

## GUIDELINES FOR PARTICIPANTS

Thank you for taking part in this research study, your participation is greatly appreciated. This leaflet explains your rights as a volunteering participant in this study.

### **What is the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Human Research Ethics Committee (HREC)?**

The RANZCO HREC was established in 2005 to review scientific studies that involve human participants and to protect the welfare and rights of these participants.

### **What does RANZCO HREC approval mean?**

1. If a project has RANZCO HREC approval, this means that the RANZCO HREC has reviewed the research proposal and has agreed that the research is ethically acceptable and in accordance with relevant standards and guidelines.
2. RANZCO HREC approval does not imply that you are obligated to participate in the study.

### **Voluntary participation:**

3. Participation in this research study is voluntary. You may pull out from the project at any time. Withdrawing from a research study will not disrupt your medical care or future medical care, but please keep in mind that it may not be possible to withdraw data that has already been collected. This will depend on the study that you are enrolled in and should be discussed with the investigators.
4. At no time should you feel pressured to participate or to continue if you do not wish to do so.
5. If you do not wish to continue, it would be useful to the researcher to know why, but you are under no obligation to give reasons for not wanting to continue.

### **Informed consent:**

6. Before starting the project, you will be given a participant information leaflet and an informed consent form. These explain the project, your role in it and any potential risks. You should only participate in a clinical trial after careful consideration of this information. Supervised clinical trials are costly but essential to making sure the drugs or devices available to you and your doctor are safe and effective. Please consider your reasons for enrolling in a clinical study and, if necessary, your reasons for early withdrawal from the study. Please keep in mind that withdrawing from a study early can cause delays with development, directly affecting people who genuinely need the drug or device.
7. You must make sure that you understand the information that is given to you. If there is anything that is unclear to you ask the researchers for clarification.
8. You must be happy that the consent form is easy to understand and that you are aware of what you are agreeing to do or participate in.
9. If you are satisfied that you understand the participant information leaflet and the informed consent form and agree to participate, you can then sign the form and ask for a copy for you to keep.