ACT Government
Health

ACT Health
Human Research Ethics Committee

Dr Rohan Essex
Division of Surgery
Building 6, Level 1
Canberra Hospital
Garran ACT 2605

Dear Dr Essex

ETH.11.13.319

The ACT Health Human Research Ethics Committee considered the proposed:

The utility of multifocal pupillographic perimetry (mfPOP), in the management of patients with age-related macular degeneration (AMD) at its meeting of 9 December 2013.

I am pleased to inform you that your application has been approved.

Approval includes:

- HREC Application
- Participant Information Sheet 1
- Consent Form 1
- Participant Information Sheet 2
- Consent Form 2
- NHMRC Grant Notification

I confirm that the ACT Health Human Research Ethics Committee is constituted according to the National Statement on Ethical Conduct in Human Research 2007 and is certified for single review of multi-centre clinical trials. ACT Health HREC operates in compliance with applicable regulatory requirements and the International Conference on Harmonization Guidelines on Good Clinical Practice.

I attach for your records an Outcome of Consideration of Protocol form.

You are reminded that this letter grants ethical approval only. The research project must not commence at any non-ACT Health site until site-specific governance approval has been granted.

Yours sincerely

John Biggs.

Professor John SG Biggs MA MD
FRCOG FRANZCOG DHMSA
Chairman
ACT Health Human Research Ethics Committee

15 January 2014

ACT HEALTH HUMAN RESEARCH ETHICS COMMITTEE

Outcome of Consideration of Protocol

Submission No: **ETH.11.13.319** **Date of Approval:** **15 January 2014**

Project Title: The utility of multifocal pupillographic perimetry (mfPOP), in the management of patients with age-related macular degeneration (AMD)

Submitted by: Dr Rohan Essex

Your project was considered by the ACT Health Human Research Ethics Committee and Approved for a period of 5 years from December 2013 to December 2018

First Annual Review due: January 2015

Conditions of Approval:

- At regular periods, and not less than annually, Principal Investigators are to provide reports on matters including:
  - adverse affects on participants
    - Serious Adverse Events as they occur on site
    - SUSAR/Line Listing reports
  - unforeseen events that could affect the continued ethical acceptability of the project
  - proposed changes in the protocol
  - updates of the investigator brochures
  - continued compliance with approved consent procedures and updates of consent documentation
  - Data Safety Monitoring Board Reports (where applicable)
  - security of records
  - updated insurance coverage
  - compliance with other approved procedures.
- All published reports are to carry an acknowledgement stating:
  - Approved by ACT Health Human Research Ethics Committee on 15 January 2014

John Biggs

Professor John SG Biggs, Chairman 15 January 2014