User Guide No.: 016QRes
User Guide Title: Making a Project Application: Details of the application form, data specification, lay summary, and CVs

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1. Purpose

The purpose of this User Guide is to support researchers to complete the application form, create a data specification, write a lay summary and provide CVs as required for consideration by the QResearch Scientific Committee when applying for approval for a QResearch project and access to a dataset.

2. Scope

This User Guide includes guidance for sections of the QResearch application form where clarification might be useful. It explains the type, quantity and purpose of the information to be included. It includes guidance on how to specify the data being requested, both in QWeb and the data specification template. It includes guidance on writing a lay summary for our website. The aim is to ensure researchers make eligible, complete, high-quality applications, preventing ineligible applications, and saving time spent on revisions and requests for further information. This guide should be used by all researchers writing an application. It does not include information on any other aspects of the research, project or application process, these can be found on our website or on enquiry.

3. Associated Documents

User Guides and Videos can be found in the Guides section of the QResearch website. Creating a QWeb Account (User Guide 1) and Making a Project Application (User Guide 2) are essential reading ahead of this User Guide. User Guides 3-15 relate to using QWeb as a collaborative researcher environment and to specify data. A data specification template will be provided to you once an initial assessment of your application has been made.

4. Procedure

Once researchers have an approved QWeb account and have started a new Application Form they can complete the application form and other documentation.

Application Form

See User Guide 2. Making a Project Application

A. General Details

Experience

Researchers should explain what experience each team member has in each area, focusing on those that are most relevant. For example, what experience with **statistics** the researcher working most closely with the data has, and the experience of the most experienced statistician, or the statistician who will be overseeing the work. Any experience working with Electronic Health Record (EHR) data can be included in the section titled **CPRD data.** All experience cleaning, manipulating and transforming data is relevant to the section titled **Data Management.**

B. Funding

The **Proposed Study Start Date** and **Proposed Study End Date** will match the dates documented in the Costing Agreement for Data Access Start and Data Access End dates. The **Funding Amount** will match the total agreed in the Costing Agreement. The **Budget** Code may not be available if a project grant is still in set up.

C. Datasets

The **Brief description** should describe the type of patients whose data is being used. It will include a list of the linked databases used in the project, and the types of variables being used from each.

Any datasets requested for which a section in the form is not provided will labelled with the name of the dataset.

D. Protocol

9.1 What is the scientific justification for the research? What is the background? Why is this an area of importance? (Must be in language comprehensible to a lay person)

This will be a scientific justification for the research with references and does not need to be comprehensible to a lay person.

9.2 Please provide a lay summary for publication on the QWeb site.

This should be a summary easily understandable by a lay audience

9.11 Where will the analysis of the data from the study take place and by whom will it be undertaken?
The names of the researchers who will directly accessing the data will be listed with their institutions. Please note, the data is held on the QMUL servers and cannot be accessed from outside the UK.

10.9 Has the size of the study been informed by a formal statistical power calculation?
The researchers should complete this section or provide a strong scientific rationale for not needing to. Please note, QResearch is bound by its ethical approvals to provide only as much data is scientifically justified.

E. Invoices

This is will be the CI, or a contact in the finance team of the CI's department.

F. Data Sharing Agreement

This is will be the CI, or a contact in the research services/legal team, or the SIRO of the CI's department.

G. Declarations

Data retention, storage and destruction

14.1 How long do you wish to retain the data?
This will be how long the researchers wish to have access to the data for the purposes of this research project, the duration will match the period agreed in the Costing Agreement. Please note, QResearch keeps all datasets it provides, and work generated by researchers on its servers for as long as ethics permission and data sharing agreements are in place. Datasets can be accessed after the data access period agreed, in line with ethical approvals and data sharing agreements with data providers, for example, to respond to a reviewer's comments.

Details of Data Custodian

15.1 What arrangements are in place for monitoring and auditing the conduct of the research?
Researchers will specify how good research practice will be upheld for this project, for example, oversight, training, guidelines.

Researchers

Researchers will be listed here if they are not co-applicants but will work on the project.

Data Specification

See User Guide 3. QWeb and Projects

A data specification is required; it will be used to extract and prepare the dataset for the research project. The Scientific Committee will not review the data specification but will have access to it.

The research team is responsible for the data specification.
The data specification will be developed by the research team and agreed with the QResearch team.
It will be documented using the data specification template provided AND the project linked to the application form in QWeb.
The QWeb project and data specification template must not contradict each other and between them will contain a complete set of information.
All fields of the template will be completed.

Data specification template

Researchers will follow all guidance in the **Instructions** tab of the data specification template to complete the data specification template for their project

QWeb

Researchers will follow all User Guides to complete the **Linked Library Items** for their project.

Lay Summary

A lay summary is required; it will be published on our website so that the public can learn how their data is being used for research. The Scientific Committee will review this lay summary.

Study Title
This is the full title of the study.

Page Title
This is used as the main header of the page for this project on the QResearch website. It should be short and clear. It could be the same as the Study Title.

Aims and Objectives
While the project is active this will be displayed as "What is the aim of the study and why is it important?".
When the project is complete this will be displayed as "What were the objectives of the study?"
This will be an explanation of why the study is important, and a list and description of the aims and objectives of the study.

Researchers
This will be a list of the title, name and affiliations of all researchers on the project, excluding the CI.

Chief Investigator
This will be the title, name and affiliations of the CI.

Brief summary of the dataset to be accessed
This will be a brief description of the characteristics of patients from whom data is being used. It will also be a list of the linked databases that are being used in this project, and the types of variables being used from each. It could be a lay version of the dataset description in the application form.

Research Methods
While the project is active this will be displayed as "How is the research being done?". When the project is complete this will be displayed as "How was the research done?" This will be a description of what methods are being used in the study, and explanation of why.

Findings
This will be displayed as "What were the main findings?", either when a project is ongoing or complete.
This will be a description of what results have been found.

Other outputs
This will be a list of all outputs from the study, other than publications in scientific journals. It may include any algorithms, tools etc.

Implications
This will be displayed as "How will this study be helpful?". If the project is complete this will be displayed as: "What are the implications of the research findings?"
This will be an explanation of what the research means, how it may change (or not change) knowledge, or care patients receive, or the health system.

Funding Source
This will be a full name and link to the website of all funders.

Is there any other information the research team would like to include?
This will be an explanation for the QResearch team, not for publication, listing any other information or materials the research team would like include in their lay summary webpage (or link to from it).