

# **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 research database manager ("Data Controller")

Name:	Julia Hippisley-Cox
Address:	Nuffield Department of Primary Care Sciences, University of Oxford
Telephone:	10865 289 593
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.	The Data Custodian is Dr Karen Melham, Senior Clinical Research Support Manager, Clinical Trials and Research Governance, University of Oxford.
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 Relocation to Oxford in 2019

The QResearch database moved from the University of Nottingham to the University of Oxford following the appointment of the Data Controller (Professor Julia Hippisley-Cox) as Professor of Clinical Epidemiology and General Practice at Oxford.

#### 3.2 Data collection

There have been no changes to the type or scope of data collected during the year. More recent data from general practice, cancer registry, mortality and hospital episodes has been collected during the year and uploaded onto the QResearch linked database.

#### 3.3 Collaborations with other databases or programmes

- The Oxford team collaborate with researchers using similar databases (e.g. CPRD) to undertake research projects using both databases using similar protocols. The analyses are undertaken using a similar approach and the summary results are compared. An example is the following study examining the risk of thrombosis in users of HRT (see link). <u>https://www.bmj.com/content/364/bmj.k4810</u>. This paper was awarded the BMJ Research Paper of the Year award for 2019.
- The Oxford team have also collaborated with a number of other data custodians who are potentially interested in linking their dataset to QResearch for example, data for images such as chest x-rays or scans. At this early stage, the team is working to understand the scope of the data and the potential benefit it would bring regarding research which could not otherwise be undertaken. Once this is established and there appears to be a clear case for potential increased patient benefit, we will engage with patients/service users, advisors and stakeholders. We will then prepare an application for a substantial amendment to our ethics approval as appropriate.

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

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

#### 3.4.1 QResearch Scientific Committee.

- Membership of this committee has been extended to include academics from the University of Oxford. Professor Rafael Perera-Salazar has been appointed as the Chair of the committee. More details on members are published on the relevant section of the QResearch website. <u>https://www.qresearch.org/about/scientificcommittee/</u>.
- Minutes of the Scientific Committee are published <u>here</u>.
- There is now an online application form (rather than a paper one) to improve efficiency of the application process
- There is a new process for researchers applying for grants to request a letter of support to enclose with their grant application.

## 3.4.2 QResearch Advisory Board.

 The advisory board met in October 2019. Dr Mike Walton has been appointed as the chair of the QResearch Advisory Board. Membership of the board now includes Professor Rafael Perera as Chair of the Science Committee. Further information, including minutes of meetings, is published here <u>https://www.gresearch.org/about/advisory-board/</u>

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

- Engagement with practices: all practices contributing to QResearch were contacted to inform them of the move from Nottingham to Oxford and provide an updated notice for patients (using the text approved by the REC).
- 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.
- **QResearch website lay summary**: more information about new and ongoing projects is now published here 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/
- A newsletter has now been prepared which will be distributed to contributing practices twice a year with the first issue due in the first quarter of 2020. This will also be on the QResearch website and the relevant pages of the Oxford University website.
- QResearch Data Showcase; There is a new 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/

#### 3.6 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:	24.12.2019

## 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.

	Project title	name of	lead	dataset requested	QR	link to lay summary where data released
		chief investigator	institution		science outcome	(200 words)
Q110	QFracture - risk of	Julia	University of	Risk factors for osteoporotic fracture linked to	approved	https://www.gresearch.org/research/approved-
	osteoporotic fracture	Hippisley-	Oxford	outcomes (hip, knee, wrist and spine fracture) on		research-programs-and-projects/qfracture-risk-
		Cox		either GP, hospital or mortality records		of-osteoporotic-fracture/
Q115	QDiabetes Risk	Julia	University of	Risk factors for diabetes from GP records linked to	approved	https://www.gresearch.org/research/approved-
	Assessment Tool	Hippisley-	Oxford	diagnoses of type 1 and type 2 medication		research-programs-and-projects/qdiabetes-risk-
		Сох				assessment-tool/
Q112	QKidney - predicting the	Julia	University of	Risk factors for kidney disease linked to outcomes	approved	https://www.gresearch.org/research/approved-
	risk of chronic kidney	Hippisley-	Oxford	(development of stage 3-5 kidney failure) on GP,		research-programs-and-projects/qkidney-
	disease	Сох		hospital or mortality records		predicting-the-risk-of-chronic-kidney-disease/
Q108	QStroke - risk of	Julia	University of	Risk factors for ischaemic stroke linked to	approved	https://www.gresearch.org/research/approved-
	ischaemic stroke	Hippisley-	Oxford	outcomes recorded on GP, hospital or mortality		research-programs-and-projects/qstroke-risk-
		Сох		records		of-iscahemic-stroke/
Q88	QThrombosis - risk of	Julia	University of	Data for risk factors for thrombosis linked to	approved	https://www.gresearch.org/research/approved-
	thrombosis	Hippisley-	Oxford	diagnoses of thrombosis on GP, hospital or		research-programs-and-projects/qthrombosis-
		Сох		mortality records		risk-of-thrombosis/
Q110	QAdmissions, QFrailty	Julia	University of	Risk factors for unplanned hospital admissions,	approved	https://www.gresearch.org/research/approved-
	and QMortality	Hippisley-	Oxford	frailty and mortality linked to these outcomes		research-programs-and-projects/qadmissions-
		Сох		recorded on GP, hospital or mortality records		<u>qfrailty-and-qmortality/</u>
Q54	QStatin - risk of	Julia	University of	Risk factors for unintended effects of statin	approved	https://www.gresearch.org/research/approved-
	unintended effects from	Hippisley-	Oxford	medication linked to both the outcomes and		research-programs-and-projects/qstatin-risk-of-
	statin medication	Сох		prescription data for statins		unintended-effects-from-statin-medication/
Q102	QCancer Risk	Julia	University of	Risk factors and symptoms which might suggest	approved	https://www.gresearch.org/research/approved-
	Assessment Tools	Hippisley-	Oxford	indicate an existing diagnosis of cancer or an		research-programs-and-projects/qcancer-risk-
		Cox		increased risk of developing it over the next 10		assessment-tools/

