National Research Ethics Service



# RESEARCH DATABASE Annual Report to Research Ethics Committee

Research databases with approval from a Research Ethics Committee are required to provide the REC with an annual report on their activities. This form sets out the minimum content of the report and a template format, which may be adapted appropriately.

### 1. Details of the Chief Investigator of the Research Database ("Data Controller")

Name:	Julia Hippisley-Cox
Address:	Nuffield Department of Primary Health Care Sciences, University of Oxford
E-mail:	julia.hippisley-cox@phc.ox.ac.uk

#### 2. Details of the Database

Title:	QResearch@Oxford Data Linkage Project
Establishment responsible for management of the database:	University of Oxford
Data Custodian  This should be a senior individual, not part of the research database team, who is responsible for oversight of the database within the establishment.	Phil Nieri, Information Governance Manager Department of Primary care Health Sciences, University of Oxford philip.nieri@phc.ox.ac.uk
Main REC:	East Midlands – Derby Research Ethics Committee
REC reference number:	18/EM/0400

#### 3. Summary of activity for [period covered by report]

Please provide an overall summary of the database's activities during the year, including:

- Data collection
- Use /release of data
- Collaborations with other databases /programmes
- Engagement with patients/service users and publicity
- Any significant developments in the database's scope, operation or governance.

#### 3.1 Data collection

More recent data from general practice, cancer registry, civil registry, hospital episode statistics, Intensive Care National Audit and Research Centre (ICNARC) and from Public Health England Second Generation Surveillance System (PHE SGSS) statistics have been collected during the year and uploaded into the QResearch linked database. COVID-19 vaccination data from the National Immunisation (NIMS) Database have been added into the QResearch linked database.

Arrangements are being made currently to add transplantation data and new therapeutics for COVID-19 including antivirals/monoclonal antibody data (progressed as a non-substantial amendment with an update to the protocol to version 9.0).

#### 3.2 Use/release of data

Please see appendix for a list of the currently approved projects most of which are using combinations of the GP data linked to HES, cancer registry, mortality, ICNARC and COVID-29 and NIMS COVID-19 vaccination data.

#### 3.4 Database Scope, Operation and Governance.

There have been no major changes to the database scope, operation or governance. There are continual improvements to the QResearch Scientific and the QResearch Advisory Board as follows

#### 3.4.1 QResearch Scientific Committee.

- Following an open recruitment process, we have recruited a new chair (Dr Paul Dhiman) and deputy chair (Dr Brian MacMIllan) to bring the total membership of the committee to 15 members. The committee continues to become more diverse with both academics and lay representatives from within and external to Oxford. More details on members are published on the relevant section of the QResearch website. <a href="https://www.gresearch.org/about/scientific-committee/">https://www.gresearch.org/about/scientific-committee/</a>.
- Minutes of the Scientific Committee are published here.
- There is an ongoing process for researchers applying for grants to request fast track approval of urgent projects including but not limited to COVID-19.

#### **QResearch Advisory Board.**

 The advisory board met in several times during 2021 and provided guidance and advice on a number of initiatives to support the COVID-19 pandemic including new data linkages. Further information, including minutes of meetings, is published here <a href="https://www.qresearch.org/about/advisory-board/">https://www.qresearch.org/about/advisory-board/</a>

#### Engagement with patients and service users and publicity

- Engagement with practices: we continue to produce a quarterly newsletter which is disseminated via social media and our website (QResearch) and the Oxford University Website.
- Engagement with patients: There are three patient representatives on the QResearch Advisory Board who provide feedback on aspects relevant to patients including information provided to patients, lay summaries of ongoing projects, governance and potential benefits of QResearch. As a response to these patients, we have now included lay representatives on our science committee
- QResearch website lay summary: more information about new and ongoing
  projects continued to be published including a lay summary. This continues to be
  reviewed by our patient representatives on the advisory board.
  https://www.gresearch.org/research/approved-research-programs-and-projects/
- QResearch Data Showcase; We have continued to update data section on the
  website which gives a high-level overview of the types of data collected and broad
  summaries for some major conditions (e.g. the total numbers of patients with cancer
  on the database). This is intended to provide more information to both services
  users and researchers interested in using the resource.
  https://www.gresearch.org/data/

#### Use and release of data

In accordance with our protocol, all data is held on Oxford servers. No data is
physically released to researchers – rather researchers who have approved projects
and have met the eligibility criteria (including appropriate IG training) are provided
with remote access to the server where the relevant subset of data is located. A full
list of all current projects (including ongoing projects approved under the previous
REC application prior to the move to Oxford) is appended.

