

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 1048310

27 March 2020

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 Database:	QRResearch-Oxford Data Linkage Project
REC reference:	18/EM/0400
Amendment number:	amendment number: 1 (COVID 19 EXPEDITED)
Amendment date:	26 March 2020
IRAS project ID:	257790

We need to link our existing GP database to the national ITU database

There are two main changes required:

1. to expand the GP practices contributing to Research to include practices which use a different computer system known as Systeme which is supplied by a company known as TPP. This will give a larger population of patients and enable more national coverage of patient who subsequently go into hospital and onto ITU and then die from COVID.

2. to link to a new database of data from 185 Intensive Care Units nationally which has the clinical data for all patients on ITU including those with severe disease requiring ventilation. This data will be anonymised at source using the existing approved processes and governance controls for anonymising and linking data. The resulting database will continue to be anonymised. No direct identifiers are received or will be received by Oxford.

The above amendment was reviewed by the ad-hoc Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (RD) [QResearch Amendment 1 - 26th March 2020]	amendment number: 1 (COVID 19 EXPEDITED)	26 March 2020
Protocol for management of the database [QResearch Protocol version 5 - Clean]	5	26 March 2020
Protocol for management of the database [QResearch Protocol version 5 - Marked.]	5	26 March 2020

Membership of the Committee

The members of the Ethics Committee who took part in the review 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.

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/>

18/EM/0400

Please quote this number on all correspondence

Yours sincerely



Dr John Fenlon
Chair of Committee

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

Enclosures: List of names and professions of members who took part in the review

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

East Midlands - Derby Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 27 March 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Brian Hands	Retired General Practitioner	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	Meeting Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Sarah Graves	HRA Approvals Officer