Q92	QDiabetes - risk of diabetes related complications	Julia Hippisley- Cox	University of Oxford	years or factors which affect the survival for people who have a diagnosis of cancer. This is linked to diagnoses of cancer from GP, hospital, mortality and cancer records. risk factors and outcomes for patients with diabetes from GP, HES, mortality	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/gdiabetes-risk- of-diabetes-related-complications/
Q136	Predicting survival outcomes for patients with a new diagnosis of cancer	Julia Hippisley- Cox	University of Oxford	Risk factors and symptoms which affect the survival for people who have a diagnosis of cancer. This is linked to diagnoses of cancer from GP, hospital, mortality and cancer records.	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	risk factors and outcomes for multiple clinical conditions on GP, HES, cancer regsitry and mortality data	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/validation-of- gprediction-scores-in-gresearch-and-cprd/
Q104	QRISK3 - a new cardiovascular risk score	Julia Hippisley- Cox	University of Oxford	GP data for risk factors for cardiovascular disease (CVD) linked to outcomes for CVD recorded on either GP, hospital or mortality data.	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/grisk3-a-new- cardiovascular-risk-score/
Q81	QBleed - risk of bleeding	Julia Hippisley- Cox	University of Oxford	Risk factors for bleeding linked to outcomes recorded on GP, hospital or mortality records	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/gbleed-risk-of- bleeding/
OX4	Epidemiology of sepsis in adults in primary care - an exploratory study using QResearch	Michael Moore	University of Southampton	GP data linked to hospital admissions and mortality data to identify cases of sepsis and associated predictive risk factors including age, sex, chronic diseases (eg COPD, kidney failure, immunosuppression) and symptoms suggestive of infection recorded in the GP consultation	approved	https://www.qresearch.org/research/approved- research-programs-and-projects/epidemiology- of-sepsis-in-adults-in-primary-care-an- exploratory-study-using-gresearch/
R109	Prostate specific antigen (PSA) testing in the UK population and its implications	Julia Hippisley- Cox	University of Oxford	Anonymised subset of GP data from the QResearch database (IAR 377) including a Cohort of men aged 40-75 years registered with the GP practices between 1998 and 2017. GP data included age, deprivation score, ethnicity, body mass index, smoking status, family history prostate cancer, mental health diagnoses, diabetes, prostate specific antigen tests, urinary tract symptoms. Mortality data included cause of death and date of death; Hospital Episode	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/prostate- specific-antigen-psa-testing-in-the-uk- population-and-its-implications/

				Statistics Diagnoses of prostate cancer; Cancer Registry Diagnoses of prostate cancer and associated dates		
R67	Diabetes treatments and risk of cancer: a series of nested case-control studies	Carol Coupland	University of Nottingham	Anonymised subset of GP data from the QResearch database (IAR 377) including a cohort of men and women with type 2 diabetes with outcomes and exposures recorded on linked Hospital Episode Statistics Data supplied by NHS Digital, cancer registry and civil registration date	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	Anonymised subset of GP data from the QResearch database (IAR 377) including GP data for women aged 40-79 years registered between 01/01/1998 and 31/01/2017 who had a thrombosis diagnosed in the study period. Variables include risk factors for thrombosis and prescriptions for HRT. Linked mortality and hospital data for diagnosis of thrombosis.	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	Anonymised subset of GP data from the QResearch database (IAR 377) including Men and women aged 55+ between 2004 and 2015 diagnosed with dementia or prescribed medication for dementia (cases) matched to 5 controls without dementia matched by age, sex, practice and calendar time. GP data includes diagnoses and medication for dementia along with prescriptions for anticholinergic drugs, antidepressants, antipsychotics and risk factors for dementia. Linked mortality data for diagnoses of dementia	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	Anonymised subset of GP data from the QResearch database (IAR 377) cohort of men and women prescribed anticoagulants between 2011 and 2016. Outcomes were major bleeding, death, cardiovascular disease or thrombosis on GP, hospital or mortality records.	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/

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OX20	Antidepressant Decision Aid Tools and Risk Assessment	Carol Coupland	University of Nottingham	GP data for patients prescribed antidepressants; linked hospital and mortality data for mental health diagnoses.	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	GP data for patients aged 40-74 who are eligible for health checks from 2009-2017 and have a diagnosis or treatment for hypertension or diabetes. Data will include age, sex, ethnicity, social class, BMI, behavioural advice or support for weight loss or diet, information on diagnosis and treatment of hypertension and diabetes	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	Anonymised subset of GP data from the QResearch database linked to Hospital Episode Statistics Data supplied by NHS Digital.	approved	https://www.gresearch.org/research/approved- research-programs-and-projects/validating-a- postpartum-venous-thromboembolism-risk- prediction-model-using-gresearch/