Royal Papworth Hospital
NHS Foundation Trust

# Document Title: Using the Local Portfolio Management System (Edge)

# Document Number: R&D SOP035

| | |
|---|---|
| **Staff involved in development:** *Job titles only* | Senior R&D Manager, R&D Operational Manager, Clinical Project Managers, Research Governance Team |
| **Document author/owner:** | Senior R&D Manager |
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| **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** |
| Version 9.0 | **Amendments throughout in relation to updated processes** |

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|---|---|
| **Key related documents:** | Trust Research Policy<br>Research and Development Standard Operating Procedures entitled:<br>SOP013 Trial Master File Creation & Maintenance<br>GD059 Resolving CPMS Confirmation Queries |

**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 Local Portfolio Management System (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 under the Support tab on the Edge website.
- Edge is used to capture research study information, track a study's status, store compliance certificates (e.g. training documents, competencies, certificates) and to record key dates and other data points associated with the minimum dataset for performance reporting.

# 1 Purpose and Content

a. This document defines the Trust's procedures for the recording of research study related information and documentation in the Local Portfolio Management System (Edge).

b. The procedures are designed to comply with the Trust's policies on Information Governance and Patient confidentiality as well as ensure accurate data collection by the NIHR for measuring performance.

# 2 Definitions

## 2.1 General

a. **Local Portfolio Management System (LPMS)** – various digital systems used by Regional Research Delivery Networks (RRDN) and their Partner Organisations to manage local research delivery and associated processes. The East of England RRDN and its associated delivery organisations (including RPH) use Edge as our LPMS. Data is transferred between LPMS and CPMS through a digital interface.

b. **Central Portfolio Management System (CPMS)** – a cloud-based system that holds the NIHR Research Delivery Network (RDN) Portfolio. Recruitment activity uploaded to CPMS

(usually via LPMS), and other study data stored in CPMS, are used to support performance management of studies so that Portfolio studies achieve recruitment and time targets

## 2.2 Edge Specific

a. **Project Level** – When you click on a Project, you will see information on the 'Project level'. This is also referred to as the 'Green level' due to the green band across the top and left-hand side of all pages at this level. It can also be thought of as the 'Sponsor level' as it contains information which the Sponsor or Lead site would be responsible for updating (e.g. recruitment target for whole study, planned end date of study). Project level pages have a green icon in the top left corner which resembles a clipboard.

b. **Project Site Level** – When you click on our site within a Project record, you will see information on the 'Project Site level'. This is also referred to as the 'Red level' due to the red band across the top and left-hand side of all pages at this level. This level contains information about the study delivery at our site (e.g. site target recruitment, planned open date for our site). Project Site level pages have a red icon in the top left corner of a capital H.

c. **Participant Level** – When you click on a Participant within the Participant tab on the Project Site level you will see information on the 'Participant level'**.** The Participant tab and its contents should only be accessed by those with clinical access who are adding recruitment information to Edge. The Participant level has a blue band across the top and left-hand side of all pages at this level. This level contains information about participants at our site who are involved in the study or have been pre-screened (e.g. visit costs, participant status). Participant level pages have a blue icon in the top left corner which resembles a head and shoulders.

d. **Admin** – Edge Admins are responsible for managing Edge as a system. They have full edit rights to all aspects of Edge and additional functionality such as Project creation and access to the Report tab.

e. **User** – Users are able to view data that their organisation has access to. They can edit information at Project/Project Site level where they have manage access, and can edit Participant level information where they have clinical access.

f. **Inactive User** – Inactive users do not have login details to Edge. These are created when reference to an individual is required, without them needing to have access to Edge (e.g. Chief Investigator).

# 3 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 5. 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 is responsible for Edge Admin duties such as:

- Creation of new User accounts and logins
- Management of User 'Teams' (these are not Project specific)
- Training of R&D Staff in using Edge
- Working in line with guidance provided by the East of England RDN, and distributing any guidance which has relevance for other R&D staff
- Running reports

d. In the case of RPH Sponsored or Managed studies, a designated member of R&D staff should be named to take on the following Sponsor responsibilities:

- Creation of new Project records*
- Reviewing Project involvement requests to RPH Sponsored studies from other organisations*
- The timely management and maintenance of Project records
- Reviewing external Project Site creation
- Managing staff access to the Project

