



Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

27 December 2018

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

Dear Professor Hippisley-Cox

Title of the Research Database:	QResearch-Oxford Data Linkage Project
REC reference:	18/EM/0400
IRAS project ID:	257790

Thank you for your email of 20.12.2018, responding to the Committee's request for further information on the above research database.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study

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.

This application was for the renewal of a Research Database application. The previous REC Reference number for this application was 03/4/021.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter 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

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]	1.0	19 November 2018
IRAS Checklist XML [Checklist_20122018]		20 December 2018
Other [CV Prof Julia Hippisley-Cox]		19 November 2018
Other [University of Oxford letter]		29 November 2018
Participant consent form [Practice Information Sheet]	3.0	10 August 2015
Participant information sheet (PIS) [QResearch Patient Information Sheet]	3.0	05 December 2017
Protocol for management of the database [QResearch Protocol]	4.0	19 November 2018
REC Application Form [RD_Form_20122018]		20 December 2018
Summary of research programme(s) [QResearch Summary of Research Program]	1.0	19 November 2018

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



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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

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.

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 Training

We are pleased to welcome researchers and R&D staff at our training days – see details at:

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



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Please quote this number on all correspondence

Yours sincerely

PP *Seija Ryhä*

Dr John S Fenlon
Chair

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: Approval conditions

*Copy to: Professor Richard Hobbs, Nuffield Department of Primary Care
Sciences, University of Oxford*