PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol no: _____

Protocol title: Fight Retinal Blindness! Registration of treatment data in an international register

Participant no: _____

Name of investigator: _____

1. Introduction

Dear Participant

You are invited to participate in a registry study with medications available in the South Africa market. Your eye doctor participates in an international project 'Fight Retinal Blindness!' (Literally: "Fight against retinal blindness"). It is an international register to gather information about treatment in wet age-related macular degeneration (AMD), Diabetic Macular Oedema and Retinal Vein Occlusion. Before you agree to take part in this registry STUDY, you must please read this information sheet as it contains important information to help you decide whether or not it is in your best interests to do so.

You are encouraged to ask as many questions as needed in order to ensure that you understand the registry procedures, including possible risks and benefits. If you have any questions that are not properly explained or answered in this information leaflet, please feel free to ask a study staff member to give you more information. You are welcome to take this document home with you and to discuss your possible participation in this registry study with your family and friends.

This registry study has been approved by the Pharma-Ethics Research Ethics Committee for compliance with medical and ethical standards. The study doctor will be not be paid additional fees to conduct this study.

2. Your rights as a participant

If you decide not to participate in this study, nothing changes to your current therapy. Your participation in this study is voluntary. You may choose not to be in the study or to leave the study at any time by telling the study doctor. If you decide not to participate in the study or to withdraw your consent, you will not lose any benefits to which you are otherwise entitled. The study doctor has the right to withdraw you from the study if it is considered to be in your best interests, in which event, the reasons will be given to you. If we find out that you did not

provide the correct medical history or did not follow the guidelines in this document and the study protocol, you may be withdrawn from the study at any time.

3. Purpose of the study

Wet age-related macular degeneration (AMD)
Wet AMD is a painless condition in which new blood vessels in and below the retina grow, especially in the macula (yellow spot). These new blood vessels are leaking. This leak causes damage to the retina, causing one to experience a dark spot in the center of the vision as well as a decrease in vision. Decline of function of the retina is an important cause for visual impairment and blindness.
The treatment of wet AMD
At present, the treatment of wet AMD consists of regular administration of intravitreal injections with an anti-VEGF (Vascular Endothelial Growth Factor) agent. The frequency of administration and the type of anti-VEGF agent varies per patient and is dependent on clinical findings and specialized investigations to determine the presence and the degree of leakage from the new vessels.

Diabetic Macular Oedema (DMO)
This condition is a complication of Diabetes Mellitus affecting the central retina and causing swelling and leakage from blood vessels within the macula (central retina). This causes loss of vision.
The treatment of DMO
At present, the treatment of DMO consists of regular administration of intravitreal injections with an anti-VEGF (Vascular Endothelial Growth Factor) agent. The frequency of administration and the type of anti-VEGF agent varies per patient and is dependent on clinical findings and specialized investigations.

Retinal Vein Occlusion (RVO)
This condition results from an occlusion in a retinal vein. This leads to swelling within the central retina (macula) causing loss of vision.
The treatment of RVO
At present, the treatment of RVO consists of regular administration of intravitreal injections with an anti-VEGF (Vascular Endothelial Growth Factor) agent. The frequency of administration and the type of anti-VEGF agent varies per patient and is dependent on clinical findings and specialized investigations.

With this research, information is gathered about the way in which these conditions are treated with our current registered medications. This can contribute to improving the existing treatment protocols of these retinal conditions and provide insight into the safety and effectiveness of current treatments.
The study medicines have been registered by the South African Health Products Regulatory Authority in South Africa and/or other regulatory authorities in other countries.
There is no limit to the number of participants in this study. The study is conducted world-wide, and has been ongoing for a number of years.

4. Study design

Your ophthalmologist will decide which treatment to administer for your condition. The treatment will be recorded into the registry as well as some of your basic demographic data.

All treatment decisions are made by your ophthalmologist. Any change in treatment will be based according to what your ophthalmologist feels most appropriate for your condition based on their clinical findings and investigations.

5. Study procedures

To determine if you are eligible to participate in this study, your ophthalmologist will ensure that there are no contra-indications to administering the relevant therapy. If you meet the study inclusion criteria and you agree to participate, you will be required to do no more than any patient suffering from a retinal condition who is to receive the relevant treatment.

Nothing changes for your treatment. Your ophthalmologist will give you the treatment as he / she thinks is best for you. You do not have to do anything extra for yourself for this study/registry. The medical information that we register is your demographic data (birth year, gender, ethnicity, postal code), eye examination, visual acuity, treatment and whether you have experienced side effects on the treatment. Your data will be encrypted in the registry so that these data are not directly traceable to you (pseudonymization). This data is merged with the data of other participants who have undergone treatment. There are no additional risks for your treatment associated with this research. It is only about registration of your treatment. You can stop participating at any time during this study by withdrawing your consent. You must report this to your ophthalmologist. Your data will then be taken off the register.