**These tasks must be completed by a staff member with Admin access*

e. For all studies where RPH is a site or a PIC, irrespective of Sponsor, the Research Governance Team is responsible for:

- Requesting organisation involvement from the Project owner
- The timely creation of Project Site records
- Adding relevant staff members to the Project Site level
- Entry of research study related information onto the Project Site level prior to Trust Confirmation of Capacity and Capability (TCCC)
- Supporting the Study Team in resolving CPMS queries
- Adding finance templates to Projects
- Adding amendment costs where applicable
- Adding and updating Governance Workflows and Forms at the Project Site level

f. The Study Delivery Teams (including relevant support teams e.g. Pharmacy) are responsible for:

- Maintaining and updating Project Site level information for studies post-TCCC
- Uploading and maintaining patient and recruitment information in a timely manner
- Reviewing and resolving CPMS queries as soon as possible
- Updating and maintaining the Project Site Staff Tab including assigning relevant access to Project Site level
- Adding participant and project site costs in a timely manner (with the exception of amendment costs)
- Creating and managing invoices on Edge
- Updating assigned workflows

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

h. R&D staff members are responsible for uploading their own competency training certificates to the Training section of Edge as set out in Guidance Document 028.

# 4 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.

# 5 Procedure

## 5.1 Staff Access

### 5.1.1 Edge Account Management

a. The Research Governance Team will create User accounts and logins for all R&D staff members, with Multi-factor Authentication (MFA) enabled.

b. The Research Governance Team will also create a User account for each Chief Investigator, Principal investigator, researcher and visiting researcher. These accounts will be inactive where the researcher does not require Edge access.

c. If an R&D staff member leaves the department, their line manager should contact the Research Governance Team to request deactivation of their Edge account. The Research

Governance team will also deactivate the accounts of any external researchers upon the expiry of their Honorary Research Contract or Letter of Access.

d. All R&D staff will be assigned to a 'User Team' in Edge. The Research Governance Team will be responsible for maintaining these teams, including granting leadership rights to Senior Managers and Team Leaders.

### 5.1.2 Managing User Access Types

a. Users may be granted different types of access to Projects and Project sites; these are detailed in the tables below.

| Project (Green) Level Access Type | Description of Access |
|---|---|
| Basic Access | User can view the data on the Project level except for finance information |
| Manage Access | User can view and edit Project level data, including finance information, and assign user access types on this Project |

| Project Site (Red) Level Access Type | Description of Access |
|---|---|
| Basic Access | Can view the data on the Project Site level except for finance and participant information |
| Manage Access | Can view and edit Project Site data, including finance information but not participant information, and can assign user access types on this Project Site |

| | |
|---|---|
| Clinical Access | Can view the data on the Project Site except for finance information, and can view and edit participant information |

b. At the Project level, users can either have basic or manage access. At the Project site level, users can have basic access, manage access, clinical access, or a combination of manage and clinical access. The flow charts in **Appendix 1** can be used to determine which access type a user should be granted.

c. For RPH Sponsored/Managed studies, the staff member responsible for creating the Project record will be responsible for adding the required users to the Project level only. If there is an associated Project site record required, the Research Governance team will be responsible for adding staff members to the Project site level during the set-up of the study. Once TCCC has been issued, the lead Clinical Trial Coordinator (CTC)/ lead Research Nurse (RN) for that study will be responsible for ensuring that relevant staff members have the appropriate access.

d. For non-RPH Sponsored studies, The Research Governance Team will be responsible for adding staff members to the Project level, and to the Project site level during the set-up of the study. Once TCCC has been issued, the lead Clinical Trial Coordinator (CTC)/ lead Research Nurse (RN) for that study will be responsible for ensuring that relevant staff members have the appropriate access.

e. At the Project site level, users can also be assigned as 'Key Staff'. This offers no additional user functionality but means that the user is listed on the overview page. The PI, Team Leader and lead CTC/lead RN for the study should be assigned as Key Staff, so it is clear who can be contacted regarding the study at our site.

## 5.2 Project Level

### 5.2.1 RPH Sponsored/Managed Studies

a. A designated member of R&D staff with Admin access is responsible for the creation of all Project records for RPH Sponsored/Managed studies. An appropriate member of staff (e.g. CPM for the study, PI) should then be given manage access to the Project to maintain the Project record.

b. Project details should be completed as fully as possible, as the information becomes available, if not initially available at Project creation (see **Appendix 2**).

c. The Project details should be updated and managed in a timely manner.

