Royal Papworth Hospital
NHS Foundation Trust

Document Title: Using the Research Governance Database (EDGE)

Document Number: R&D SOP035

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
Version 7.0	**Amendments throughout in relation to updated processes**
Version 8.0	**Minor amendments throughout**

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the receipt and management of research study related information and documentation, and the research governance process.

- It provides guidance on what needs to be recorded within the Royal Papworth Research and Development's Research Governance Database (EDGE), to ensure compliance with both Royal Papworth Research & Development's (R&D), and the Trust's, policies. Instructions for how to use the research database can be found in the user guide.

1 Purpose and Content

a. This document defines the Trust's procedures for the recording of research study related information and documentation in the Research Governance Database (EDGE).

b. The procedures are designed to comply with the Trust's policies on Information Governance and Patient confidentiality.

2 Roles & Responsibilities

a. This Policy applies to all personnel conducting research at the Trust.

b. Staff involved in the management and recording of the documentation used in research studies must comply with the requirements set out in section 4. The maintenance of accurate and up-to-date information is essential for the generation of accurate reports reflecting research study activity being undertaken at Royal Papworth Hospital NHS Foundation Trust.

c. The Research Governance Team are responsible for the timely creation of records, upload of documentation and entry of research study related information onto the Research Governance Database (EDGE), with the exception of patient information and recruitment information which is uploaded and maintained by the relevant Study Team.

d. The study team are responsible for notifying the Research Governance Team of new studies, amendments, the local end date, post approval change in status and other changes that could affect the conduct of the study, and are responsible for assisting with the collection and input of research study related information .

e. The maintenance, management, and functionality of EDGE are managed by its owner, the University of Southampton.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

4.1 The Research Governance Database (EDGE) is used to capture research study information, track a study's status, store CV's, GCP certificates, Letters of Access and Honorary Research Contracts and to record key dates and other data points associated with the minimum dataset for performance reporting.

4.2 Creation of a new project record:

a. A new project record consists of allocating an R&D code number (a pre-fix 'P0' for research studies, a 'T0' for Tissue Bank studies, 'S0' for Service evaluations),creating a Research Governance Database (EDGE) entry and attributing an N drive folder space. The R&D Governance team will 'register' the study by utilising the next sequential R&D code number from the Governance team's Study Registration spreadsheet. see SOP013 for more details on electronic Trial Master File management.

The study Team Leader / Clinical Project Manager will be informed of the details for the above and asked when the study should be presented to the next Research Governance Project Approval System (RGPAS) meeting, for the study to be agreed to progress to the next stage. All research studies should be presented to RGPAS for approval to progress through to study setup / Sponsorship (see SOP34: Trust Confirmation of Capacity and Capability to Conduct Research Studies).

4.3 Study Status

a. The status of each research study must be updated on the Research Governance Database (EDGE) as appropriate throughout its lifecycle.

The following statuses are used:

Status	Definition
Expression of Interest	Study is of interest to the Trust and an Expression of Interest has been logged with the Sponsor team by the Trust.
Feasibility	Research study undergoing feasibility prior to trust approval.
Rejected	Research study will not progress to trust approval.

b.

Project site in set up	Research study going through Governance set up process, prior to issuing Trust Confirmation of Capacity and Capability.
Open	Research study which is actively recruiting; Trust Confirmation of Capacity and Capability (C&C) issued.
Closed to recruitment – in follow up	Research study ongoing, but recruitment complete.
Closed – Follow up complete	Research study is now going through its final stages; recruitment and patient follow ups are completed.
Complete	Research study has concluded at Royal Papworth Hospital.
Closed – COVID 19	Research study closed permanently due to COVID-19 making the study no longer feasible.
Suspended	Recruitment has halted but may resume.
Withdrawn	Recruitment stopped prematurely and permanently by Sponsor.
Abandoned	Recruitment stopped prematurely and permanently by Royal Papworth Hospital.
Archived	Study gone through its lifecycle and now archived.
Service Evaluation	Service Evaluation or 'research study not requiring ethical approval'.

b. There is a minimum dataset for each research study shown in appendix 1. This dataset should be completed in the Research Governance Database (EDGE) green zone by the Sponsor team, including Papworth Sponsored studies. Commercial and Non-commercial Sponsor teams will complete the EDGE green zone prior to Papworth issuing Trust Confirmation of Capacity and Capability (C&C).

c. Information will be entered as it becomes available during study setup.

d. A check for completeness will be conducted at Trust Confirmation of C&C by the R&D Governance team.

