001-FORM-HREC NEW PROTOCOL APPLICATION FORM

Protocol No:					
Protocol Title:					
Meeting date for review by Scientific Review Sub-Committee					
Meeting date for review by Human Research Ethics Committee					
Sponsor:					
Site:					
Phase:		Planned start: _ _/_ _/ _		Anticipated duration (including follow-up):	
Brief summary of project (including sub-studies):					
Australian Clinical Trials Registry Number?					
Anticipated number of subjects to be enrolled at site?					
Anticipated number of subjects to be enrolled worldwide?					
CTN project: Yes ❑; CTX project: Yes ❑ ; Other: Yes ❑ If CTN project please justify (*e.g. Is the investigational approved in Australia? Is the investigational product being used for an unapproved indication*)?					
Has the trial ever been submitted, nationally or internationally, to any person, group or committee for Scientific or Ethical review? (*if yes, please indicate the review person/group/committee and the current status of the trial with regard to that review*). *Please indicate if this study has not been approved by other Ethics Committees.*					
Please indicate the current regulatory status of the product (locally and internationally) including the extent or conditions or the authorisation:					

The Royal Australian and New Zealand College of Ophthalmologists ACN 000 644 404
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Do you have any conflicts of interest? Yes ❑ No ❑ *If yes, please complete Conflict of Interest Declaration FORM-HREC-002 downloadable from the HREC page of the website.*			
Has a power calculation been performed? Yes ❑ No ❑ *If no, please provide reason:*			
Is this an active controlled trial seeking to define non-inferiority? Yes ❑ No ❑ *If yes, please justify the margin of non-inferiority that is pre-specified*			
Is the trial to be conducted according to ICH GCP Yes ❑ No ❑ *If not, please justify*:			
Principal Investigator:			
Name:			
Address:			
Telephone:		Email:	
Suitable contact times during SRC and HREC meeting dates:			
Co-Investigator(s): *Each co- investigator is to be listed (add additional pages if necessary)*.			
Name:			
Address:			
Telephone:		Email:	
Suitable contact times during SRC and HREC meeting dates:			
Note: First time applicants to the RANZCO HREC must also attach proof of medical registration and a copy of their Curriculum Vitae			
For multi-centre studies, please attach a list of each investigator and relevant site where the study will be conducted			
Nominated contact: *Name and address for correspondence from the RANZCO HREC*			
Name:			
Address:			
Telephone:		Email:	

I approve this project to be carried out at Name of Institution:			
CEO/Manager:			
Signature:		Date:	

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Signature of person submitting application:		Date:	
Name:		Fax:	
Telephone:		Email:	

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