#### 5.2.1.1 NIHR Portfolio Studies

a. When a study is deemed eligible for the NIHR RDN Portfolio by the NIHR Coordinating Centre, a new linked-to-CPMS record is created in Edge containing all the project details from the CPMS record. Any further updates made to the CPMS record will feed back down and update the Edge Project record.

b. It is essential that the NIHR Portfolio ID (CPMS ID) is filled in if a Project record is created before a study is deemed eligible by the Coordinating Centre. If the RPH created Edge record does not contain the CPMS ID, CPMS will create a duplicate record and no data from the original record can be exchanged between Edge and CPMS.

c. Projects on Edge which are linked to CPMS will have their core details updated each night by CPMS. For these studies, core Project information should be updated via CPMS, not Edge (these fields are specified in **Appendix 2**).

### 5.2.2 Non-RPH Sponsored Studies

a. Where a Project record already exists on Edge, the Research Governance team is responsible for searching for and requesting involvement in that Project.

b. Where a Project record does not exist, the Governance team will contact the Sponsor/lead site and request creation of a record.

## 5.3 Project Site Level

a. The Research Governance Team will create a Project Site record during the feasibility stage of set-up.

b. Project Site information will be updated, as it becomes available, by the Research Governance Team until TCCC is issued.

c. Once TCCC is issued, updating the Project Site information becomes the responsibility of the Study Delivery Team.

d. **Appendix 3** details which fields should be completed at the Project Site level.

## 5.4 Recruitment

a. For each study, the relevant study team members (as per the delegation log) are responsible for uploading participant recruitment information, as timely as possible: including recording and maintaining participants' statuses and uploading patient visit related finances, throughout the study duration.

b. The participant's tab is located on the Project Site Level, where all participants that have been added to the project can be viewed, and where new participants can be added. Widgets can be added to a user's homepage for quick access to adding participants.

c. The mandatory identifiers/information required to be recorded per participant will be set, either by the default Participant Data Collection Plan, or by a study specific Data Collection Plan, if one has been implemented. The Participant Data Collection Plan is noted on the Project Site Level.

## 5.5 CPMS Queries

a) Data is shared between LPMS and CPMS through a digital interface. CPMS Queries are used to confirm whether both site and Sponsor's recruitment data aligns.

b) CPMS queries are computed via recorded patient recruitment on LPMS vs what the Sponsor is expecting on CPMS, confirming whether what has been inputted by site is line with what is expected by Sponsor. Where the data matches, this confirms accruals. Where data has discrepancies, this results in CPMS Confirmation Queries.

c) CPMS queries are captured on the CPMS Tab on EDGE, located on the Project 'site' level (Red).

d) CPMS queries are managed and reviewed by the Governance team.

e) Actions and investigations are completed by the research delivery team with support from the Governance Team. Please refer to the Guidance Document, (GD059 Resolving CPMS Confirmation Queries).

f) Once a query is under review, the status of the query should be changed in line with the appropriate action under the CPMS Confirmation Tab.

g) Where queries have been resolved, and the Sponsor is happy their data aligns, these should be marked as Resolved under the CPMS Confirmation Tab.

### 5.6 Finance

a. For each study, the Research Governance team are responsible for uploading a finance template onto Edge. The finance template is created using the finalised budget information from the study site agreement.

b. The relevant Study Delivery Team members are responsible for entering the costs incurred per patient in the Participant level. These costs should be added as soon after the participant visit as possible, to ensure accurate record keeping. All costs need to be invoiced within the timeframe stipulated in the study site agreement and therefore should be entered in a timely manner.

c. Those within the R&D Department tasked with invoicing the Sponsor will liaise with the Research Governance team to produce a ledger report. This is then sent to the Study Delivery Team for cross checking, before an invoice is raised via the method detailed in the Site Agreement.

d. Once the invoice is raised, the invoice number and the relevant costs should be added to the invoice under the Finance Tab on the Project Level.

### 5.7 Study Documents

a. All study documentation, including a version control, will be saved as per SOP013 Trial Master Creation and Maintenance, not in Edge.

