look at the back of your eye. Coloured photographs of your retinas will be taken using flashes of a bright light.

Fundus Auto Fluorescence (FAF): Your eyes will be illuminated with a blue light causing certain cellular components to "glow" without injecting any dye. This glow (fluorescence) returning from your retina can be used to create a black-and-white image which can be interpreted by recognizing characteristic patterns.

Near-infrared Fundus Reflectance (NIFR): This is a special imaging technique used to capture different layers of the retina (back of the eyes).

Optical coherence tomography (OCT): The study doctor will use an OCT instrument to look at the back of your eye in great detail and to take some pictures. This will help the study doctor determine if there are any changes in your retina or macula, including if there are any changes in the thickness of your retina. You may have drops placed on your eyes to make your pupil bigger and to make it easier to see the back of your eye.

Blood Samples: Blood will be taken for testing during most of the study visits. The blood that is collected will be used for standard safety laboratory tests.

The number of samples and the amounts of blood collected will vary at each visit. A blood sample (approximately 36 mL or 2 tablespoons) will be taken prior to the study drug injection for blood chemistry measurements and complete blood count examination. Total Blood Volume for the study will be 148.5 mL.

Pregnancy Test: If you are female and of child-bearing potential (able to get pregnant), you will have 1 screening urine test to see if you are pregnant.
Blood Sample for fludrocortisone acetate: Some of the blood will be used to test how long the study drug stays in the body. This is called pharmacokinetic (PK) analysis.

The visit table below shows the procedures that will be performed at each study visit.

Study Visits

Procedures	Screening Day -14 to -1	Baseline Visit 1, Day 0	Study Visit 2 Day 1 +/-1 day	Study Visit 3 Day 7 +/- 1 day	Study Visit 4 Day 14 +/-1 day	Study Visit 5 Day 28 +/-1 day	Study Visit 6 Day 60 +/-1 day	Study Visit 7 Day 90 +/-1 day	Final Study Visit 8 Day 150 +/-1 day
Informed consent	X								
Demographics	X								
Medical history	X								
Concomitant Medications	X	X	X	X	X	X	X	X	X
Adverse event review			X	X	X	X	X	X	X
Administer study drug		X							
Physical exam	X	X			X			X	X
Vital signs	X	X	X	X	X	X	X	X	X
Best corrected visual acuity (BCVA)	X	X	X	X	X	X	X	X	X
Height and Weight	X						X		X
Visual Function Questionnaire (VFQ-25)		X							X
Goldmann Intraocular Pressure (IOP)	X	X	X	X	X	X	X	X	X
Slit lamp biomicroscopy, incl. lens grading	X	X	X	X	X	X	X	X	X
Dilated ophthalmoscopy	X	X	X	X	X	X	X	X	X
SD-OCT	X	X	X	X	X	X	X	X	X
FAF and NIFR	X	X	X	X	X	X	X	X	X
Colour Fundus Photography	X						X		X
Fluorescein angiogram	X								X
Blood tests (Haematology & Serum chemistry & Urinalysis)	X	X		X		X			X
Urine Pregnancy test	X								X
Pharmacokinetic sampling		X		X		X			X

Unscheduled Visits

If you or the study doctor feels you should come in another time between scheduled visits or after Final Study Visit, another appointment will be arranged for you. Your study doctor may suggest additional testing at this time.

In addition, you will be followed up for 6 months after the Final Study Visit.

Note: There is some flexibility (visit windows) for scheduling some visits. The study doctor or nurse can discuss these with you, i.e., transportation and visit expense assistance. You should be aware that your study doctor may ask you to attend extra unscheduled visits, at any time during the study. This would happen if any side effects from fludrocortisone acetate occur, if you develop new health problems, or if your lab test results are abnormal enough that additional testing is needed.

Reimbursement:
You may be reimbursed for any reasonable travel, parking, meals, and other expenses associated with the research project visit. As a participant in this study, you will be paid back (reimbursed) for travel expenses related to the research project visit. In the event that you wish to be reimbursed for study-related travel expenses, you must save and give all receipts for travel expenses to the study nurse during your clinic visits. Examples of reimbursed expenses include travel mileage, parking, tolls and meals.

Images/Photographs:
Images/photographs may be taken of your eyes during the study. You cannot be identified from the images/photographs. The images will be identified with your allocated study number. If you do not want to have the images/photographs taken, you cannot participate in the study.

