



# Health Research Authority

2 Redman Place  
Stratford  
London  
E20 1JQ

Email: [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk)

17 November 2025

Professor Julia Hippisley-Cox  
University of Oxford  
Nuffield Department of Primary Care Health Sciences  
Radcliffe Observatory Quarter  
Woodstock Road  
OX2 6GG

Dear Professor Hippisley-Cox,

**Application title:** QRResearch Data Linkage Project  
**CAG reference:** 25/CAG/0147  
**IRAS project ID:** 329187  
**REC reference:** 23/EM/0166

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

This application was considered at the Confidentiality Advisory Group (CAG) meeting held on 06 November 2025. This outcome should be read in conjunction the [minutes](#) of this meeting.

## Confidentiality Advisory Group advice and Health Research Authority decision

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority.

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out in the minutes, has determined the following:

- The application is **Conditionally supported**, subject to compliance with the **standard** and specific conditions of support

***Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.*** A summary of the scope of support is provided in Appendix A.

Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of

confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

### Specific conditions of support

1. 's251' support is provided for 5 years initially, with a duration amendment required to extend.
2. CAG urge the applicant to ensure that participating GP practices are updating their websites with the QResearch privacy notice to ensure transparency. An update is required in 3 months.
3. Develop a poster for GP practices, that links on to further information on a website, and provide within 3 months.
4. Update the patient privacy notice, and make sure the poster to be developed includes the following, and provide to CAG within 3 months:
  - a) Clearly state that pseudonymised data would no longer be obtained at source from the GP data, and that identifiers are disclosed to QMUL via the IM1 platform, where QMUL effectively anonymise (with the exception of full date of death).
  - b) The link to the NDOO should be removed and should merely state that the NDOO is respected.
  - c) The statement 'NHS England do not apply it as per policy' should be removed.
  - d) Include that this use of identifiers without consent has been supported under 'section 251' by the HRA following CAG advice.
  - e) Consider if it is possible to provide access to translated versions of the patient notification documents.
5. Please ensure that the Q Research specific SNOMED code can be resurrected, to use as a QResearch specific opt out option, ensure this is clear on the patient notification documents, the practice information sheet, and provide additional guidance to GPs about how to manage this QResearch specific opt out. Provide an update to CAG in 3 months.
6. Further, wider public involvement should be conducted with many more people. Provide feedback on discussions on the use of confidential patient information without consent, and provide feedback within 3 months.
7. Please discuss with NHS England about whether they would now like 's251' support for this flow from NHS England to QMUL that includes full date of death, and provide an update to CAG in 3 months.
8. Favourable opinion from an NHS Research Ethics Committee. **Confirmed for 23/EM/0166/AM02 23 October 2025.**
9. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant [Data Security and Protection Toolkit \(DSPT\) submission\(s\)](#) has achieved the 'Standards Met' threshold. **Confirmed:**

The NHS England **24/25** DSPT review for **Optum (EMISWeb) ODS code: 8GW39, The Phoenix Partnership (Leeds) Ltd (TPP) (SystemOne) ODS code: YGM24 & QMUL – Queen Mary University of London – Qresearch – Centre For Primary Care And Public Health, London ODS code: 8HX8** were confirmed as 'Standards Met' on the NHS England DSPT Tracker

This letter provides confirmation of final support, and all the above conditions are expected to be met within the stated timeframe. I will arrange for the register of approved applications on the HRA website to be updated with this information.

### **Maintaining CAG support: Reporting requirements**

Please note the following guidance on reporting requirements in order to maintain CAG support for the duration of the activity.

- **Annual review report:** It is your responsibility to submit an annual review report every 12 months for the entire duration that confidential patient information is being processed without consent. The next annual review should be provided no later than **17 November 2026** and preferably 4 weeks before this date. Further guidance and the annual review form is available on the [IRAS website](#).
- **Notifying amendments to the scope of CAG support:** Guidance on submitting CAG amendments and the amendment form is available on the [IRAS website](#).
- **Notifying the end of activity:** Guidance on notifying the end of activity and the end closure report form is available on [the IRAS website](#).
- **Register of supported applications:** It is a statutory requirement to publish all supported applications to process confidential patient information without consent. Supported applications are published on the [HRA website](#).
- **Maintaining your Research Ethics Committee Favourable Opinion.** Supported research applications must have a favourable opinion from an NHS Research Ethics Committee for the duration of Regulation 5 support. Closing your REC application prior to notifying CAG about the end of your activity risks you no longer having a common law legal basis.

### **Approved documents**

The list of documents reviewed and approved at the meeting are as follows.