## 6 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.

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.<br>UK Policy Framework for Health and Social Care Research (2023) |

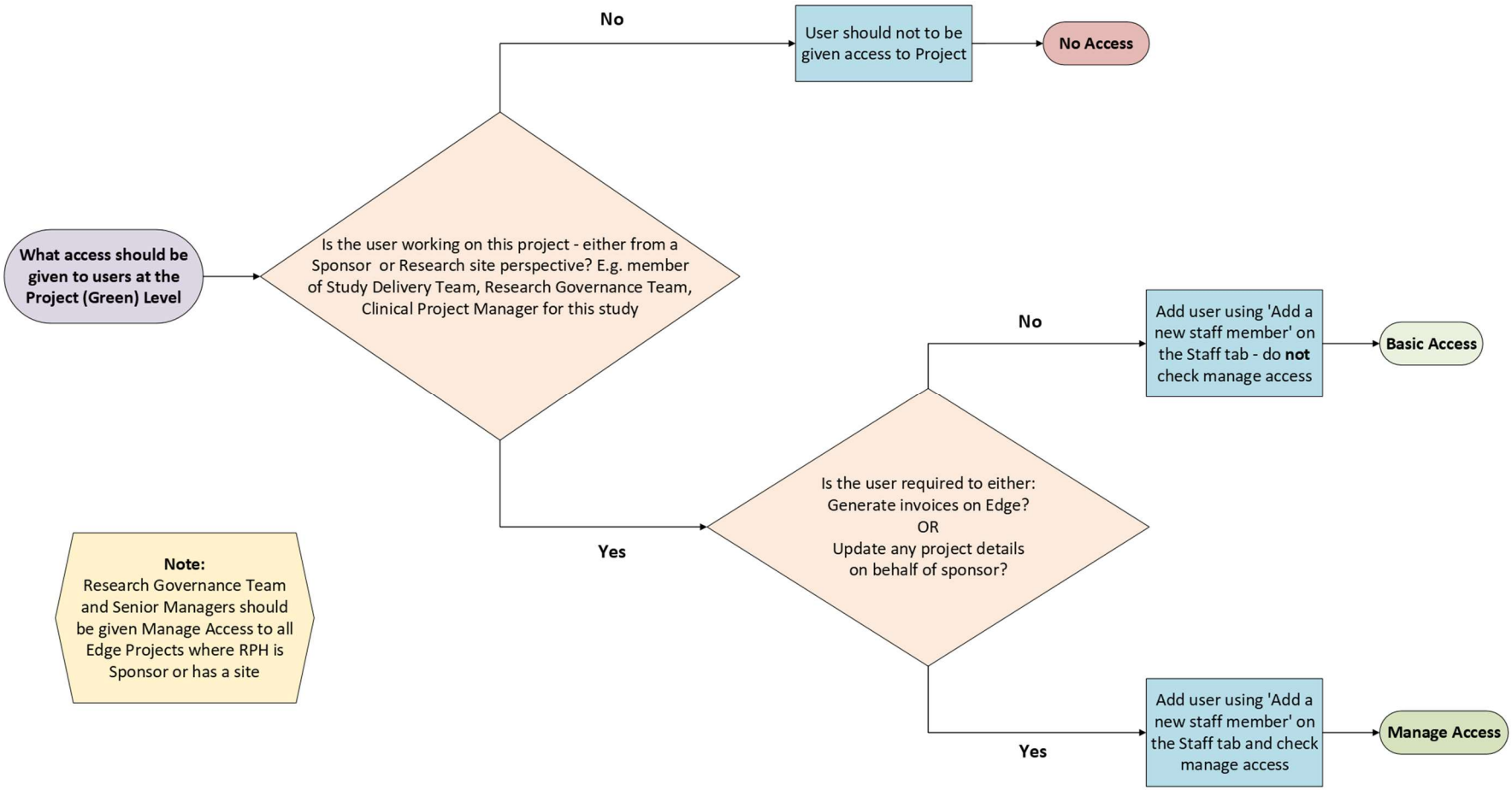
Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

