



# Health Research Authority

## NRES Committee South Central - Oxford C

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07 July 2014

Professor Kenneth Young  
Royal Surrey County Hospital  
Department of Medical Physics  
Royal Surrey County Hospital  
Guildford  
GU2 7XX

Dear Professor Young

**Title of the Research Database:** OPTIMAM Image Database: Version 1  
**REC reference:** 14/SC/0258  
**IRAS project ID:** 145706

Thank you for your letter of 03 July 2014, responding to the Committee's request for further information on the above research database.

The further information was considered at the meeting of the Sub-Committee of the REC held in correspondence. A list of the members who were present at the meeting is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC manager Miss Lauren Allen, [nrescommittee.southcentral-oxfordc@nhs.net](mailto:nrescommittee.southcentral-oxfordc@nhs.net).

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation

### Additional conditions of approval

In addition to the standard conditions attached, ethical approval is subject to the following:

### Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may

be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		17 April 2014
Other [OPTIMAM2 Research Protocol]	1	17 April 2014
Other [SOPs for release of data]	1	12 June 2014
Protocol for management of the database	1	17 April 2014
REC Application Form		17 April 2014
Response to Request for Further Information [Letter to Ethics]		03 July 2014

## Research governance

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research databases.

## 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

## Health Research Authority

The attached standard conditions give detailed guidance on reporting requirements for research databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA 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 HRA website:

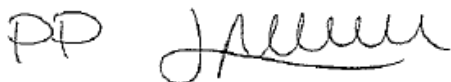
<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**14/SC/0258**

**Please quote this number on all correspondence**

Yours sincerely



**Professor Nigel Wellman**  
**Chair**

E-mail: [nrescommittee.southcentral-oxfordc@nhs.net](mailto:nrescommittee.southcentral-oxfordc@nhs.net)

*Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments  
Approval conditions*

### Attendance at Sub-Committee of the REC meeting in correspondence

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Yes	
Mrs Rachael Quinn	Nurse Member	Yes	
Professor Nigel Wellman (Chair)	Professor of Health and Human Sciences	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Lauren Allen	REC Manager