Additional Costs:
There are no additional costs associated with participating in this research project. You will not be paid for being in this study. All medication, tests, and medical care required as part of the research project will be provided to you free of charge.

4 What do I have to do?

As a participant in an investigational drug study, you are responsible for showing up for all study visits and following study instructions. You should honestly answer all study questions (including medical history), disclose all medications that you are currently taking in order to protect your safety while participating in this study, and report any side effects. You must also notify your study doctor of any changes in your health while participating in this study and of any changes in your medications (over-the-counter and prescription). Your study doctor will explain to you which treatments or medications you can have, or that need to be stopped, for the time you are involved in the research project. If you (for female participants) or your partner (for male participants) becomes pregnant, you must notify your study doctor immediately. You may not participate in any other research study, without approval from the study doctor. If you choose to stop your participation in the study for any reason, you must notify your study doctor immediately so that a plan can be made for your continued medical care. At that time, you must have the final clinical evaluations and laboratory tests performed as described above.

During this study, you should notify any doctor who is taking care of you that you are participating in a research study that involves the use of this investigational product.

5 Other relevant information about the research project

10 participants will participate in this study in Australia.

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

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

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

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital/clinic. There are currently no therapies approved for the treatment of GA. Your study doctor will discuss other options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor. If you decide not to take part in this study, or change your mind later, there will be no penalties or loss of benefits to which you are otherwise entitled.

8 What are the possible benefits of taking part?

There is a potential benefit that treatment with fludrocortisone acetate may slow the rate of GA progression. There is no guarantee that there will be any benefit to you. The results of this study may help Study Doctors and the Sponsor of the study learn to decide whether the study drug can be further developed for the treatment of GA.

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

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

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

Side effects may go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. Your study doctor will discuss the best way of managing any side effects with you.

Risks Associated with Study Medication (Fludrocortisone acetate)

One of the reasons for this study is to learn more about the safety and tolerability of Fludrocortisone acetate. Fludrocortisone acetate has been studied in research animal clinical studies. Fludrocortisone has not been used intravitreally in human, there are potential unknown risks. To reduce such risks, this study is being conducted in two parts, restricting treatment to a single individual together with extended assessment, prior to application in other participants. Numerous follow-up visits and numbers of testing procedures have also been instituted in the assessment schedule for all participants to ensure adverse events, or other safety issues that arise are identified and addressed in a timely manner.

Intravitreal Injection
The possible risks for an ocular injection include conjunctival haemorrhage (bleeding at the site of needle injection), eye pain, floaters (spots in the vision), retinal detachment (separation of the retina), retinal tear (rip in the retina), cataract (cloudy lens inside the eye), endophthalmitis (an inflammation/infection inside the eye) and increased eye pressure. There may be redness and irritation in the eye after study drug injection.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

Risks associated with study procedures

Risk of Eye Examinations and Photographs
You may feel temporary discomfort during the eye examinations and photographs due to the bright lights. When the study doctor is examining the back of your eye, he/she will sometimes need to put mild pressure on your eye (through the eyelid). This causes mild to moderate, momentary discomfort.

Risk of Fluorescein Angiography/Fundus Photography
These are procedures used to look at the blood circulation in the back of the eye. It involves a series of photographs. For some of the photographs, a dye will be injected into a vein in your arm before a rapid series of photographs are taken of both eyes. The photographs may cause discomfort because of the bright flashes of light. Potential risks associated with injecting fluorescein dye into a vein in your arm include, dizziness, bruising, pain and infection at the puncture site.

The dye sometimes causes nausea or vomiting. There will be a yellow/orange discoloration to your urine for several hours after the test. Some people may have an allergic reaction to fluorescein. An allergic reaction to fluorescein dye is rare. If it does happen, you may have a rash or experience hard time breathing, wheezing when you breathe, sudden drop in blood pressure, swelling around the mouth, throat, or eyes, fast pulse and sweating, severe allergic reaction can be life-threatening.

If you have experienced allergic reactions to fluorescein in the past or have history of kidney disease/injury, please tell the study doctor. You should avoid direct sun exposure for a few days after the test as the dye may cause skin hypersensitivity to sunlight. You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Risk of Blood Tests
There are no major risks associated with a blood test. It is possible that you may feel some discomfort associated with the needle prick. We can use a cream to numb the skin before the blood is taken if it is taken during a clinic visit. It is possible that there may be some bruising,

swelling or bleeding where the needle enters the skin. Although rare, infection or localized clot formation may develop at the site of the needle puncture. You may also feel dizzy or light-headed when blood is taken.