For this study to be successful, it is important that you co-operate fully with the study doctor and follow his or her instructions precisely. Please inform the study doctor of all the medications that you are currently taking. Do not take any other medication, including over-the counter, prescription, herbal, traditional or vitamins, without first informing the study doctor.

6. What will happen to my blood and tissue samples?

No blood or tissue samples will be taken from you for the purposes of this registry study.

7. What are the possible risks or side-effects of being in the study?

- *The risks of this registry study are those of having an intravitreal injection into the eye. The risks of administering an injection can be minor such as redness or scratchiness at the injection site. Serious complications are rare but may lead to severe or permanent loss of vision (risk is 1 in 2000). Other less serious outcomes are:*
    - *Glaucoma (increased pressure in the eye) – occurs with steroid injection only and treatable with topical medication.*
    - *Cataract formation (blurred vision due to clouding of the lens).*
    - *Retinal detachment is rare.*

You must inform the study doctor immediately if you experience any negative effects, complications or injuries while taking the study medication.

8. Risks to women of childbearing potential

The medication to be administered is contra-indicated in pregnancy. If you are currently pregnant, or are planning a pregnancy, you will not be included in the registry study. Please discuss this with your ophthalmologist. If you become pregnant during the study, you must stop the study medication and inform the study doctor immediately.

9. What are the possible benefits of being in the study?

Your retinal *condition is expected to improve while you are on the medications.* If the medication is not effective, your ophthalmologist will decide on the next step in your treatment regime. The information gained during the study can benefit society by gaining useful information on our current treatment.

10. Alternative treatments

Your ophthalmologist will be administering the standard of care therapy for your condition as accepted internationally and in local and international guidelines.

11. Compensation in the event of a trial-related injury

The medication will be administered according to internationally accepted standards in routine clinical practice. There will be no compensation in the event of an injury while being a participant in the registry study by the manufacturers of any of the medications nor by the Save-sight Institute.

12. Confidentiality

All research data from participants will not be entered under the name of the participant, but kept under a code (pseudonymization). The research data will be to be sent via a secure connection to the University of Sydney (Australia) for storage on secure computers. All research data will be carefully pseudonymised by the University of Sydney in a database on the basis of appropriate technical and organizational security measures. Only a limited group of persons (statisticians, data recorders and system administrators) within the University of Sydney have access to the data in the database. The data is saved as long as they are important for the results of the research (and as long as your permission to participate has not been withdrawn).

Your ophthalmologist has access to the database through a personal code. Your ophthalmologist only gets access to the data of his / her own patients for evaluation of the treatment. Your ophthalmologist can also compare his / her own results with all the results in the system. The data can also be used for specific analyzes based on individual requests or research projects of participating ophthalmologists.

Your ophthalmologist and the University of Sydney are on contract to establish the mutual responsibilities regarding the processing of your data and your rights in that respect.

You have the right to control the use and disclosure of your personal information. The following people may also access these records:

- Study monitors who may work for the Sponsor or its affiliates/authorized representatives, who check that the study is being performed correctly and that the information collected about you is accurate;
- Research Ethics Committees that approved this study and ensures that your rights and well-being are safeguarded;
- National and international regulatory authorities involved in keeping research safe for participants.

All personnel accessing your records are required to respect your confidentiality at all times. Representatives from government agencies such as the Medicines Control Council of South Africa, the National Health Research Ethics Council (NHREC) and Pharma-Ethics Research Ethics Committee, the Sponsor and or the sponsor's authorized representatives may need access to your original medical records and study records to confirm that the study data collected about you is correct and relates to you.

All records identifying you will be kept confidential, and to the extent permitted by applicable laws and regulations, will not be made publicly available. No personal information will be included in the study data that will be forwarded to the sponsor or sponsor representatives. You will be identified by a coded number in any reports of publications produced from this study (study data). By signing this document, you are authorizing such access.

Under data protection law *"Protection of Personal Information Act 2013"* your study site will be responsible as 'controller' to ensure that your information is safeguarded. Your data might be transferred to a country that may not have the same level or personal data protection as South Africa. If your data is transferred outside South Africa the sponsor is responsible for protecting your data.

The representatives of the study may use the study data sent to them for the following purposes:

- To see what the efficacy and the safety of the medication is
- To compare the medication to other medications used for the same condition.
- For other activities relating to the medication administered to control your condition.

You have the right to ask the study doctor about the data being collected on you and to see your personal health information and, if applicable, ask for corrections.