#### 4. Applications for access to data

Please append a listing of applications made to the database for release of, or access to, data during the reporting period, together with a lay summary of the purpose of each approved project. Include any releases authorised following a further project-specific application to a REC, as well as those authorised under generic approval.

#### 5. Declaration

Signature of database manager:	Juli Hippuly lox
Date of submission:	17/12/2021

## Applications for release of data

Please also provide a lay summary (maximum 200 words) for each project for which release of data was approved. Include both projects conducted within the research database team and by external researchers. Where further project-specific approval was given by a REC, please include the REC Reference Number in the additional comments.

## Projects approved in 2021

	Project title	name of chief investigator	lead institution	Type New application or amendment	QR science outcome	link to lay summary where data released and summary of data set (200 words)
OX107	Uptake and comparative safety of new COVID-19 vaccines by age, sex, region, ethnicity, comorbidities, medication, deprivation, risk level and evidence of prior COVID infection	Prof Julia Hippisley-Cox	University of Oxford	New application	Approved	Uptake and comparative safety of new COVID-19 vaccines by age, sex, re ethnicity, comorbidities, medication, deprivation, risk level and evidence COVID infection - QResearch
OX125	CoMPuTE: Complex Multimorbidity Phenotypes, Trends, and Endpoints	Prof Rafael Perera	University of Oxford	New application	Approved	Complex Multimorbidity Phenotypes, Trends, and Endpoints -
OX128	Exploring the Long Term health outcomes of a Pregnancy with gestational Diabetes (ELOPE-GDM)	Dr Nerys Astbury	University of Oxford	New application	Approved	Exploring the Long Term health outcomes of a Pregnancy with gestationa (ELOPE-GDM) - QResearch
OX30	Development and validation of personalised risk prediction models for early detection and diagnosis of hepatocellular carcinoma (HCC) among the English population from primary care	Professor Ellie Barnes	University of Oxford	New application	Approved	Development and validation of personalised risk prediction models for eadetection and diagnosis of hepatocellular carcinoma (HCC) among the Enpopulation from primary care - QResearch
OX102	Quantifying the association between ethnicity and COVID-19 outcomes: a	Prof Julia Hippisley-Cox	University of Oxford	Amendment	Approved	Quantifying the association between COVID-19, ethnicity and mortality: a study across three UK national databases - QResearch

	population-based study using QResearch linked databases					
OX123	The impact of the COVID-19 pandemic on the diagnosis of childhood, teenage and young adult cancers	Dr Defne Saatci	University of Oxford	Amendment	Approved	The impact of the COVID-19 pandemic on the diagnosis of childhood, tee young adult cancers - QResearch
OX300	Optimising NHS blood cancer patient care in the Covid-19 pandemic	Prof Julia Hippisley-Cox	University of Oxford	New Application	Approved	Optimising NHS blood cancer patient care in the COVID-19 pandemic - QI
OX153	Development and validation of a decision risk tool (QPancreasD) for early diagnosis of pancreatic ductal adenocarcinoma (PDAC) among newonset diabetes in UK primary care	Dr Pui San Tan	University of Oxford	New Application	Approved	Decision risk tool (QPancreasD) for early diagnosis of pancreatic ductal adenocarcinoma (PDAC) among new-onset diabetes - QResearch
OX37	The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases (DART)	Prof Julia Hippisley-Cox	University of Oxford	Amendment	Approved	The Integration and Analysis of Data using Artificial Intelligence to Impro Outcomes with Thoracic Diseases (DART) - QResearch
OX86	COVID-Associations between COVID-19 infection, common respiratory conditions, drugs used for their treatment, tobacco and nicotine use: a prospective QResearch-Case Mix Programme data linkage study January-May 2020	Prof Julia Hippisley-Cox	University of Oxford	Amendment	Approved	COVID-19, smoking and respiratory conditions: a prospective QResearch-Programme study - QResearch
OX54	Characteristics of Chronic Hepatitis B associated with Cirrhosis and Cancer: analysis of a large UK primary care database.	Ms Cori Campbell	University of Oxford	Amendment	Approved	Characteristics of Chronic Hepatitis B associated with Cirrhosis and Cance QResearch
OX57	Impact of GP intervention and smoking cessation on secondary prevention of cardiovascular disease in individuals	Ms Angela Wu	University of Oxford	New Application	Approved	Examining effects of GP intervention and smoking cessation on secondar prevention of cardiovascular disease - QResearch

