

VERSION 1.5

ACADEMIC RESEARCHERS GUIDE TO USING QRESEARCH

What is the purpose of this document?

This document provides guidance on researcher's access to QRESEARCH. Researchers should also consult the website <http://www.qresearch.com> for general information about QRESEARCH. Appendix 1 lists supporting documentation. Researchers are encouraged to check the website to ensure they have the current version of this guidance.

What is QRESEARCH?

QRESEARCH is a not-for-profit partnership between the University of Nottingham and EMIS. The QRESEARCH database is a patient level aggregated database which contains the health records of over 7.5 million patients in total – of whom 2.5 million are currently registered and the others have left or died –from approximately 500 practices in the UK. For many practices longitudinal data are available back to the early 1990s. QRESEARCH will provide extracts of data to bona fide academic researchers to undertake specific research projects.

How does it work?

The flow chart describes the process. In summary, the researchers originate a research question or hypothesis; write an outline protocol; and contact QRESEARCH to discuss the feasibility of undertaking the study. If the study is feasible, QRESEARCH will give an estimate of the costs of providing the data and will provide a letter to accompany any application for funding. The researcher then secures the necessary funding and completes the QRESEARCH application form, including a detailed protocol and data specification. This application is sent for scientific review and feedback is given to the researcher. The researcher makes any necessary modifications to the protocol and then submits the proposal to Trent MREC (see Appendix 2). Once MREC approval is obtained, the researcher is given a timescale for the data extraction. Once the researcher has the data, they have to approve it within one month of receipt.

How much does it cost?

QRESEARCH is not-for-profit and is entirely self-funding so needs to cover the costs associated with providing a research service. We will estimate the cost of each data extraction plus VAT. The estimate will take account of the complexity of the data required and the time taken to extract it. QRESEARCH will submit an invoice to the Principal Investigator for the work concerned.

Who is eligible to apply for research access?

QRESEARCH was established specifically to provide access for research projects by academics employed by UK universities. At least one member of the research team must be a medically qualified academic registered with the General Medical Council who signs the guarantee.

What types of studies are most suitable?

We will provide extracts of data on samples of patients with sufficient data to be able to test the hypothesis. The sample size will depend on the sample size calculation. We do not license the use of the whole database. Any research analyses which might

involve the whole database or which need a practice level analysis need to be done on site and are subject to QRESEARCH having adequate capacity.

The following studies are most suitable:

- ✚ Case control studies designed to examine risk factors for onset of disease
- ✚ Cross sectional surveys
- ✚ Cohort studies
- ✚ Sample size calculations

Are there studies which cant be done on QRESEARCH?

Yes, there are some types of studies which are not suitable for QRESEARCH. The QRESEARCH team will let researchers know at an early stage if a study is not suitable. In particular, QRESEARCH cannot undertake studies which involve:

- ✚ any intervention on practices or patients
- ✚ any need to contact the practices or patients since this is impossible
- ✚ any changes to the fundamental principles underpinning QRESEARCH.

Is it possible to link QRESEARCH data to external data sources?

No.

What if a pharmaceutical company wants to access data for research?

QRESEARCH does not provide data for pharmaceutical companies under any circumstances.

Are there any data items which are not released?

In order to safeguard the identity of the practices, we do not release any practice level data. We also make special consideration of data items relating to patients with very rare or unusual disease. If QRESEARCH is not a suitable data source for a project, we will endeavour to suggest other more appropriate data sources where possible.

What are the conditions of using the data?

QRESEARCH releases data to independent academics to undertake bone fide research. We assess eligibility of applications using the following questions. An answer of 'no' to any of the questions is likely to invalidate the application:

- ✚ Did you have the original idea for this research project?
- ✚ To your knowledge is this work original and capable of publication as original research in a peer- reviewed journal?
- ✚ Are you free to undertake this study and publish its findings regardless of the findings?
- ✚ Do you agree to acknowledge the source of QRESEARCH data in any publication, paper or report?
- ✚ Do you agree NOT to attempt to identify patient(s) or practice(s)?
- ✚ Do you undertake to provide a copy of the final report of the project and copies of any publications within one year of the project completion?
- ✚ Do you agree NOT to release the data to any third party including the funder, sponsor or other such body?

- ✚ Do you undertake to check the data you are given within a month of receipt and report back any problems within that time?
- ✚ We do not require researchers to send us copies of paper prior to submission. However, bearing in mind QRESEARCH is a new database, the academic team at Nottingham are happy to read and comment on papers.

What happens if a researcher contravenes these conditions?

Attempts to break the confidentiality of the practices or patients or clear evidence of research misconduct will be treated extremely seriously by QRESEARCH and, if proven, will result in a bar on further access to data for the research team and their university. It may also lead to referral to the General Medical Council which is why one of the core teams needs to be registered with the GMC.

I have been approached by a pharmaceutical company to undertake some research using QRESEARCH. Is this OK?