If you should withdraw from the study, data collected prior to your withdrawal may still be processed along with other data collected as part of the study. No new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side-effects you may suffer are documented and reported. To complete the study findings, your long term health status may also be recorded (unless you object). You have the right to require that any previously retained samples are destroyed.

13. Payment, expenses and costs

You will not receive payment for participating in this study.

14. Termination of participation

Your participation in the study may be stopped for the following reasons:

- If you don't follow the study doctor's instructions.
- If the study doctor decides that it is in your best interests.
- If the sponsor of the registry stops the study or closes the study site for unknown reasons.

15. Study results

Findings that result from this research project can be found in professional journals that are published. These findings can also be presented during (inter) national congresses for ophthalmologists. These findings will not be able to be traced back to you. You will be able to obtain information about your study results by contacting your ophthalmologist *[Dr name.] Patients can obtain information on the trial from the South African National Clinical Trials Registry.*

16. Contacts for answers relating to the research, and your rights as a research participant in the event of trial-related injuries or side-effects

The study

Who can I contact if I have any doubts or questions about this research project?

If you have any doubts or have any questions, please contact your ophthalmologist.

Study-related injury (your rights as a registry participant)

Pharma-Ethics Research Ethics Committee
PO Box 786
Irene, 0062
Tel: (0) 12 664 8690
Fax: (0)12 664 7860
e-mail: marzelle@pharma-ethics.co.za

If you have questions about this trial, you should first discuss them with the study doctor or the abovementioned ethics committee. If you do not receive answers that are to your satisfaction,

you should write to the National Health Research Ethics Council or the Medicines Control Council at:

The Chair
National Health Research Ethics Council
Regulatory Authority
Tel: (012) 395 8113
Fax: (012) 3958467
E-mail: nhrec@health.gov.za

The Registrar
South African Health Products

Department of Health
Private Bag X828
Pretoria, 0001
Fax: (012) 3959201
Email: gouwsj@health.gov.za or mogobm@health.gov.za

University of Sydney University of Sydney, Save Sight Registries, Save Sight Institute, Level 1 South Block, 8 Macquarie Street, Sydney NSW 2000, Australia
E-mail: ssi.ssr@sydney.edu.au

17. Consent statement **Initial Blocks**

By signing below, I agree that:

• I have read or had read to me the information sheet and consent form, version 3 for this registry study.	
• The purpose, treatment and procedures of this registry study have been explained to me and I understand them.	
• I understand my responsibilities as a registry study participant.	
• I understand that participation in the registry study is voluntary and that I can refuse to participate or withdraw at any time, without it affecting my ongoing care.	
• I understand that when I withdraw my permission to participate my data will be removed from the database, but that this does not affect the lawfulness of the processing of my data before the withdrawal of my consent.	
• I have been informed of the possible risks, harm and inconvenience of participating.	
• For women: I am not pregnant, breastfeeding or trying to fall pregnant and, if required, will use acceptable birth control during the registry study.	
• I have been informed of the expected benefits of the registry study.	

• I have had sufficient time to ask questions and they were answered to my satisfaction.	
• I have been given time to discuss the study registry with others and to decide whether or not to take part.	
• I am aware that the results of the registry study, including personal details about me and my health information may be reasonably disclosed to the sponsor, regulatory authorities and research ethics committees, if required by law.	
• I agree for my pseudonymised data to be transferred to a secure data repository outside South Africa.	
• I understand that in Australia there may be a less adequate level of protection of personal data than in the South Africa, but that appropriate technical and organizational protection measures have been put in place protect my data against unauthorized or unlawful processing and against unintentional loss, destruction or damage.	
• I will receive a signed and dated copy of this informed consent form.	
• I agree to participate in this registry study.	

_____
Printed name of participant

_____
Date (personally completed by participant)

_____
Signature of participant

_____
Printed name of person conducting consent (if other than the investigator)

_____
Date

_____
Signature of person conducting consent (if other than the investigator)

_____

Printed name of investigator

_____

Date

_____

Signature of investigator

I hereby verify that verbal consent was obtained from the above participant. The participant has been informed about the risks and the benefits of the research, understands such risks and benefits and is able to give consent to participate, without coercion, undue influence or inappropriate incentive.

_____

Printed name of witness (*Witness signature is required in instances where the participant is illiterate. Verbal consent must be obtained from the participant, in the presence of an independent witness who is present during the entire informed consent discussion. The witness's name, signature and date must be completed by the witness at the same time when consent is obtained by the participant and the document is signed and dated by the study doctor/delegate. A competent witness for research purposes is a person who is 18 years or older, and of sound mind and who is not involved with the trial in any way)*

_____

Date

_____

Signature of witness