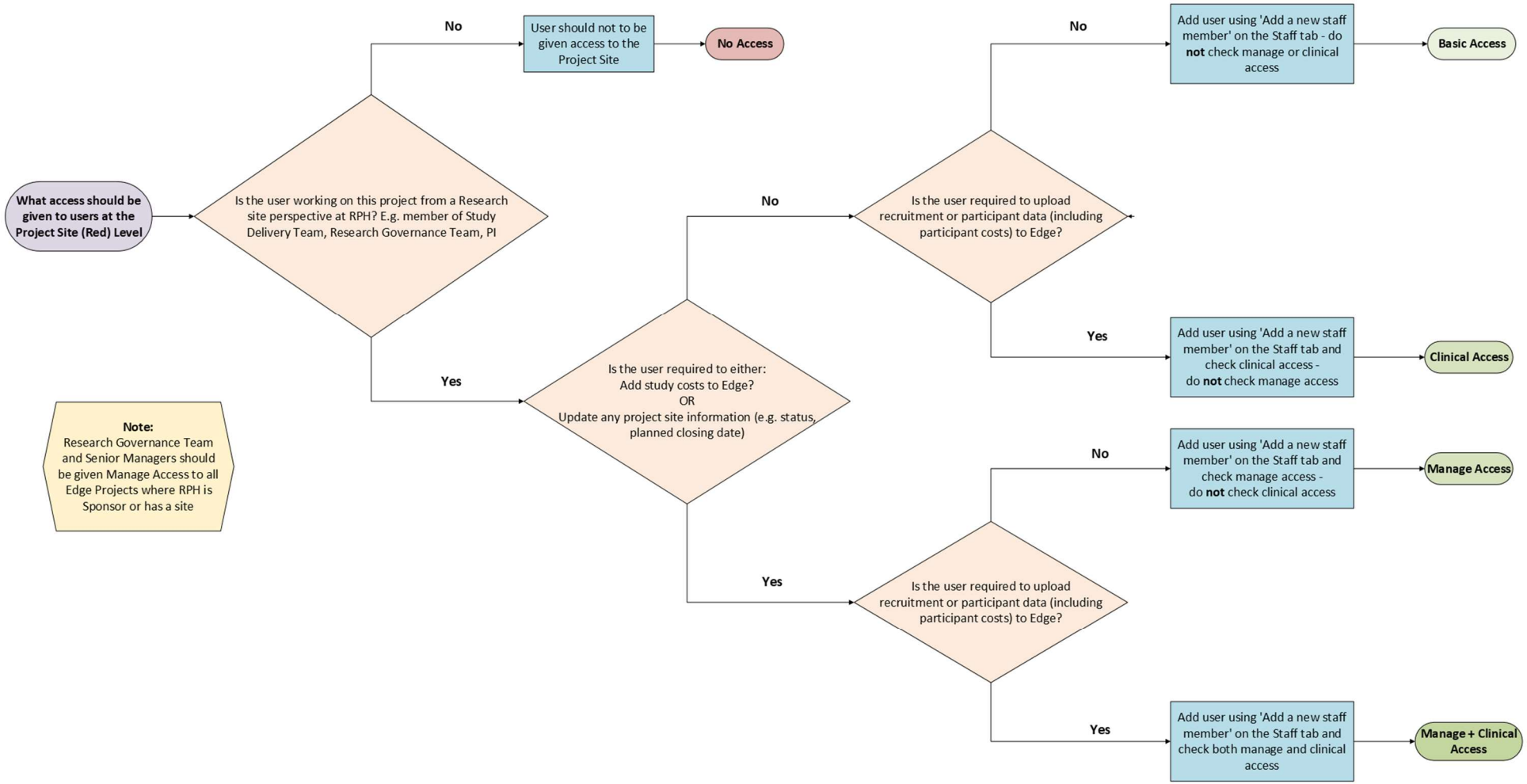
| **Groups** | Disability | Race | Gender | Age | Sexual orientation | Religious & belief | Other |
|---|---|---|---|---|---|---|---|
| **Yes/No** | No | No | No | No | No | No | No |
| **Positive/Negative** | | | | | | | |