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	diagnosed with coronary heart disease and stroke					
OX7	Antipsychotic prescribing and monitoring of physical health in children and adolescents with mental health problems: a cohort study using primary care data	Prof Yana Vinogradova	University of Oxford	Amendment	Approved	Antipsychotic use in children and adolescents - QResearch
OX90	The Impact of Miscarriage on Mental Health Outcomes	Prof Stavros Petrou	University of Oxford	Amendment	Approved	The Impact of Miscarriage on Mental Health Outcomes - QResearch
OX24	Use of hormone replacement therapy and survival from cancer	Dr Christopher Cardwell	Queens University of Belfast	Amendment	Approved	Use of hormone replacement therapy and survival from cancer - QResea
OX79	OX79 Coronavirus Record Linkage Project	Prof Julia Hippisley-Cox	University of Oxford	Amendment	Approved	QResearch-ICNARC Coronavirus Record Linkage Project - QResearch
OX29	Maternal depression and anxiety disorders and child mental health outcomes	Dr Catia Nicodemo	University of Oxford	Amendment	Approved	Maternal depression and anxiety disorders and child mental health outco QResearch
OX3	Choosing the right antidepressant for depressive disorder	Professor Andrea Cipriani	University of Oxford	Amendment	Approved	Choosing the right antidepressant for depressive disorder - QResearch
OX69	Seasonal trends in antidepressant prescribing, depression, anxiety, and self-harm in adolescents and young adults: study using UK primary care data	Dr Ruth Jack	University of Nottingham	Amendment	Approved	Seasonal trends in antidepressant prescribing and mental health diagnos adolescents and young adults - QResearch
OX115	Evaluating diabetes as a risk pathway towards early diagnosis and prognostication of pancreatic ductal adenocarcinoma (PDAC) using the UK QResearch database	Prof Julia Hippisley-Cox	University of Oxford	Amendment	Approved	Diabetes as a risk pathway towards early diagnosis and prognostication of pancreatic cancer - QResearch
OX94	Understanding the early presenting features and long-term complications of childhood and adolescent cancer	Dr Defne Saatci	University of Oxford	New Application	Approved	<u>Understanding the early presenting features and long-term complication childhood and adolescent cancer</u>

	Long Term Complications of Childhood, Adolescent and Young Adult Cancers	Dr Defne Saatci	University of Oxford	New Application	Approved	Long Term Complications of Childhood, Adolescent and Young Adult Can

# Projects approved in 2020

	Project title	name of chief investigator	lead institution	QR science outcome	link to lay summary where data released and summary of data set (200 words)
OX24	Use of HRT and cancer survival	Chris Cardwell	Queen's University Belfast	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/use-of-hormone-replacement-therapy-and-survival-from-cancer/
OX66	Hormone replacement therapy and dementia risk: nested case-control studies using CPRD and QResearch	Julia Hippisley-Cox	University of Oxford	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/hormone-replacement-therapy-and-dementia-risk-nested-case-control-studies-using-gresearch-and-cprd/
OX54	Hepatitis B - natural history and burden of disease	Cori Campbell	University of Oxford	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/characteristics-of-chronic-hepatitis-b-associated-with-cirrhosis-and-cancer/
OX29	Maternal depression and anxiety disorders and child mental health outcomes	Catia Nicodemo	University of Oxford	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/maternal-depression-and-anxiety-disorders-and-child-mental-health-outcomes/
OX85	The effect of obesity on incidence and severity of COVID-19	Nerys Astbury	University of Oxford	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/examining-the-effects-of-obesity-on-the-severity-of-covid-19-symptoms/
OX86	Associations between COVID-19 infection, tobacco smoking and nicotine use, common respiratory conditions and drugs used for their treatment, : a prospective QResearch-Case Mix	Nicola Lindson	University of Oxford	Approved	https://www.qresearch.org/research/approved-research-programs-and-projects/covid-19-smoking-and-respiratory-conditions-a-prospective-qresearch-case-mix-programme-study/

