NHS
Health Research Authority
NRES Committee East of England - Cambridge South
Victoria House
Capital Park
Fulbourn
Cambridge
CB21 5XB

Telephone: 01223 597653
Facsimile: 01223 597645

09 November 2012

Professor Peter Scanlon
Consultant Ophthalmologist
Gloucestershire Hospitals NHS Foundation Trust
GDRRRG office, 3rd Floor
Centre Block, Cheltenham General Hospital
Sandford Road
Cheltenham GL53 7AN

Dear Professor Scanlon

Study title:	**Extension of the dataset for development of a cost-effectiveness model for optimization of the screening interval in diabetic retinopathy screening.**
REC reference:	**12/EE/0517**
Protocol number:	**N/A**

The Proportionate Review Sub-committee of the NRES Committee East of England - Cambridge South reviewed the above application on 08 November 2012.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering Letter from Professor Peter Scanlon		31 October 2012
Investigator CV - Professor Peter Scanlon		
Protocol	Version 2	31 October 2012
REC application	Submission code: 118959/378858/1/981	31 October 2012
Referees or other scientific critique report from Rebecca Whitlock-Neill		15 December 2012

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/EE/0517	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

pp S. Davies

Dr Leslie Gelling
Chair

Email: susan.davies@eoe.nhs.uk

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers" [SL-AR2]

Emailed to: Professor Peter Scanlon peter.scanlon@glos.nhs.uk
Dr Sally Pearson sally.pearson@glos.nhs.uk
Mr Mark Walker mark.walker@glos.nhs.uk

NRES Committee East of England - Cambridge South

Attendance at PRS Sub-Committee of the REC meeting on 08 November 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Leslie Gelling	(Chair) Reader in Research Ethics	Yes	
Mr Colin Green	Drugs & Therapeutics Pharmaceutical Advisor	Yes	
Miss Angela Palmer	Retired Patent Litigator	Yes	
Dr Frank Wells	(Vice-Chair) Retired Pharmaceutical Physician	Yes	