003-FORM-HREC

SUBMISSION CHECKLIST

Protocol title:
Principal Investigator:
Human Research Ethics Committee meeting date:
Scientific Review Sub-Committee meeting date:

No.	Description: **All documents should be submitted electronically. The HREC members have signed individual confidentiality agreements and documents will not be distributed except for the purpose of review.**	Yes. Please tick	No. Please tick
1.	New Protocol Application form (001-FORM-HREC) if it used	❑	❑
2.	Completed Ethics Application Form - Low and or Negligible Risk Form (LNR) or Human Research Ethics Application (HREA) (https://hrea.gov.au/) if used	❑	❑
3.	Participant Information and Consent Form (PICF)	❑	❑
4.	Questionnaires, diaries, product information and other documents to be given directly to participants	❑	❑
5.	Recruitment procedures and advertising material (if applicable). If this is not in the protocol please write this as separate document.	❑	❑
6.	Protocol	❑	❑
7.	Short, current signed Curriculum vitae of Principal Investigator (*if not already submitted previously*)	❑	❑
8.	Copy of current medical registration (if required) for Principal Investigator and co-investigators (*if not already submitted previously*)	❑	❑
9.	RANZCO HREC services agreement for commercially sponsored research	❑	❑
10.	Investigator's Brochure for the investigational drug or Product Information (where applicable). *If an Investigator's Brochure is not available then the following information should be provided:* • *Chemical and pharmaceutical data (chemical structure, stereochemistry, physiochemical data, formulation, stability and bioavailability*); • *Preclinical data*; • *Clinical data*; *References to support efficacy and safety of proposed use.*	❑	❑
11.	Australian or overseas product information for the standard treatments used in the trial	❑	❑
12.	NSW Shared Scientific Assessment scheme report (if available)	❑	❑
13.	CTN (where applicable). *For a CTX application include*: • *Section 4 of the CTX;* • *TGA comments and evidence of satisfactory resolution of any issues raised;* • *TGA approved usage guidelines.*		
14.	Conflict of Interest Declaration 002-FORM-HREC if there is a conflict	❑	❑
15.	Medicines Australia Indemnity Form - HREC review only or Standard	❑	❑
16.	Sponsor and Investigator Clinical Trial Agreement	❑	❑
17.	Sponsor Certificate of Insurance	❑	❑
18.	Cover Letter to HREC Chair	❑	❑

Signature of person submitting report:		Date:	_ _/_ _/ _ _
Name:		Fax:	
Telephone:		Email:	

The Royal Australian and New Zealand College of Ophthalmologists			Version:	2.0
Authorised:	DCO: *A. Kiernan*	Date: 2/3/2016	Doc #	003-FORM-HREC
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