No. We do not accept projects initiated and/or designed by the industry.

Does QRESEARCH mind where the funding for my study has come from?

We ask you to declare the source of funding and we ask you to guarantee all the conditions above. All applications are reviewed by the Scientific Board and the MREC and if there are concerns then we will discuss it with you.

Duplication

A list of currently supported projects is available from QRESEARCH and we will inform prospective researchers if their project [or one very similar] is already being undertaken by another team in order to avoid duplication. Currently, we do not intend to supply the same data to different teams to answer very similar questions. We also hope this will avoid disappointment and wasted effort by one team if the other team publishes first. However, if the second team can come up with good reasons why the analyses need to be performed again, then the QRESEARCH Scientific Board will be asked to consider the best way forward.

Non Exclusivity

QRESEARCH undertakes research and analysis for a variety of organisations covering a wide scope of questions including both research and audit. Details of these projects are available from QRESEARCH. Nothing in any agreement with a third party will prevent QRESEARCH from supplying services to any other party at any time. At all times copyright in core material from the QRESEARCH database purchasable by any client remains the absolute property of QRESEARCH.

What happens to the results of research projects?

We expect research to be published in peer-reviewed journals. Every form of publication arising from the work utilising the QRESEARCH database shall acknowledge it as the source of the raw data in keeping with the conditions of access to the database. Publications should also refer to the version of the database and the date of last data download for the data used in the study.

What criteria are used for the Scientific review?

The Scientific Board judge applications against the following criteria

1. Is there a clear research question or hypothesis which is likely to lead to a generalisable findings capable of publication in a peer reviewed medical journal?
2. Are the researchers likely to be able to conduct the study and its analysis?
3. Is QRESEARCH the appropriate database to be used to conduct the research?
4. Is the methodology appropriate to answer the question (including the possibility of bias and confounding)?
5. Are there any potential risks to the ethical position of QRESEARCH in undertaking this research (including the potential identification of patients or practices)?
6. Do you have any conflict of interest in reviewing this application? If so, please give brief details?
7. Overall do you think QRESEARCH should approve this research project??

Why do we need to secure funding first?

We get many of enquiries from academics who then don't proceed to undertake the project. This can be for a variety of reasons including a failure to identify the necessary funds. Our Scientific Board is unpaid and so we only ask them to review projects which are almost certainly going ahead. We ask the Scientific Board to review them before the MREC to ensure that the protocol which then goes to MREC doesn't need to be amended and hence re-submitted.

I just want all the data for the patients of interest. Is this OK?

No. We expect researchers to have a specific research question/hypothesis that requires specific data. We do not license the whole database or give out entire medical records.

What do I need to do if my research question changes?

The approval you gain is on the basis of the protocol submitted to MREC and the Scientific Board. If you would like to answer another research question which is not in your original protocol then you must re-submit it as a new project for peer review and MREC approval. If you can answer it from the data you already have, then you can proceed at no additional cost. Otherwise if you need additional data, you will need a new submission to QRESEARCH and to the MREC and to identify additional funding.

What if I don't want to do the research but I want to know the answer?

QRESEARCH may also do commissioned research if appropriate. This can be done in collaboration or as a service for which QRESEARCH will give a formal quote. QRESEARCH has a standard draft contract for this type of work which is available on request.

What happens if there is a mistake in the data?

QRESEARCH will take every precaution to ensure that the data requested match the exact specification which has been agreed and signed off by the principal investigator. The data extraction process will be subject to routine quality assurance procedures. It is the principal investigator's responsibility to confirm receipt of the data and check the data and notify QRESEARCH of any errors or omissions within 28 days. In the absence of any such notification we shall consider that the data are correct. If there is

a mistake in the data, then the principal investigator should contact QRESEARCH who will investigate the problem.