Unknown Risks
There may be side effects or discomforts from the study drug which are not yet known, including worsening of the disease. If the study doctor learns any new information while you are in the study which may affect your decision to stay in the study, the study doctor will tell you about it.

Pregnancy and Reproductive Risks:

The effect of Fludrocortisone acetate on your fertility, including future fertility, may not be known.

For female participants:
The effects of Fludrocortisone acetate on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breastfeeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. You must use a highly effective method of contraception/birth control (methods which result in low failure rate, i.e. less than 1% per year, when used consistently and correctly).

Examples of acceptable forms of highly effective contraception include:

1. Established use of oral, injected or implanted hormonal methods of contraception.
2. Placement of an intrauterine device (IUD) or intrauterine system (IUS).
3. Sterilised male partner (with the appropriate post-vasectomy documentation of the absence of sperm in the ejaculate).

If you are uncertain of what form of contraception is acceptable for use during the study, then please ask your study doctor. If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. You will not be able to continue participation in the study if you become pregnant. In the event you do become pregnant the Sponsor will be monitoring your pregnancy and the birth and health of your child.

For male participants:
Because the experimental agents in this study may affect an unborn baby, you should not father a baby while on this study. The effect the drug has on your fertility may not be known. It is recommended that a condom be worn for all sexual intercourse as the study medication may affect your sperm risking the potential for an abnormal child being born. It is also highly recommended that you inform your partner of your participation in the study and that contraception has been strongly recommended. Further, you must agree that if your partner becomes pregnant while you are on the study, you will advise the study doctor who will then provide you with an authorisation form to present to your partner. If she is in agreement, that authorisation will function as consent to approve the study doctor's access to medical information to allow long-term monitoring of the pregnancy, and the birth and the health of the child.

Payment for all aspects of obstetrical care, child or related care will be your responsibility.

10 What will happen to my test samples and photographic images?

Your samples (blood and urine) will be coded (identified by your study number) before being shipped to a local or central laboratory and will be stored there awaiting analysis. The local or central laboratory being used in this study is Douglass Hanly Moir who are experienced in handling and testing samples from research studies. Only authorised study staff and laboratory personnel will have access to your samples and the results. The results will be on hand for the study doctor as they become available. The collected samples will be stored at the local or central laboratory and will be destroyed by incineration, as per laboratory standard operating procedures, after they are analysed. All samples will be destroyed no later than 1 year after the study is completed and will not be stored for future use.

11 What if new information arises during this research project?

Sometimes during 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 arrange 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.

You will be told of any changes in the way the research is being done. 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, he/she will explain the reasons and arrange for your regular health care to continue.

12 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 GA, or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications. You should tell your study doctor about any changes to these during your participation in the research project. Your study doctor will explain 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. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13 What if I withdraw from this research project?

Your participation in this study is entirely voluntary. You may refuse to participate or may withdraw from this study at any time without penalty or loss of any rights or benefits to which you are otherwise entitled.

Your study doctor and relevant study staff will discuss any health risks or special requirement linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected (including sensitive information such as health information) 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, including sensitive information such as health information, may nevertheless subsequently be used and disclosed to others for the purposes described in this consent and will form part of the research project results. By agreeing to participate in the study, you consent to the use and disclosure of data collected about you prior to your withdrawal (including sensitive information such as health information) in this manner.

14 Could this research project be stopped unexpectedly?

The Sponsor, study eye care provider or study doctor can decide to stop the study at any time. The study eye care provider, study doctor, the Sponsor or its representatives, Ethics Committees, or regulatory agencies may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study eye care provider or study doctor's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- If you become pregnant (Females)
- If the drug is shown not to be safe

15 What happens when the research project ends?

Information obtained from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you. After you exit the study your study doctor will discuss treatment options available to you and their important potential benefits and risks.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the Consent Form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained during this research project that can identify you will remain confidential.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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 be recorded in your health records.

All information collected about you that is provided to the sponsor will not directly identify you (for example, by name, address etc.). Instead, a unique code number will be used to label your information. This coded personal data will be processed electronically by representatives of the study sponsor. The study doctor is responsible for keeping the code list which makes it possible to link your unique code number to your name. This list will be kept in a safe place to ensure that in case of an emergency you can be identified and contacted. The code list and your coded study data will be retained for at least 15 years after the completion of the research project. If the results of this study are published, you will not be identified by name.