4.4 Dates to be captured for a research study

a. The key dates to be captured for each research study record are shown in Appendices 1 and 2. Appendix 2 also outlines the minimum information to be entered into the Research Governance Database (EDGE) red zone. The red zone will be completed by the R&D Governance team.

b. Dates will be entered into both red and green zones as they become available, by the applicable teams, throughout the life of the study.

4.5 Finance and Recruitment Entries to the Research Governance Database (EDGE).

a. For each study, the R&D Governance team are responsible for entering a finance template onto the Research Governance Database (EDGE). The finance template is populated by using the finalised budget information from the study contract agreement.

b. **The relevant study team members are responsible for entering the costs incurred per patient on to the Research Governance Database (EDGE).** Per patient and setup costs are invoiced within the timeframe stipulated in the study contract agreement and therefore all costs should be entered in a timely manner.

c. Those within the R&D Department tasked with invoicing Sponsors for research activity undertaken, will liaise with the R&D Governance team produce an invoice which is then sent to the study team for cross checking, before sending on to the Sponsor team for payment.

d. The research study team members are responsible for adding recruitment information and recruitment figures to the Research Governance Database (EDGE) in a prompt manner. The recruitment figures are gathered daily by the Clinical Research Network as part of site recruitment target monitoring. –

4.6 Documentation to be stored

a. All study documentation, including a version control, will be saved as per SOP 013 Trial Master Creation and Maintenance.

4.7 Creation of a new personnel contact in the Research Governance Database (EDGE).

a. A record is created for each Chief Investigator, Principal investigator, researcher and visiting researcher.

b. Data and Records to be captured for each contact are shown in Appendix 3.

c. The R&D Governance team will run regular reports from the Research Governance Database (EDGE) to allow reminders for renewal of expiring relevant training and Research passports. These will then be sent to the individual concerned or their team leader for them to arrange renewal.

4.8 Other changes

a. The Research Governance Database (EDGE) must be kept up-to-date with general changes in the study that do not require ethical approval e.g. new research team members, additional course dates etc. The R&D Governance team will work with the study teams to ensure the EDGE entry is kept up to date.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Appendix 1

Minimum Information to be captured for Portfolio and Non-portfolio research study records entered on to the Research Database (EDGE) green zone by the Sponsor team.

Information to be collected:
R&D Lead
Short Title
Full Research Title
Chief Investigator
Principal Investigator
Sponsor
Funder
Ethics Reference Number
Portfolio Status
UK CRN ID (portfolio studies only)
Project site number (project reference number)
Study status
If the study is a clinical trial
If the research study is interventional or observational
If the research study is a medicinal trial
If the study is a commercial trial
Key staff other than CI & PI

Appendix 2

Information to be captured for a research study entered on to the Research Database (EDGE) red zone by the R&D Governance team.

RGPAS governance workflow
RGPAS Date of discussion and Approval / Decline.
Target recruitment as documented in the Trial Agreement
Total number of patients recruited to the project
Principal Investigators name
Directorate authorisation comments
Archiving information (when available)
Whether samples are collected and associated information
Lead Directorate
Lead R&D Group
NIHR Time and Target & FPFV
Risk Assessment outcome
HRA approval date
Trust confirmation date
Date site invited (the date that the protocol was first received by R&D or date Expression of Interest was accepted by the Sponsor; whichever was first)
Date site selected (the date that the full submission pack including the HRA initial assessment letter, is received into the R&D enquiries mailbox)
Date site confirmed by Sponsor (date of Sponsor's signature on the contract)
Date site confirmed (date the contract is signed by the Trust)
Target date to recruit the participants (planned recruitment end date as per the contract)

Site initiation Visit date
Date site open to recruitment
Date site closed to recruitment
Planned closing date (as per the contract)
Amendment workflow(s)

Appendix 3

Information and Records to be captured for a new contact on the Research Governance Database (EDGE).

	Title and contact details	CV	GCP certificate	Honorary research contract or Letter of Access issued	Research Passport or NHS confirmation of pre-engagement checks
Chief Investigator	✓				
Principal Investigator	✓	✓	✓		
Researchers	✓	✓	✓		
Visiting Researchers	✓	✓	✓	✓	✓

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current active version approved date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	Current active version approved date
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy Research and Development Standard Operating Procedures entitled: SOP011 Archiving, SOP016 Monitoring Royal Papworth Sponsored Studies, SOP021 Trial closure and end of trial reporting, SOP037 Substantial Protocol Amendments Trust Policy DN48 Case Note Retention & Disposal of Patient Records

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative							

Review date:	June 2024

I certify the contents of this SOP has been reviewed and ratified

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Signed by Dr Ian Smith, Clinical Director of R&D

19th June 2021

Date

SOP release date: 25th June 2021