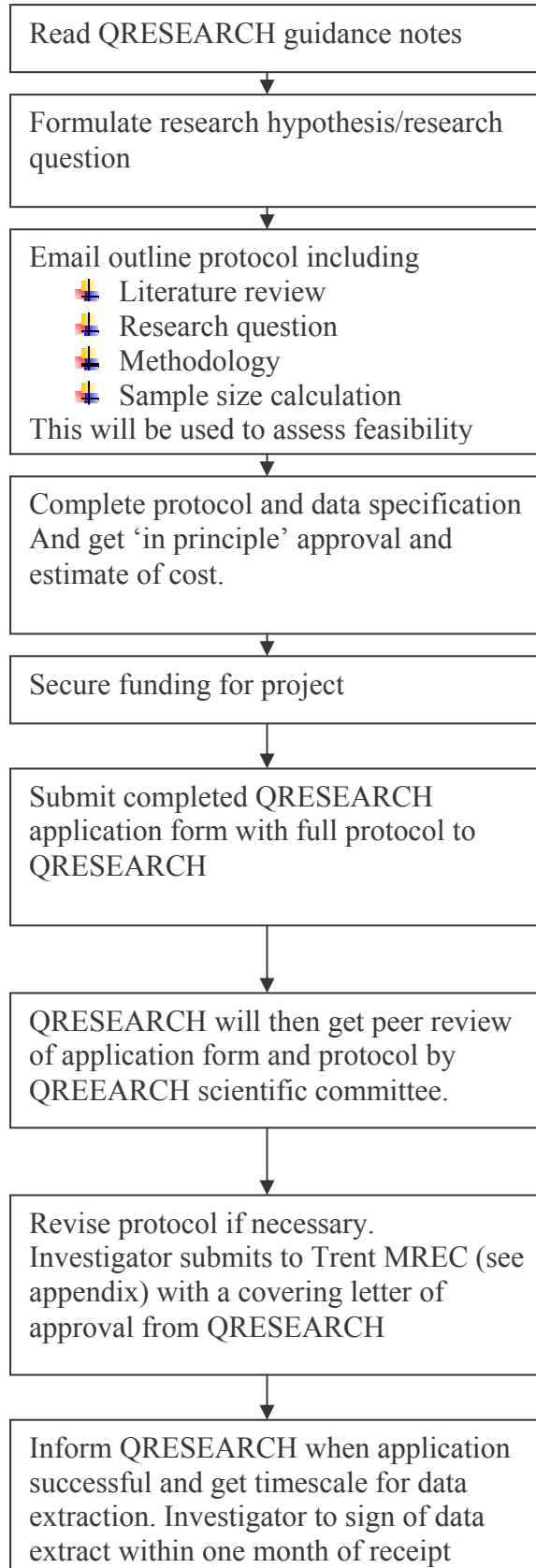
If there is a mistake in the data extraction caused by QRESEARCH error, then the principal investigator will be provided with a corrected dataset within 28 days or as soon as is reasonably possible. QRESEARCH cannot be liable for the cost of any staff time spent working on the data.

If the mistake is due to an error in the data specification drawn up by the researchers (eg the researchers have selected the wrong Read codes), then QRESEARCH will endeavour to help by re-running the data extraction routine with the new codes within the following 3 months. There may be an additional cost for this.

How long do I have to undertake my research?

We will write to you after two years to invite you to submit for an extension to continue to use the data or to ask you to archive the data if the project has finished.

FLOW CHART FOR RESEARCHERS TO ACCESS QRESEARCH DATA



APPENDIX 1: Supporting documentation

Name of document	Description
Researchers guide to using QRESEARCH.pdf	This is the current document you are reading.
Understanding QRESEARCH data structures.pdf	This document describes the data structures in QRESEARCH
QRESEARCH application form version 3.0.doc	This is the proforma which needs to be completed to make a formal application to use QRESEARCH
QRESEARCH ethics form guide version 10 th August 2004.doc	This form will help you complete the MREC form. It has pre-filled in answers for the general questions. It should only be completed when you have full approval from QRESEARCH and also have secured funding. We will send you a copy of this document when we have approved your application
Trent MREC Investigator guide.doc	This document has been produced by Trent MREC and tells you how to proceed with MREC approval. It is also contained in the appendix of this document
QRESEARCH draft services rendered contract version 1.0.pdf	This document sets out the standard terms for commissioned analysis or research undertaken by the QRESEARCH team

Appendix 2: Statement from Trent MREC

PROCEDURE FOR CONSIDERING APPLICATIONS TO USE TISSUE/DATA BANKED UNDER TRENT MREC APPROVAL FOR ESTABLISHMENT OF ORIGINAL BANK

1. Applicant applies to custodian of data (i.e. chief investigator of the study approved to set up the original bank) for agreement to the use of banked tissue/data for the purposes of his/her specific research project.
2. Custodian of data writes to the chief investigator for the specific research project to use banked tissue/data giving agreement (provided MREC favourable opinion also obtained).
3. Chief investigator for research project prepares REC application (ticking 'Yes' at Q A6 – No Local Investigator).
4. Chief investigator for research project registers a new REC application with COREC via central allocation system, specifying that study should go to Trent MREC, as the REC which approved original establishment of the bank.
5. Application sent to Trent MREC within 4 working days of registration. Must contain at least:
 - Protocol
 - Chief investigator's CV
 - Letter from custodians of data, indicating willingness to release tissue subject to MREC favourable opinion
 - Referees' comments if available
6. Questions to be considered by MREC:
 - Value of research
 - Scientific validity
 - Conforms with basis on which original samples were obtained
 - Appropriate arrangements for storage/handling of data
 - Suitability of researcher
7. CI may attend MREC meeting venue if he/she wishes, but unlikely to be invited into meeting since it is expected that the use of the data, already agreed by the custodian, should not raise significant ethical issues.
8. CI notified of committee's response within 10 working days of the meeting.

Trent MREC guidance for investigators
June 2004