

South Central - Oxford C Research Ethics Committee

Health Research Authority
2 Redman Place, Stratford, London
E20 1JQ

Professor Kenneth Young
Royal Surrey NHS Foundation Trust
Department of Medical Physics
Royal Surrey NHS Foundation Trust
Egerton Road
GU2 7XX

Dear Professor Young

Title of the Database:	OPTIMAM Image Database: Version 3
REC reference:	24/SC/0099
IRAS project ID:	336625

The Research Ethics Committee reviewed the above application at the meeting held on 26 April 2024. Thank you for attending to discuss the application.

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 19/SC/0284.

Conditions of the favourable opinion

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

Publication of Your Research Summary

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. Where a deferral is agreed, [a minimum research summary](#) will still

be published in [the research summaries database](#). At the end of the deferral period, we will publish the [full research summary](#).

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: [Research summaries - Health Research Authority \(hra.nhs.uk\)](#)

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 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 12.07.2019 to 12.07.2024. 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 [Covering letter]		01 March 2024
Other [Annual report to REC]	1	03 August 2023

Other [Guidelines for data access committee]	1	02 August 2023
Other [Applicant's CV]	1	01 March 2024
Participant information sheet (PIS) [Patient Information poster]	4	04 June 2015
Protocol for management of the database [Database management protocol]	2.8	14 March 2023
REC Application Form [RD_Form_05032024]		05 March 2024
Summary of research programme(s) [Research protocol]	3	09 January 2024
Summary of research programme(s) [Research protocol with changes]	3	09 January 2024

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/>

IRAS project ID: 336625

Please quote this number on all correspondence

Yours sincerely

PP.

Hayleigh Keating
Approvals Specialist

Dr Lee Potiphar
Chair

E-mail: oxfordc.rec@hra.nhs.uk

Copy to: Mr Ross Dunworth, Royal Surrey NHS Foundation Trust

South Central - Oxford C Research Ethics Committee

Attendance at Committee meeting on 26 April 2024

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Susan Adams	Site Integration Manage and Regional Infrastructure Manager	Yes	
Dr Linda Cartwright	Retired Consultant Epidemiologist	Yes	
Dr Ben Caswell	Accountant	Yes	
Dr Colin Cowan	Locum Consultant Psychiatrist	Yes	
Dr Chantel Cox	Lecturer Adult Nursing	No	
Mrs Elizabeth Cray	Neurosurgical Advanced Clinical Practitioner	Yes	
Mrs Vivienne Laurie	Barrister	Yes	
Dr Nadia Muspratt-Tucker	ST5 Registrar in Obstetrics and Gynaecology	No	
Dr Lee Potiphar	Assistant Professor in Adult Nursing and Learning Support Lead	Yes	
Ms Anna Rathmell	Associate Director Learning and Development, Pharmaceuticals	Yes	
Dr David Scott	Lecturer	No	
Dr John Andrew Sutton	Medical Director	Yes	
Mr Ioan Wigley	Regulatory Affairs Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Hayleigh Keating	Approvals Specialist
Dan Lewis	Approvals Administrator
Mark Thompson	Approvals Officer
Dr Jazz Urquhart	Approvals Administrator