Who Will See Your Data

Any information obtained in connection with this research project that can identify you will remain confidential. Medical records of study participants are stored and treated as confidential.

A description of this clinical study may be available on www.ANZCTR.org.au as required by Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The results of this study may be shown at scientific meetings and published in journals to inform other doctors and health professionals. Your identity will be kept private in any publication or presentation.

Several people and organisations may review or receive your identifiable information. They will need this information to look at the data. These groups include:

- Members of the research team at *(Insert institution name)*
- The doctor who is treating your medical condition for GA
- People from the ethics committee or health authorities who have responsibility to protect human participants involved in research
- People from Sponsor, or companies and laboratories that work for them, including groups who look at the safety of this study (e.g., Data Safety Monitoring Board)
- The Therapeutic Goods Administration (TGA)

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of:

- The Sponsor, Eye Co
- The institution relevant to this Participant Information Sheet/Consent Form, *[Name of institution]*
- Or as required by law

By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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.

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

In accordance with relevant Australian and/or *[Name of state/territory]* privacy and other relevant laws, you have the right to access and correct the information that is collected and stored about yourself. Please contact us if you would like to access this information.

Some of the organisations that will have your data will be located outside of Australia, including in countries where data protection requirements may be different or less restrictive than in Australia. However, Eye Co will take reasonable measures to keep your personal health information confidential. However, absolute confidentiality cannot be guaranteed. By signing this document, you agree to the transfer of your personal health information.

Rights To Your Data
You may have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

17 Complaints and compensation

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

If you are injured as a result of your participation in this trial you may be entitled to compensation.

Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Issues/Information – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

If you are hurt or get sick from something that was done as a part of this study, doctors at the clinic or hospital can arrange for emergency medical care. If your injury is caused by the experimental drug, Eye Co will pay for treating the injury. This does not mean that a mistake happened. The Hospital does not offer financial compensation or payment if you are injured as a result of participating in this study.

If you think you have been injured from taking part in this study, call ***(Insert appropriate institution name and phone number)***. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

You will not receive any payment for being in this study.

18 Who is organising and funding the research?

This research project is being conducted and locally sponsored in Australia by Eye Co Pty Ltd.

Eye Co may benefit financially from this research project if, for example, the project assists Eye Co to obtain approval for a new drug.

By consenting to take part in this research project, you agree that samples of your blood and/or urine (or data generated from analysis of these materials) may be provided to Eye Co.

Eye Co Pty Ltd may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Eye Co Pty Ltd.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Eye Co the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

[Name of institution] will receive a payment from Eye Co Pty Ltd 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).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by Bellberry Limited.

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

20 Further information and who to contact

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

If you want any further information concerning this project, or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Bellberry Ltd*
Telephone	*08 8361 32222*
Email	*bellberry@bellberry.com.au*

Consent Form - *Adult providing own consent*

Title	A Phase Ib, study of safety and tolerability of Intravitreal Fludrocortisone Acetate (FCA) in Patients with Geographic Atrophy (GA)
Protocol Number	EC-FCA-001
Project Sponsor	Eye Co Pty Ltd
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location where the research will be conducted]*

Declaration by Participant

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

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

By signing this permission document, none of my legal rights are waived.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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

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

I authorise the use of my personal health information for purposes of this research study as explained above. I understand that I cannot participate in the study if I decide not to give my authorisation, or take away my authorisation.

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

Name of Participant (or the name of participant's legally authorised representative): (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

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

Declaration by Study Doctor/Senior Researcher†

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

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood and urine samples taken from me for use, as described in the relevant section of the Participant Information Sheet/Consent Form, for:

- This specific research project

By signing this consent section, I agree to the use of my blood and urine samples for, as outlined in the relevant section of the Participant Information Sheet/Consent Form.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

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

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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

Form for Withdrawal of Participation - *Adult providing own consent*

Title	A Phase Ib, study of safety and tolerability of Intravitreal Fludrocortisone Acetate (FCA) in Patients with Geographic Atrophy (GA)
Protocol Number	EC-FCA-001
Project Sponsor	Eye Co Pty Ltd
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Associate Investigator(s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location where the research will be conducted]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

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