

East Midlands - Derby Research Ethics Committee

The Old Chapel Royal Standard Place Nottingham NG1 6FS

Telephone: +442071048276

09 February 2021

Professor Julia Hippisley-Cox Nuffield Department of Primary Care Sciences, University of Oxford 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: REC reference: Amendment number: Amendment date: IRAS project ID: QResearch-Oxford Data Linkage Project 18/EM/0400 Amendment 7 03 February 2021 257790

The above amendment was reviewed by the 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:

| Document | Version | Date |
|---|---------|------------------|
| Notice of Amendment (RD) [Qresearch Amendment 7 20.01.2021] | | 03 February 2021 |
| Participant information sheet (PIS) [QResearch Patient Information 3.7 marked_REC_commented_reply copy] | 3.7 | 08 February 2021 |
| Participant information sheet (PIS) [QResearch Patient Information 3.7 clean] | 3.7 | 08 February 2021 |
| Protocol for management of the database [QResearch Protocol version 7.3-marked] | 7.3 | 08 February 2021 |
| Protocol for management of the database [QResearch Protocol version 7.3-clean] | 7.3 | 08 February 2021 |

Membership of the Committee

The members of the Ethics Committee who took part in the review are listed on the attached sheet.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. 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 have not 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.

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/

IRAS Project ID: 257790

Please quote this number on all correspondence

Yours sincerely

Dr John S Fenlon Chair

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 02 February 2021

Committee Members:

| Name | Position (or reason for attending) | |
|------------------|--|--|
| Dr John S Fenlon | Statistical Consultant – Meeting Chair | |
| Ms Margret Vince | Translator | |

Also in Attendance:

| Name | Profession | Present | Notes |
|----------------|-------------------------|---------|-------|
| Ms Sarah Ferry | Approvals Administrator | Yes | |