

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)

QResearch-Oxford Data Linkage Project

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Combined trial of an investigational medicinal product and an investigational medical device
- Clinical investigation or other study of a medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

3. In which country of the United Kingdom is the database established?

- England
- Scotland
- Wales
- Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying data to the database be located?

(tick all that apply)

- England
- Wales
- Scotland
- Northern Ireland

4. Which applications do you require?

- Social Care Research Ethics Committee
- Research Ethics Committee
- Confidentiality Advisory Group (CAG)

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

- Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

- Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify substantial amendments to approved research databases only. The form should be submitted by the Data Controller (i.e. the person with overall responsibility for management of the database).

Details of Data Controller:

	Title	Forename/Initials	Surname
	Professor	Julia	Hippisley-Cox
Work Address	Nuffield Department of Primary Care Health Sciences		
	Radcliffe Observatory Quarter		
	Woodstock Road, Oxford		
Post Code			
Email	julia.hippisley-cox@phc.ox.ac.uk		
Telephone	07879708647		
Fax			

Title of the Database:

QResearch-Oxford Data Linkage Project

Name of the establishment:

Nuffield Department of Primary Care Sciences, University of Oxford

Name of main REC:

East Midlands - Derby

REC reference number:

18/em/0400

Protocol reference (if applicable), current version and date:

Protocol version 10, 6th June 2022

Amendment number and date:

8 26th July 2022

Type of amendment

(a) Amendment to information previously given in IRAS

Yes No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

Yes No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

please see revised protocol with track changes

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting

documentation for the study

Yes No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold. please see revised protocol which includes participant information

Is this a modified version of an amendment previously notified and not approved?

Yes No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance.

If this is a modified amendment, please explain how the modification address the concerns raised previously by the ethics committee.

Section 3.2 and 3.5 of the protocol has been updated to include addition of new data linkages to undertake research into safety of medicines in pregnancy including but not limited to COVID-19 vaccination

- Maternal confidential enquiry data (lead Marian Knight, MBRRACE-UK)
- UK teratology dataset (lead Ken Hodson, UK Teratology Information Service)
- NHS number for babies (NHS Digital)
- Specialised prescribing for other hospital-only prescriptions (NHS England)
- Civil registration births (ONS)
- Maternity dataset (NHS digital)

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of the Research Ethics Committee is sought.

The additional data for linkage will be anonymised at source using 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.

List of enclosed documents

Document	Version	Date
Protocol	10	26/07/2022

Declaration by the Data Controller

1. I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I confirm that the establishment responsible for management of the database has been notified of the proposed amendment.

Date:

Signature: