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Research Database SOP for Cardiff JRO projects

Introduction and Aim

Data that is collected for research without a specific study hypothesis or research question in mind, with the eventual aim being to act as a resource for researchers, may be known as a Research Database. Setting up and maintaining ongoing oversight of a Research Database is a major undertaking and has resource implications for the Joint Research office (JRO), Chief Investigator (CI) and the Research Database Team.

This SOP will outline the steps the JRO, CI and Research Database Team must follow to set up a Research Database within a Cardiff JRO organisation.

Objectives

Outline the steps required to set up a Research Database as part of a Cardiff JRO organisation for which Cardiff & Vale University Health Board (CAVUHB) or Cardiff University (CU) have been approached to provide JRO oversight.

Scope

This procedure applies to all staff in locations throughout CAVUHB and CU who intend on setting up and maintaining a Research Database.
This includes:

- Research Databases set up using National Health Service (NHS) data previously collected as part of routine care.
- Research Databases set up using NHS data collected prospectively.

This SOP does **not** apply to the following:

- Research Databases set up using non-NHS data hosted within the University.
- Research Databases that also involve the collection of human tissue. This then becomes a Research Tissue Bank.
- Instances where CAVUHB is acting as a Data/Tissue Collection Centre for a Research Database, Research Tissue Bank or Surveillance study. Please refer to the CAVUHB workplace instruction for more information on this (WI 001-001-06).

Equality and Health Impact Assessment	An Equality Health Impact Assessment has been completed on the Research Governance Policy and Procedure (UHB099) under which this procedure sits.
Documents to read alongside this Procedure	SOP/001/02 Data Management in Clinical Trials (UHB449) Links in section 6 of this SOP
Approved by	Joint Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	JRO Research Governance Team

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1.0	02/05/2025	*24.06.2025*	N/A new document

Contents

1.0 DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CAVUHB	Cardiff and Vale University Health Board
CRIS	Clinical Record Interactive Search
CU	Cardiff University
D-CRIS	Dementia Clinical Record Interactive Search
DPIA	Data Protection Impact Assessment
EPR	Early Project Review
HCRW	Health and Care Research Wales
HRA	Health Research Authority
IRAS	Integrated Research Application System
JRO	Joint Research Office
NHS	National Health Service
NICOR	National Institute for Cardiovascular Outcomes Research
NIHR	National Institute for Health and Care Research
OID	Organisation Information Document
REC	Research Ethics Committee
R&D	Research and Development
SAIL	Secure Anonymised Information Linkage
SOP	Standard Operational Procedure
Sponsor	The individual, company, institution or organisation, which takes on the ultimate responsibility for the initiation, (management or arranging the initiation) of and/or financing (or arranging the financing) for that research
TRE	Trusted Research Environment
UKPF	UK Policy Framework for Health and Social Care Research 2017 (as amended)

2.0 GENERAL INFORMATION

A “Research Database” means: “A structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research project with defined endpoints.”

There should be a clear justification of the benefits of setting up a Research Database. Consideration should be given to the background scientific justification for the work, for example, whether it is based on literature reviews, lack of existing Research Databases in the field, precedent from other UK nations, or potential impact on public health and future medical treatments etc.

There are many national datasets for particular conditions that have been set up in the UK and internationally with standard processes in place for individuals to request access to data for particular projects. Examples include:

- National Institute for Cardiovascular Outcomes Research (NICOR)
- NIHR Health Informatics Collaborative
- Clinical Record Interactive Search (CRIS) and the Dementia CRIS (D-CRIS)
- NHS England (NHS Digital)
- Secure Anonymised Information Linkage (SAIL) database

These datasets normally have Research Ethics Committee (REC) approval and have a governance structure that handles requests for the data. Most requests for data must be for specific studies that have their own Health Research Authority (HRA)/Health and Care Research Wales (HCRW) and REC approval, and there is often a charge for processing and the release of data, as well as contractual arrangements that need to be put in place.

Following an approved request and in line with valid Data Sharing Agreements, data is often shared via a Trusted Research Environment (TRE). A TRE, also referred to as a Secure Data Environment, which offers a secure data platform for researchers to conduct their work (SAIL Databank., 2024). Researchers, scientists or other experts are granted secure access to approved, anonymised data, and can utilise the analytical software inbuilt into the TRE to collaborate, link data, share code and results within specific research projects. Researchers can then safely export their findings, ensuring only approved formats and analyses are sent to authorised users. Using this option saves time for the researchers as they do not need to wait for the Host organisation to provide reports containing the required pseudo anonymised/anonymised data for the research project.

Where a suitable Research Database resource does not already exist, researchers may wish to set one up.

Please note: If a study involves the collection and/or storage of tissue samples, it can no longer be considered a Research Database. This would be considered a Research Tissue Bank or Biobank. A Research Tissue Bank is a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethics approval or for which ethical approval is pending.

3.0 PROCEDURES

3.1 FUNDING, JRO OVERSIGHT AND ETHICAL APPROVAL

Databanks should have specific funding in place to support set up and long-term data collection, oversight and maintenance.

As per the REC SOPs, “REC approval is required by law where the activities of a research database would include accessing or otherwise processing the identifiable data of patients or services users in England and Wales outside the normal care team without consent. This would require application to both the Confidentiality Advisory Group and a Research Ethics Committee under Section 251 of the NHS Act 2006 to set aside the common law duty of confidentiality owed by care professionals to their patients or clients.”

Where a Research Database will be managed by staff from Cardiff and Vale University Health Board (CAVUHB) or Cardiff University (CU), oversight from the JRO, and NHS Research Ethics Committee approval is required.

Health Research Authority (HRA) & Health and Care Research Wales (HCRW) approval is not required for research databases. However, local approval from the R&D of the NHS organisations.

3.1.1 Funding Arrangements

Consideration should be given to the scope and remit of any available funding, including whether it is sufficient to fully support the infrastructure required to run a Research Database.

This includes costing NHS staff time for any involvement in the day to day running of the database or any payments required between the University and the NHS to facilitate access to data.

In addition, CI’s and Research Database Teams should liaise with the JRO to determine whether there are any ongoing contractual or governance requirements during the life of the Research Database that may incur additional JRO costs. This can be discussed at an Early Project Review (EPR) meeting with the JRO.

3.1.2 JRO Oversight

All Research Databases require ongoing JRO oversight.

It is recommended that the CI or Research Database Team contacts the JRO Research Governance Team for initial advice during the database

development or grant application phase. The contact details for the relevant CAVUHB/CU team are:

Proposed Sponsor organisation	Contact email address
Cardiff and Vale UHB	research.governance@wales.nhs.uk
Cardiff University	resgov@cardiff.ac.uk

The CI or Research Database Team should liaise with the JRO Research Governance Team as early as possible to discuss the approval requirements for the database and to arrange a JRO EPR meeting.

Any CAVUHB or CU employee planning to apply for a research grant to fund a research database for which JRO oversight is required, should arrange an EPR meeting prior to submitting the grant application.

3.2 ARRANGING AN EPR MEETING

The EPR meeting is the first stage in the approval process for a Research Database. Databases led by either CAVUHB or CU are required to arrange an EPR meeting with the JRO. CIs (or their delegates) should request an EPR meeting through the JRO website (New Study - Cardiff Joint Research Office (cardiffjro.com)).

The purpose of the EPR meeting is to confirm the following:

i. whether any additional contracts or research governance support is required to manage the database and whether this can be incorporated into the grant application stage (determined in accordance with the JRO Costing Model);
ii. which JRO organisation will be the most appropriate to provide oversight of the database;
iii. the ethical and governance approvals that will likely be required for the database following an initial discussion, as well as discussing any potential barriers to gaining these approvals;
iv. the relevant JRO Research Governance Team contact to take the application forward.

3.3 JRO DATABASE SET-UP MEETING

Where databases are deemed to be more complex and/or higher risk, the JRO Director may determine that an additional Database Set-Up Meeting(s) are required. This may be arranged following confirmation of funding, or where further information and detail about the database is required. Database Set-Up Meetings are agreed following the initial EPR meeting and are arranged via the JRO Administrative team.

4.0 JRO ASSESSMENT PROCEDURE

Following the EPR meeting, the CI or Research Database Team should liaise with the relevant Lead JRO Research Governance Contact (as agreed at the EPR Meeting) to commence the JRO assessment procedure. This consists of the following stages:

i. Submission of the Research Database protocol and accompanying documents (e.g., Participant information sheets, Consent Forms etc.) to the relevant JRO Research Governance Team
ii. JRO Assessment Process - conducted by the JRO Research Governance Team
iii. Confirmation of JRO Support

4.1 DEVELOPMENT OF A RESEARCH DATABASE APPLICATION

It is important that the oversight of a Research Database is provided by the most appropriate JRO organisation; CU or CAVUHB. This should be determined as part of EPR meeting and made clear throughout all associated database documents.

An application to set up a Research Database must be supported by a Data Custodian. The Data Custodian should be a senior person within the relevant JRO organisation responsible for the Database and be able to provide assurance that appropriate information governance is in place. For Research Databases set up by a Cardiff JRO organisation, this should be the Chief Investigator. The Data Custodian will need to complete a full Data Protection impact Assessment (DPIA), liaising with NHS Information Governance and University Data Protection teams as appropriate.
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4.1.1 Governance Arrangements

When a protocol is designed for a Research Database, a section should be dedicated to the governance arrangements for the Database outlining the management and accountability structure. This may be in the form of a diagram outlining the roles within the database team, including project management, associated responsibilities, and how roles interlink.
If the Research Database includes data collected across organisations, a lead investigator must be identified for each organisation.

Consideration should be given to any Standard Operating Procedures (SOPs) that should be in place prior to commencing Research Database data collection, or whether this information is clearly defined within the protocol.
For example;

- Obtaining consent (including verification of consent)

- Obtaining consent remotely
- Research team access to patient level data
- Management of the application process for researchers wishing to utilise data from the database
- The role of any data access committees
- Identification and transfer of data to researchers
- Any patient follow-up processes
- Withdrawal of participants

Before developing any database specific SOPs, the Research Database Team should check whether the JRO organisation providing oversight of the database have existing SOPs in place.

4.1.2 Data Collection and Management

The protocol should clearly set out the process for data collection and management. Consideration should be given to the following:

- Participant groups/disease areas should be clearly defined, including where they are being identified from e.g., clinics/sites.
- The type of data that will be collected.
- Whether data will be collected prospectively, or whether existing NHS data will be included.
    - If existing data will be included, ensuring that the direct clinical care team have accessed it and how will it be sufficiently anonymised.
- What the consent model will look like.
- any potential capacity issues.
- The development of an online data catalogue and how will this be managed.
- The criteria for the types of studies/research groups data will be shared with.
    - The role of the access committee should be clearly mapped out.

In addition, all processes should be clearly mapped out, including:

- The data request process.
    - What role will University and/or NHS staff have in this?
- The data retrieval process.
    - What role will University and/or NHS staff have in this?
- The data release process e.g., deidentification, method of transfer etc.
    - What role will University and/or NHS staff have in this?

If patient follow up is planned, the protocol should outline:

- how often this will happen.
- what data will be collected.

- whether follow-up requires contact with patients or just a review of notes.

Suitable agreements should be put in place with data collection centres. This should be discussed with the relevant contracts team, local research coordinator and Directorate and/or School through the JRO discussions.

4.2 CONFIRMATION OF JRO OVERSIGHT

Upon satisfactory completion of the JRO Assessment Process, a letter is issued to the CI (with all key study contacts copied in), confirming that CU or CAVUHB agrees to provide oversight for the research database, and outlining any key requirements for the database (e.g. certain contracts).

Agreement to provide oversight for the project is granted on the assumption that the database:

- achieves a favourable REC approval (and any other approvals as specified in the letter)

AND that it is conducted in compliance with:

- the principles of GCP;
- the applicable CU and CAVUHB policies and procedures;
- applicable laws and regulations, including but not limited to the Data Protection Act and the Mental Capacity Act (as amended).

A PDF copy of the letter will be issued to the CI and any other key study team members by email. A copy of this letter should be retained by the CI.

The letter is then uploaded by the CI (or their delegate) to the Research Database IRAS Form as part of the IRAS submission.

4.3 AMENDMENTS TO RESEARCH DATABASES

If amendments to the Research Database or accompanying documentation are required, following review by any of the relevant authorities, the JRO Research Governance team will liaise with the CI (or their delegate) in order to discuss and review the required changes.

The process for submitting an amendment to a Research Database differs to that for project-based research. A Notice of Substantial Amendment form available in IRAS should be completed. This is created from the Amendment tab associated with the Research Database IRAS form.

A copy of the form should be shared with the Research Governance Team of the relevant managing organisation for review and support. The completed Notice of Substantial Amendment form should be electronically authorised by all parties listed on the form’s authorisations tab in IRAS.

When authorisations are in place, a PDF copy of the form (created via the Submission Tab of amendment form) should be submitted to the REC, together with all relevant enclosures. This is done via online amendment submission according to the instructions provided on the amendment form's submission tab.

Non-substantial amendments for Research Database projects do not need to be notified to the REC but should still be shared with the Research Governance Team of the relevant JRO organisation providing oversight for review and support.

If you wish to update the REC of any minor changes, for example to update key study personnel contact details, you can do this by emailing the relevant REC directly.

4.4 DURATION OF JRO OVERSIGHT

JRO oversight should be agreed for the duration of the Research Database until the database is archived, providing the following approvals and funding requirements are maintained by the CI (or their delegates):

- A valid favourable NHS REC opinion;
- Continued support for the Research Database from the NHS organisation(s) acting as data collection centres for the database;
- All other database approvals are maintained as outlined in the letter confirming JRO oversight;
- All changes and updates to the Research Database are formally recorded via the HRA Amendment process and approved by the relevant JRO organisation providing oversight;
- There is adequate funding and resource in place to support the Research Database.

NHS REC approval of a Research Database is valid for a period of 5 years following confirmation of a favourable REC opinion. During this time, a Research Database may be subject to an annual review carried out by the JRO organisation providing oversight.

NHS REC approval may be renewed (for further periods of five years) following submission and review of a renewal application to the relevant REC.

5.0 APPLYING FOR NHS REC APPROVAL

Before data collection for a Research Database can commence the following is required:

- Confirmation of JRO Oversight for the Research Database
- NHS REC Approval
- Signed DPIA
- Confirmation from the local NHS team and the Directorate management Team that they are happy to undertake the activities as agreed and outlined in the protocol.

For more information about different types of databases, and applying for ethical approval of a Research Database, please refer to the Standard Operating Procedures for Research Ethics Committees:

Research Ethics Committee – Standard Operating Procedures - Health Research Authority

6.0 USEFUL LINKS

HRA/REC

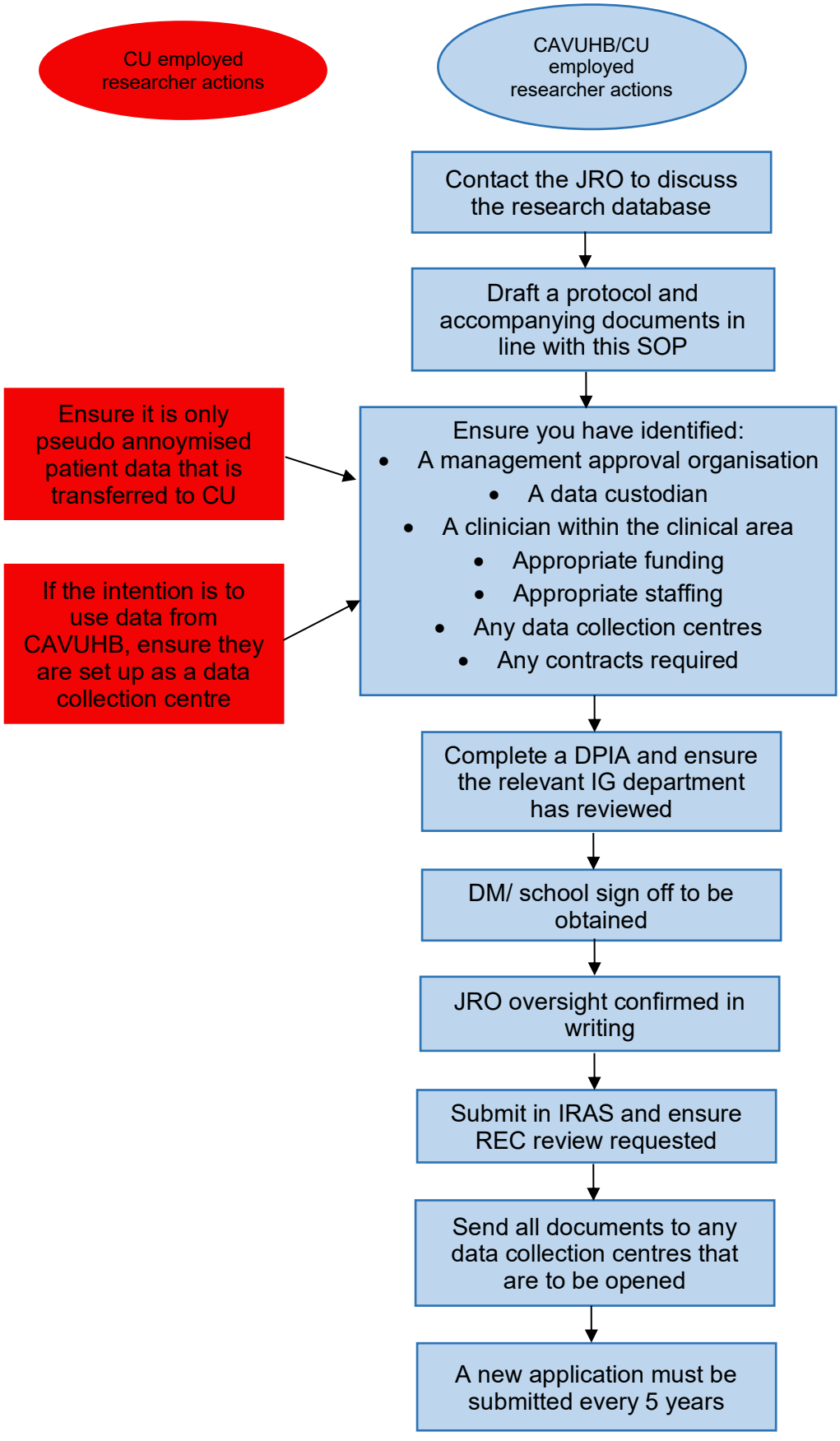
https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

IRAS

https://www.myresearchproject.org.uk/help/hlpcollatedqsg-sieve.aspx#1309

National Datasets and Trusted Research Environments

https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets
https://www.healthdatagateway.org/


CU employed researcher actions
CAVUHB/CU employed researcher actions
Contact the JRO to discuss the research database
Draft a protocol and accompanying documents in line with this SOP
Ensure it is only pseudo annoymised patient data that is transferred to CU
If the intention is to use data from CAVUHB, ensure they are set up as a data collection centre
Ensure you have identified:
A management approval organisation
A data custodian
A clinician within the clinical area
Appropriate funding
Appropriate staffing
Any data collection centres
Any contracts required
Complete a DPIA and ensure the relevant IG department has reviewed
DM/ school sign off to be obtained
JRO oversight confirmed in writing
Submit in IRAS and ensure REC review requested
Send all documents to any data collection centres that are to be opened
A new application must be submitted every 5 years