| | |
|---|---|
| **Review date:** | April 2028 |

## Appendix 1

## Decision trees for user access in Edge




What access should be given to users at the Project Site (Red) Level
Is the user working on this project from a Research site perspective at RPH? E.g. member of Study Delivery Team, Research Governance Team, PI
No
User should not to be given access to the Project Site
No Access
Yes
Is the user required to either:
Add study costs to Edge?
OR
Update any project site information (e.g. status, planned closing date)
No
Is the user required to upload recruitment or participant data (including participant costs) to Edge?
No
Add user using 'Add a new staff member' on the Staff tab - do not check manage or clinical access
Basic Access
Yes
Add user using 'Add a new staff member' on the Staff tab and check clinical access - do not check manage access
Clinical Access
Yes
Is the user required to upload recruitment or participant data (including participant costs) to Edge?
No
Add user using 'Add a new staff member' on the Staff tab and check manage access - do not check clinical access
Manage Access
Yes
Add user using 'Add a new staff member' on the Staff tab and check both manage and clinical access
Manage + Clinical Access
Note:
Research Governance Team and Senior Managers should be given Manage Access to all Edge Projects where RPH is Sponsor or has a site

**Appendix 2**

**Information to be captured for RPH-Sponsored/RPH-Managed Studies and entered on to the Project level.**

| Fields to be populated: | Location in Edge (Project Level) | NIHR Portfolio Studies Only: Update via CPMS |
|---|---|---|
| Short Title | Overview > Core Details | ✓ |
| Full Title | Overview > Core Details | ✓ |
| Summary | Overview > Core Details | ✓ |
| Chief Investigator | Overview > Core Details | ✓ (where a match can be made to a user on Edge) |
| Visibility | Overview > Core Details | ✓ |
| Status | Overview > Core Details | ✓ |
| Project Type | Overview > Core Details | ✓ |
| Phase | Overview > Core Details | ✓ |
| Planned Start Date | Overview > Core Details | ✓ |
| Planned End Date | Overview > Core Details | ✓ |
| Start Date | Overview > Core Details | ✓ |
| End Date | Overview > Core Details | ✓ |
| Disease Area | Overview > Core Details | ✓ |
| CTIMP (Yes/No) | Overview > Core Details | ✓ |
| Device (Yes/No) | Overview > Core Details | ✓ |
| Participant Status Workflow | Overview > Core Details | ✓ |

| | | |
|---|---|---|
| Participant Data Collection Plan (default should be 'Standard Collection Plan') | Overview > Core Details | |
| Sponsor | Stakeholders > Sponsors | |
| Funder | Stakeholders > Funders | ✓ |
| Local Project Reference | Overview > Project Identifiers | |
| NIHR Portfolio Study ID | Overview > Project Identifiers | ✓ |
| IRAS Number | Overview > Project Identifiers | ✓ |
| REC Number | Overview > Project Identifiers | ✓ |
| Protocol ID | Overview > Project Identifiers | |
| Participant Types | Overview > Participant Types | ✓ |
| Project Arms (where applicable) | Configuration > Project Arms | |
| Study contact details (email address where applicable) | Criteria > Support | ✓ |

**Appendix 2**

**Information to be captured for a research study and entered on to the Project Site level.**

| Fields to be populated/updated | Location in Edge (Project Site level) | Staff Group Responsible | |
|---|---|---|---|
| | | Governance | Delivery Team |
| Project Site Status | Overview > Core Details | ✓ | ✓ |
| Site Type | Overview > Core Details | ✓ | |
| Project Site Number | Overview > Core Details | ✓ | |
| Principal Investigator | Overview > Core Details | ✓ | |
| Target Recruitment | Overview > Core Details | ✓ | |
| Participant Data Collection Plan | Overview > Core Details | ✓ | |
| Participant Identifier Type | Overview > Core Details | ✓ | |
| Approval Process | Overview > Approvals | | |
| C&C assessment required? | Overview > Approvals | ✓ | |
| Date site invited | Overview > Approvals | ✓ | |
| Date site selected | Overview > Approvals | ✓ | |
| Date site confirmed by Sponsor | Overview > Approvals | ✓ | |
| Date site confirmed | Overview > Approvals | ✓ | |
| Non-confirmation Status | Overview > Approvals | ✓ | |
| SIV Date | Overview > Milestones | | ✓ |
| Open To Recruitment (Date Site Ready to Start) | Overview > Milestones | ✓ | ✓ |
| Recruitment End Date (Planned) | Overview > Milestones | ✓ | ✓ |
| Recruitment End Date (Actual) | Overview > Milestones | | ✓ |
| Closing Date (Planned) | Overview > Milestones | | ✓ |
| Closing Date (Actual) | Overview > Milestones | | ✓ |