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	Programme data linkage study January- May 2020				
OX99	A second wave of crisis in the NHS after	Catia	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-projects/a-
	the COVID-19 pandemic	Nicodemo	Oxford		second-wave-of-crisis-in-the-nhs-after-the-covid-19-pandemic/
OX100	Development and validation of a tool	Ashley Clift	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
	for predicting risk of short-term adverse		Oxford		projects/development-and-evaluation-of-a-tool-for-predicting-risk-of-short-term-
	outcomes from COVID-19				adverse-outcomes-due-to-covid-19-in-the-general-uk-population/
OX90	Economic costs associated with	Stavros	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
	miscarriage: A secondary analysis of	Petrou	Oxford		projects/economic-costs-associated-with-miscarriage-a-secondary-analysis-of-
	QResearch				qresearch/
OX102	Quantifying the association between	Julia	University of	Approved	https://www.qresearch.org/research/approved-research-programs-and-
	ethnicity and COVID-19 outcomes: a	Hippisley-Cox	Oxford		projects/quantifying-the-association-between-covid-19-ethnicity-and-mortality-a-
	population-based study using QResearch linked databases				cohort-study-across-three-uk-national-databases/
OX7	Antipsychotic prescribing and	Yana	University	Approved	https://www.qresearch.org/research/approved-research-programs-and-
	monitoring of physical health in children	Vinogradova	of		<pre>projects/qresearch-icnarc-coronavirus-record-linkage-project/</pre>
	and adolescents with mental health		Nottingham		
	problems: a cohort study using primary				
01/400	care data	2.2.6			
OX123	The impact of the COVID-19 pandemic	Dr Defne	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-projects/the-
	on the diagnosis of childhood, teenage and young adult cancers	Saatci	Oxford		impact-of-the-covid-19-pandemic-on-the-diagnosis-of-childhood-teenage-and-young-adult-cancers/
OX115	Evaluating diabetes as a risk pathway	Shivan	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
OVIII	towards early diagnosis and	Sivakumar,	Oxford	Approved	projects/diabetes-as-a-risk-pathway-towards-early-diagnosis-and-prognostication-of-
	prognostication of pancreatic ductal	Rachael	Oxidia		pancreatic-cancer/
	adenocarcinoma (PDAC) using the UK	Bashford-			puncted the editecty
	QResearch database	Rogers			
OX39	DELTA - integrateD diagnostic solution	Rebecca	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
	for EarLy deTection of oesophageal	Fitzgerald	Cambridge		projects/ox39-project-delta-integrated-diagnostic-solution-for-early-detection-of-
	cAncer				oesophageal-cancer/
OX129	Development and validation of	Ashley Clift	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
	statistical learning models to predict		Oxford		projects/development-and-validation-of-statistical-learning-models-to-predict-
	breast cancer diagnosis and breast				breast-cancer-diagnosis-and-breast-cancer-mortality-in-the-general-population-a-
	cancer mortality in the general				cohort-study/
	population: a cohort study				

OX22	Dietary or weight loss advice for	Carmen	University of	Approved	https://www.gresearch.org/research/approved-research-programs-and-
	hypertension in diabetes in primary care	Piernas	Oxford		<pre>projects/dietary-or-weight-loss-advice-for-hypertension-in-diabetes-in-primary-care/</pre>

