

South Central - Oxford C Research Ethics Committee

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Lewins Mead
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BS1 2NT
Telephone: 0207 1048 045

12 July 2019

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

Dear Professor Young

Title of the Database: OPTIMAM Image Database: Version 2
REC reference: 19/SC/0284
IRAS project ID: 265403

The Research Ethics Committee reviewed the above application at the meeting held on 28 June 2019. Thank you for attending to discuss the application.

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation, subject to the conditions specified below.

This application was for the renewal of a Research Database application. The previous REC Reference number for this application was 14/SC/0258

Conditions of the favourable opinion

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

Ethical Review - Conditions of Favourable Opinion
The Committee requested that the protocol was updated to remove reference to Dropbox being used.

Research governance

Under the UK Policy Framework for Health and Social Care Research, 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.

Assessment of site suitability is not a requirement for ethical review of research databases.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter. The favourable opinion has been renewed for five years from the end of the previous five year period 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.

Research Database Renewals

The previous five-year period ran from 07 July 2014 to 07 July 2019.

This Research Database may be renewed for further periods of five years at a time by following the process described in the above paragraph.

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		
IRAS Checklist XML [Checklist_07052019]		07 May 2019
IRAS Checklist XML [Checklist_18062019]		18 June 2019
IRAS Checklist XML [Checklist_20062019]		20 June 2019
Other		29 April 2019
Other [CV KY V3]	V3	18 June 2019

Other [OPTIMAM patient info poster V4]	V4	04 June 2015
Other [Staff Briefing Document]	2	25 June 2019
Protocol for management of the database	2.4	01 April 2019
REC Application Form [RD_Form_07052019]		07 May 2019
Summary of research programme(s)	2	16 April 2019

Membership of the Committee

The members of the Ethics Committee who were present at the meeting 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 standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received 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/>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

19/SC/0284

Please quote this number on all correspondence

Yours sincerely

P.P. Ubeda

**Dr Lee Potiphar
Chair**

E-mail: 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

Copy to: Ross Dunworth, Royal Surrey County Hospital

South Central - Oxford C Research Ethics Committee

Attendance at Committee meeting on 28 June 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	No	
Mr David Carpenter	Retired Social Scientist	Yes	
Dr Linda Cartwright	Retired Consultant Epidemiologist	Yes	
Dr Ben Caswell	Accountant	No	
Mrs Rebekah Howe	Farmer	No	
Mrs Vivienne Laurie	Barrister	Yes	
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Yes	
Mr Barry Muir	NHS Management Consultant (Retired)	Yes	
Dr Lee Potiphar	Lecturer in Adult Nursing (Evidence Based Practice)	Yes	
Ms Anna Rathmell	Medical Manager - GI	No	
Dr Pamela Susan Ross	GP Principal	Yes	
Dr Sabeena Sharma	Consultant Anaesthetist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Maeve Ip Groot Bluemink	REC Manager