Auckland DHB
Research Office
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Website:
http://www.adhb.health.nz/health-professionals/research/

27th August 2018

Institutional Approval

David Squirrel
Department of Ophthalmology
Auckland District Health Board
Greenlane Clinical Centre

Dear David,

Re: Research project A+8218 (HDEC 18/CEN/124) Eye Ai

The Auckland DHB Research Review Committee (ADHB-RRC) would like to thank you for the opportunity to review your study and has given approval for your research project.

Your Institutional approval is dependent on the Research Office having up-to-date information and documentation relating to your research and being kept informed of any changes to your study. It is your responsibility to ensure you have kept Ethics and the Research Office up to date and have the appropriate approvals. ADHB approval may be withdrawn for your study if you do not keep the Research Office informed of the following:

- Any communication from Ethics Committees, including confirmation of annual ethics renewal
- Any amendment to study documentation
- Study completion, suspension or cancellation

More detailed information is included on the following page. If you have any questions please do not hesitate to contact the Research Office.

Yours sincerely

On behalf of the ADHB Research Review Committee Dr Mary-Anne Woodnorth
Manager, Research Office
ADHB
c.c. Gayl Humphrey, Bevan Miller, Sarah Welch, Rebecca Stevenson

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AUCKLAND DISTRICT HEALTH BOARD
Te Toka Tumai

POST-APPROVAL REPORTING

Your Ethical and Institutional approval is dependent on the Research Office (RO) having up-to-date information and documentation for your research and being kept informed of any changes to your study. It is **your responsibility** to ensure you have kept Ethics and the RO up to date and have the appropriate approvals. This applies even if ADHB is not the main site for the study.

Please note, when missing or updated document reminders are sent, if the RO receives no response from you after **2 reminders** it will be assumed that your research has been completed and we will notify the relevant Department CD, the RRC and Ethics Committee that your **Locality Assessment Approval has been withdrawn**. This will not be reinstated until all issues have been resolved.

All documents / communications must be referenced with the **ADHB project number**.

ETHICS		
HDEC Annual Progress Report	Use HDEC PAF form, complete and submit **BEFORE** anniversary date of original HDEC approval	o send copy of HDEC approved annual progress report letter to RO when received
Major amendments, design, CI, safety, temporary stops etc. (see HDEC SOP section 11 for definitions)	Write letter detailing changes, mark up changes in relevant documents. Use HDEC PAF form, complete and submit and obtain HDEC approval	o copy letter, changes to RO o send fully signed ADHB amendment form to RO o send copy of HDEC approval letter to RO when received
Financial amendments, including changes in study visits, tests, funding etc.	Liaise with research accountant and adjust budget accordingly. If financial amendment is related to a major amendment also follow requirements for a major amendment.	o Send revised budget using template to RO o send fully signed ADHB amendment form to RO
Minor amendments	Amendments that are minor in nature are reported to HDEC as part of the annual progress report. Only report minor amendments to the RO if proposed amendment will a) impact ADHB resources, e.g. staffing, facilities or consumables, b) potentially impact access to ADHB services for patients NOT in the study, c) require review of revised legal documents, d) involve ADHB service areas that have not previously authorised the research.	o If required send fully signed ADHB amendment form to RO
Serious study related adverse event reporting	If an ADHB patient enrolled in a research study is seriously harmed as a result of their participation in the study the SAE must be reported to the RO	o send the detailed, written SAE report to RO

High risk studies	Studies deemed by RRC to be of high risk must notify ADHB patient enrolments and SAEs to RRC	o notify RO when new ADHB patients are enrolled in the study o immediately notify RO of any SAEs for ADHB patients o send the detailed, written SAE report to RO when available
Notification of conclusion of study	Complete HDEC PAF form and submit	o Send HDEC approved notification of conclusion of study letter to RO o Inform RO if all finance elements also complete
Final Report	Complete HDEC PAF form, upload final report and submit	o Send final report and HDEC approved final report letter to RO o Inform RO when all finance elements also complete

LEGAL		
Contracts, Indemnities, Agreements, insurance certificates, amendments both financial and non-financial of above	All legal documents must be reviewed and approved before signing. Revise budget where relevant	o Send all legal documents to RO o Send revised budget using template to RO where relevant
FINANCIAL		
Budget maintenance	It is recommended that you review and update budgets at least quarterly	o Liaise with accountant and forward update to RO

All documents must be referenced with the ADHB project number and can be sent via email to: ResearchOffice@adhb.govt.nz. All paper copies can be faxed to: 09 307 8913 or by post to: Research Office, Level 14, Support Building, Auckland City Hospital, Private Bag 92024, Auckland, New Zealand.

For further information go to http://www.adhb.health.nz/health-professionals/research/