# Ongoing projects reports in 2019 annual report.

	Project title	name of chief investigator	lead institution	QR science outcome	link to lay summary where data released (200 words)
Q110	QFracture - risk of osteoporotic fracture	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qfracture-risk-of-osteoporotic-fracture/
Q115	QDiabetes Risk Assessment Tool	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-assessment-tool/
Q112	QKidney - predicting the risk of chronic kidney disease	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qkidney-predicting-the-risk-of-chronic-kidney-disease/
Q108	QStroke - risk of ischaemic stroke	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qstroke-risk-of-iscahemic-stroke/
Q88	QThrombosis - risk of thrombosis	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qthrombosis-risk-of-thrombosis/
Q110	QAdmissions, QFrailty and QMortality	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qadmissions-qfrailty-and-qmortality/
Q54	QStatin - risk of unintended effects from statin medication	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qstatin-risk-of-unintended-effects-from-statin-medication/
Q102	QCancer Risk Assessment Tools	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qcancer-risk-assessment-tools/
Q92	QDiabetes - risk of diabetes related complications	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qdiabetes-risk-of-diabetes-related-complications/

Q136	Predicting survival outcomes for patients with a new diagnosis of cancer	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/predicting-survival-outcomes-for-patients-with-a-new-diagnosis-of-cancer/
Q71	Validation of QPrediction scores in QResearch and CPRD	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/validation-of-qprediction-scores-in-qresearch-and-cprd/
Q104	QRISK3 - a new cardiovascular risk score	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qrisk3-a-new-cardiovascular-risk-score/
Q81	QBleed - risk of bleeding	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/qbleed-risk-of-bleeding/
R109	Prostate specific antigen (PSA) testing in the UK population and its implications	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/prostate-specific-antigen-psa-testing-in-the-uk-population-and-its-implications/
R67	Diabetes treatments and risk of cancer: a series of nested case-control studies	Carol Coupland	University of Nottingham	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/diabetes-treatments-and-risk-of-cancer-a-series-of-nested-case-control-studies/
R68	Risk of thrombosis in women prescribed Hormone Replacement Therapy	Julia Hippisley- Cox	University of Nottingham	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/risk-of-thrombosis-in-women-prescribed-hormone-replacement-therapy/
R78	Anticholinergic drugs and the risk of dementia: a nested case control study	Carol Coupland	University of Nottingham	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/anticholinergic-drugs-and-the-risk-of-dementia-a-nested-case-control-study/
Q96	Unintended effects of novel oral anticoagulants (NOAC) vs warfarin in real world settings vs warfarin	Julia Hippisley- Cox	University of Nottingham	approved	https://www.gresearch.org/research/approved-research-programs-and-projects/unintended-effects-of-novel-oral-anticoagulants-noac-vs-warfarin-in-real-world-settings-vs-warfarin/
OX1	Improving Early Recognition of Motor Neurone Disease	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/improving-early-recognition-of-motor-neurone-disease/
OX2	ADEPTS: Accelerated Diagnosis in neuroEndocrine and Pancreatic TumourS.	Steve Pereira	University College London	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/adepts-accelerated-diagnosis-in-neuroendocrine-and-pancreatic-tumours/

OX3	Choosing the right antidepressant for depressive disorder	Andrea Cipriani	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/choosing-the-right-antidepressant-for-depressive-disorder/
OX6	Evaluation of the NHS Health Checks in England 2013-2017	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/evaluation-of-the-nhs-health-checks-in-england-2013-2017/
OX11	Hormone replacement therapy and risk of breast cancer	Julia Hippisley- Cox	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/hormone-replacement-therapy-and-risk-of-breast-cancer/
OX20	Antidepressant Decision Aid Tools and Risk Assessment	Carol Coupland	University of Nottingham	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/antidepressant-decision-aid-tools-and-risk-assessment/
OX22	Dietary or weight loss advice for hypertension in diabetes in primary care	Carmen Piernas	University of Oxford	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/dietary-or-weight-loss-advice-for-hypertension-in-diabetes-in-primary-care/
OX28	Validating a postpartum venous thromboembolism risk prediction model	Joe West	University of Nottingham	approved	https://www.qresearch.org/research/approved-research-programs-and-projects/validating-a-postpartum-venous-thromboembolism-risk-prediction-model-using-qresearch/