

28 November 2019

Dr David Squirrell
Department of Ophthalmology
ADHB
dsquirrell@adhb.govt.nz

Dear Dr Squirrell,

Study title: **Grading Diabetic retinopathy: comparison of outcomes generated by an AI deep learning classifier versus gold standard human graders.**

Thank you for emailing HDEC a completed scope of review form on 27 November 2019. The Secretariat has assessed the information provided in your form and supporting documents against the Standard Operating Procedures.

Your study will not require submission to HDEC as, on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the Standard Operating Procedures for Health and Disability Ethics Committees.

An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).

For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:

- one or more participants who will not have given informed consent to participate, or
- one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study), or
- standard treatment being withheld from one or more participants, or
- the storage, preservation or use of human tissue without consent, or
- the disclosure of health information without authorisation.

If you consider that our advice on your project being out of scope is incorrect please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application, but may be used as evidence that HDEC review is not required for it.

Please note, your locality may have additional ethical review policies, please check with your locality. If your study involves a DHB, you must contact the DHB's research office before you begin. If your study involves a university or polytechnic, you must contact its institutional ethics committee before you begin.

Please don't hesitate to contact us for further information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'm poulsen', written in a cursive style.

Matthew Poulsen
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Health and Disability Ethics Committees
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