East Midlands - Derby Research Ethics Committee
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London
EC20 1JQ

Telephone: N/A
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08 August 2023

Professor Julia Hippisley-Cox
University of Oxford
Nuffield Department of Primary Care Health Sciences
Radcliffe Observatory Quarter
Woodstock Road
OX2 6GG

Dear Professor Hippisley-Cox

Title of the Database:	**QResearch-Oxford Data Linkage Project**
REC reference:	**23/EM/0166**
IRAS project ID:	**329187**

The Research Ethics Committee reviewed the above application at the meeting held on 03 August 2023. 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 257790.

Conditions of the favourable opinion

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

Number	Condition
1.	The Committee request a copy of the poster displayed in the GP Practices is submitted. **Which we have received**.
2.	The Committee request the following minor changes were made to the PIS: • Remove the word "to" after "information sent", page 2, point 6. • Update the name of the REC approving the study from Derby multi- centre to just Derby.
	Recommendation
1.	The Committee recommend that the translation of documentation was re-visited, possibly with newly recruited GP Practices asking them what languages would be useful for the patients at their Practice.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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.

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/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus

disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

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 18th December 2018 to 18th December 2023.
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:

Document	*Version*	*Date*
Other [Annual report]		19 December 2022
Participant consent form		
Participant information sheet (PIS)		
Protocol for management of the database		

REC Application Form [RD_Form_05072023]		05 July 2023
Summary of research programme(s)		

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

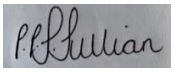
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the 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: 329187	Please quote this number on all correspondence

Yours sincerely



Mrs Janet Mallett
Chair

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

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

(RD) Conditions of Approval

Research Database – Conditions of Approval]

Copy to: [R&D office for NHS care organisation]
Mr Philip Nieri, University of Oxford

East Midlands - Derby Research Ethics Committee

Attendance at Committee meeting on 03 August 2023

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Andres Almario	Paediatric Respiratory Medicine Consultant	No	
Dr Johanna Cornwell	Retired General Practitioner	No	
Mrs Janet Mallett (Chair)	Retired Nurse & Derby REC Chair	Yes	
Mrs Esther Panek-Noble	Senior Clinical Trials Manager	Yes	
Dr Christina Peters	ST3 - Clinical Oncology	No	
Ms Bernadette Roberts (Co-optee)		Yes	
Dr Liz Simpson	Senior Research Fellow	Yes	
Dr Margaret Stone	Senior Research Fellow (Retired)	Yes	
Dr Carolyn Tang	Medical Oncology Specialist Registrar	Yes	
Ms Margret Vince	Translator	Yes	
Mr Patrick (Joe) Walsh	Retired Associate Engineering Fellow	No	

Also in attendance:

Name	*Position (or reason for attending)*
Michelle Ahmed	Approvals Specialist
Carolyn Halliwell	Approvals Specialist
Faye Siewierski	Approvals Administrator
Susan Sullivan	Approvals Administrator
Mark Thompson	HRA Approvals Officer
David Williams	Approvals Administrator