The Royal Australian and New Zealand College of Ophthalmologists

RANZCO HREC SUBMISSION FLOWCHART

Approved by: Professor Mark Radford

Approval date: 31 July 2017

Last Review: 1 August 2017

Version: 2

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Types of Studies Considered by the RANZCO HREC

***Clinical / Interventional Studies**:*

- Randomized Controlled Trial
- Double-Blind Randomized Trial
- Single-Blind Randomized Trial
- Non-Blind Trial
- Adaptive Clinical Trial
- Non-Randomized Trial

Observational Studies:

- Prospective Cohort
- Retrospective Cohort
- Time Series Study
- Case-Control Study
- Cross-Sectional Study

Please note: The committee will not review any documentation until fee payment and HREA or LNR application is submitted.

Please refer to the flowchart below to determine what type of application and documentation is required for your submission.

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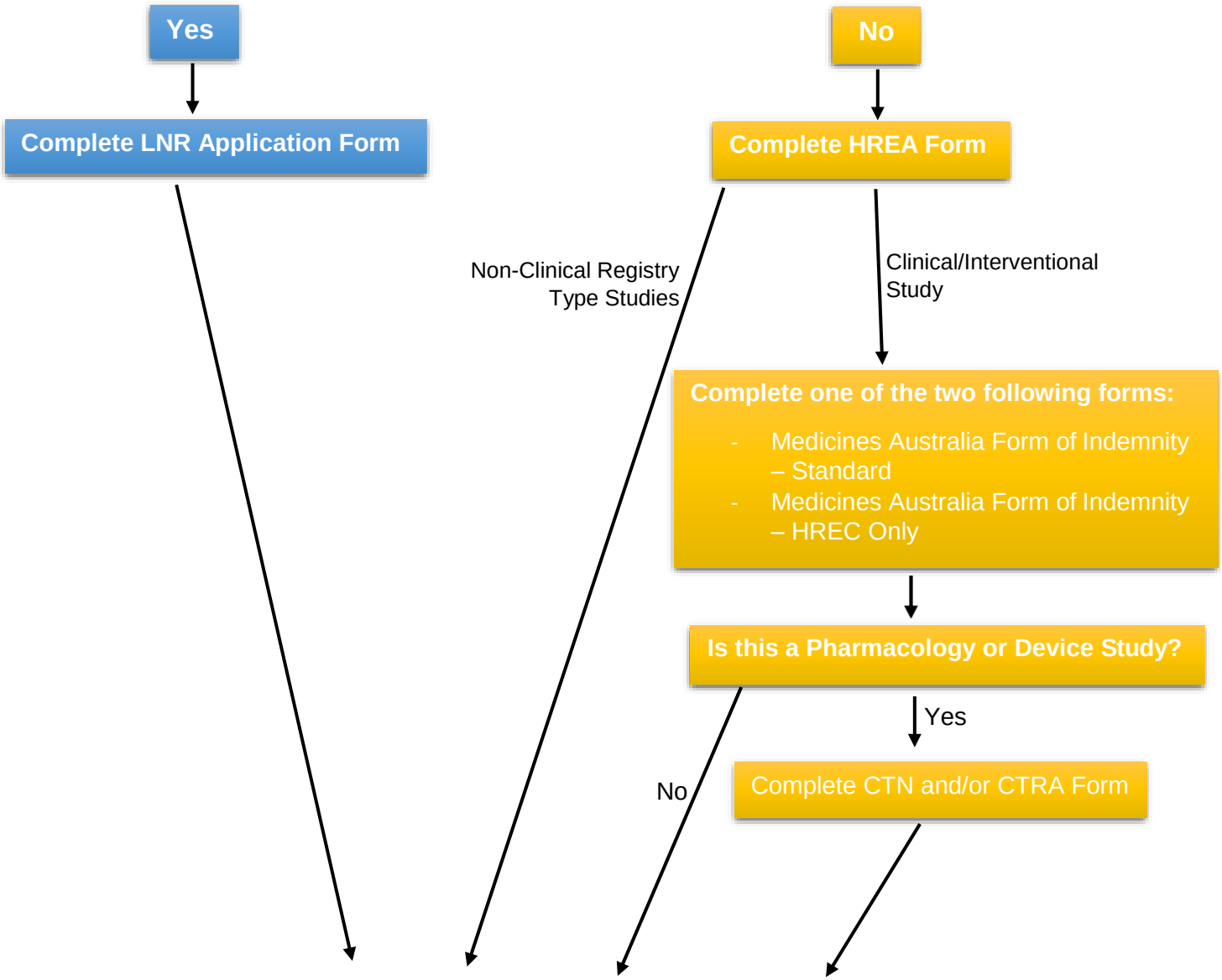
Do you think your submission is Low and/or Negligible Risk?



- ***Title:*** that reflects testable hypothesis
- ***Scientific Merit:*** Has the scientific merit of the study been checked with relevant researchers? (The RANZCO HREC website contains various resources to help guide you with your application)
- ***Research question(s)***
- ***Hypothesis***
- ***Independent and dependent variables***

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- ***Control***
- ***Quantitative parameters***
- ***Criteria used to select patients***
- ***Randomisation***
- ***Power calculations***
- ***Research Protocol:*** has been completed and versioned. Two templates can be found at the WA Health website - WA Health Research Protocol Template for Clinical Trials (MS Word) and the WA Health Research Protocol Template for Non-Clinical Trials (MS Word). A sample protocol is also available under 'templates' on the RANZCO HREC website.

- ***Patient Information and Consent Form (PICF):*** Please ensure these forms have been written in a simple easy to follow manner so patients can understand the study and consent to what they are agreeing. Sample and blank PICFs as well as Patient Information Brochures are provided under 'templates' on the RANZCO HREC website. *N.B. Registry studies or audits may not need a consent form or may need a consent waiver.*

- Description of how ***data*** is de-identified and kept secured and stored. For example, is data password protected? Is it possible for data to be re-identification if a participant needs to be contacted? *N.B. This description is also required in the protocol.*

- Read through ***'Conducting Research – Some Basic Points to Consider'*** available on the RANZCO HREC website and ensure applicable information is included in your application.

- Complete the ***'Submission Checklist'*** available on the RANZCO HREC website.

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