Participant Information Sheet and Consent Form

Title
Short Title
Project Sponsor
Coordinating Investigator
Principal Investigator
Location
HREC Reference Number

Part I – What does my participation in the study involve?

1. Introduction

You are invited to take part in XXXX, which may be suitable for you. Before you decide if you wish to participate, we would like you to understand why the study is being done, what it will involve and how your information will be used.

2. What is the purpose of this research?

This study aims to XXXX.

3. Why have I been chosen?

You have been chosen to participate in this research because of XXX.

4. Do I have to take part in the research?

It is up to you to decide whether or not to take part in this study. 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. If you decide to take part you can change your mind later and withdraw from the study at any stage, for any reason.

5. What do I have to do?

What is required of the participant?

6. What are the possible benefits of taking part?

Advise of the benefits of participating, for the patient, for development further advancements etc. Also be clear if there is no direct benefit to the participant.

7. What do I do if I wish to withdraw from the research?

Outline the instructions on how to withdraw from the study.

Part II – How is the study being conducted?

8. What will happen to information about me?

Provide information on how information will be collected, how it will be used and how it will be stored.

9. Who has reviewed the study?

This study has been reviewed and given approval by the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Human Research Ethics Committee (HREC).

10. Further information and who to contact

If you would like any further information on this study you may contact XX at XX.

PARTICIPANT CONSENT FORM

Title

Protocol No

Location

Principal Investigator

1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

4. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future health care.

Name of Participant	Signature of Participant	Date
Name of Member of Study Team	Signature of Member of Study Team	Date

Participant will be provided with a copy of the Participant Information Sheet and this Consent Form
All parties signing the Consent Form must date their own signature

WITHDRAWAL OF PARTICIPATION

To be used for participants who wish to withdraw from the project

Title

Protocol No

Location

Principal Investigator

I hereby wish to WITHDRAW my intent to participate further in the above research project and understand that such withdrawal will not jeopardise my future health care.

Participant's Name (printed) .....

Signature .....

Date .....

Participant will be provided with a copy of this Withdrawal of Consent Form

NB Withdrawal of consent for DNA is separate and the signing of this form does not constitute withdrawal of consent relating to use of DNA. Please also refer to the DNA PI Sheet