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised)		
Other [2025.01.27 QResearch Notice QMUL version 2-clean]	2	
Other [2025.10.28 QMUI letter of support for IRAS 329187-SIGNED]		28 October 2025
Other [2025.10.28 QResearch Dataflows v2.0]	2	28 October 2025
Other [QMUL-QResearch cover letter V1.0]	1	09 October 2025
Patient Information Materials [2025.10.28 QResearch Information for Patients-4.2-clean]	4.2	28 October 2025
Patient Information Materials [QResearch Information for Practices-4.1-Clean]	4.1	22 October 2024
REC favourable opinion letter and all correspondence [329187 (RD)_Favourable_opinion_of_amendment 23.10.25]		
Research protocol or project proposal [QResearch Protocol version 15.0 - Clean]	15	28 October 2025

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Wangari Njiiri  
Approvals Administrator

On behalf of the Health Research Authority

Email: [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk)

*Included:* List of members who considered application  
Summary of scope of support

*Copy to:* [derby.rec@hra.nhs.uk](mailto:derby.rec@hra.nhs.uk)

## Confidentiality Advisory Group meeting 06 November 2025

### Members present:

#### Present:

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Mr Dan Roulstone	CAG Vice Chair
Mr Thomas Bobby	CAG Member (Expert)
Dr Malcolm Booth	CAG Member (Expert)
Dr Ben Gibbison	CAG Member (Expert)
Mr Anthony Kane	CAG Member (Lay)
Dr Pauline Lyseight-Jones	CAG Member (Lay)
Dr Harvey Marcovitch	CAG Member (Expert)
Mr Umar Sabat	CAG Member (Expert)
Mrs Cath Trigwell	CAG Member (Lay)

#### Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Charlotte Miller	HRA Approvals Administrator
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Wangari Njiiri	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

## Appendix A – Summary of Scope of Support

### Summary of application

This application from Queen Mary University London is for the purpose of medical research to continue to create a research database. QResearch ([www.qresearch.org](http://www.qresearch.org)) is a research database derived from UK general practices which started in 2003. The aim of QResearch is to develop and maintain a high-quality database of general practice derived data linked to secondary care data for use in medical research. The database is used for research into the causes of disease, history, treatment and outcomes. In particular, it has been used for research into health inequalities; safety of medicines; the development of risk prediction tools to identify those at risk of a future disease, such as cardiovascular disease, ([www.qrisk.org](http://www.qrisk.org)) or those at risk of a current diagnosis of a disease such as cancer ([www.qcancer.org](http://www.qcancer.org)).

The database originally received REC approval in 2003. 'Section 251' support was previously granted in 2011 (**ECC 3-04(e)/2011**) to cover the extraction of identifiable data from GP and NHS systems for QResearch. However, following the development of new software (OpenPseudonymiser) the approach was changed so that data could be de-identified at source. Following this and after a detailed review by the ECC in Sept 2011, the committee concluded that the extraction did not constitute identifiable data and hence section 251 support was no longer required. 'Section 251' support is now being sought again, because of a technical change in the GP system suppliers' platform (Optum (EMISWeb) and TPP (SystmOne)) used to extract GP data, which means that pseudonymisation-at-source is no longer possible. 's251' support is now sought to allow the disclosure of confidential patient information from Optum and TPP to the IM1 platform ([IM1 Pairing integration - NHS England Digital](#)), where QMUL will pseudonymise the data at the point of extraction, with the exception of full date of death, which will be included in the database in full format. It will not be released to researchers in full format.

The QResearch database has defined ethics committee approval, governance processes (including an oversight Advisory Board) and data sharing agreements which limit the purposes for which the data can be used. The database is open to bona fide researchers employed by UK universities who must be able to publish whatever the findings. QResearch is non-profit-making. The QResearch Advisory Board draws up the criteria for access that will be applied by the QResearch Scientific Committee. Criteria are published here [www.qresearch.org](http://www.qresearch.org). The advisory board oversee the ongoing development of QResearch. Details of the advisory board are here: <https://www.qresearch.org/about/advisory-board/advisory-board-in-detail/>. Terms of reference are provided, and the advisory board contains lay representation. A QResearch Scientific Committee approves access to data: <https://www.qresearch.org/about/scientific-committee/>. [The committee is a virtual committee consisting of the peer reviewers selected for each application.](#) Terms of reference are provided, and the committee contains lay representation. QResearch only permits studies which are likely to lead to benefits for patients or the benefit of the health service is allowed. Results of research undertaken using QResearch are all published and can be found on the publications page.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

### Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<b>Cohort</b>	The QResearch database includes approximately 40 million patients of all ages (including children and vulnerable groups) registered with approximately 1500 GP practices
<b>Data Sources</b>	<ul style="list-style-type: none"><li>• medical health records from general practices in England Via Optum(EMISWeb) and TPP (SystemOne)</li></ul> <p>The entire database has been (and will continue to be) linked to NHS England data such as cause of death data, cancer and hospital data, covid-19 data, and also to ICNARC and NHSBT data, amongst other data sources - these other data sources are out of scope for 's251' support as are stated as provided in effectively anonymous format.</p>
<b>Identifiers required for the purposes of processing whilst effectively anonymising the dataset</b>	<ol style="list-style-type: none"><li>1. NHS number – will be scrambled using a one-way hashing algorithm to create a de-identified code which cannot be reversed</li><li>2. GP registration</li><li>3. postcode - converted to a deprivation score</li><li>4. All free text comments, names, addresses, emails, contact phone numbers are removed from the data.</li><li>5. Date of birth - rounded to years of birth</li><li>6. Date of death</li><li>7. Each patient is allocated a unique number (known as a GUID) - The collection server cannot re-identify which patient the GUID refers to.</li></ol>
<b>Identifiers required for analysis purposes</b>	N/A – not identifiable for analysis by external researchers, however full date of death is retained in the QResearch database.
<b>Additional information</b>	The data will be collected once or twice each year