

# Local Portfolio Management System (LPMS)

NJRO-INF-SOP-004

## **Contents**

- 1. Background/Introduction**
- 2. Purpose**
- 3. Scope of Document**
- 4. Administration**
- 5. Adding recruitment figures**
- 6. References**
- 7. Appendices**

## 1. Background/Introduction

This Standard Operating Procedure (SOP) defines procedures, roles and responsibilities of user of the Local Portfolio Management System (LPMS). The system often called ReDA (**R**esearch **D**atabase **A**pplication) ©, is a web based study management system used to manage all clinical research studies at The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and Newcastle University.

## 2. Purpose

The purpose of the SOP is to describe how the LPMS is used to manage all studies. It outlines what should be stored and specifies the procedures to be carried out by the Newcastle Joint Research Department (NJRO) and delivery teams across NuTH and Newcastle University to ensure sufficient oversight.

## 3. Scope of Document

This SOP is applicable to all personnel using the LPMS.

## 4. Administration

The secure and flexible web based system accessed at <http://nenc.reda.org.uk> makes it possible to capture data at any time from any location allowing study teams the ability to update studies quickly and efficiently.

### 4.1 System Administration

The Research Informatics Team ([nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net)) is responsible for system administration. Responsibilities include:

- Creating and managing users.
- Disabling or changing user types from 'Write' 'HCP' & 'Read' or disabling users who have left the organisation.
- Implementing organisation wide local customisations (fields, tabs etc.).
- Creating and managing organisation wide reports.
- Organise user training when required e.g. new user, recruitment, changes to functionality etc.
- First line support to organisation users.
- Report issues and other requests to CRN NENC BI team who have overall responsibility for the system

## 4.2 Adding a study to LPMS

The NJRO Governance Team has overall responsibility for registering a study onto the LPMS. There may be exceptions where the North East North Cumbria Local Clinical Research Network (NENC LCRN) may create the study record prior to the IRAS application being generated. To avoid duplication of studies, it will be the responsibility of the governance team to update the study record with the IRAS ID and other study references as soon as they become available to ensure they are not duplicated in the system.

## 4.3 Adding a site to a study

LPMS uses sites and location data provided by the Organisational Data Service (ODS) to identify NHS Sites and NHS Locations. The aim is to attribute recruitment and other study related data to the correct location and ensure information links between the LPMS and Central Portfolio Management System (CPMS). The study site will be confirmed when teams register a study.

## 4.4 Capacity and Capability

Capacity and capability is recorded in LPMS by the NJRO Governance Team. It is the responsibility of individual teams to ensure each form is correct before submitting to either [nuth.nuthsponsorship@nhs.net](mailto:nuth.nuthsponsorship@nhs.net) or [nuth.hostedsubmissions@nhs.net](mailto:nuth.hostedsubmissions@nhs.net) depending on the study sponsorship either NuTH or Hosted by NuTH.

## 4.5 Study Amendments

It is the role of the Sponsor to advise study teams of any study amendments. It is the responsibility of teams to ensure they are aware of any amendments and to track the status of amendments sent to the NJRO Governance Team [nuth.amendments@nhs.net](mailto:nuth.amendments@nhs.net) and updated in the LPMS.

## 4.6 Storing Documents in LPMS

Users with 'Write' access can upload study related documents via the 'Documents' page. When adding a document, users must choose the 'Trust Specific' and the 'Trust only' option if they want the documents to be visible to users from NuTH only.

#### 4.7. Reporting

All fields and data items in LPMS are reportable. When choosing to save a report as visible to all users, the report will be visible to any user of the system across the NENC CRN.

#### 4.8 Removing a study

Study deletion should only be undertaken by the Research Informatics Team [nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net). If a location has been added in error, the location should be deleted from the study via the locations screen and the reason for deletion recorded in the “reason for deletion” comments box.

#### 4.9 Archiving a study

Once a study has been closed/completed, the Research Information Team via the delivery teams or the governance team receive notification to start closure of a study following the agreed working instruction '[Completing studies on the LPMS' NJRO-INF-WI-006](#)

### 5. Adding recruitment figures

Recruitment is the enrolment of an individual person meeting specific inclusion criteria into a research study. Each study participant providing informed consent to join a study and is taking part in the study (i.e. participants who count towards the sample size of the study as set out in the study protocol) should be included in recruitment figures recorded in the LPMS.

#### 5.1 Recording recruitment

Record recruitment activity in the LPMS as soon as possible after the activity has occurred, ideally within 5 working days of the end of the month of recruitment. See the LPMS Recruitment Upload' section of '[LPMS Overview' NJRO-GEN-GUIDE-014](#). Recruitment data is a key part of the information used to monitor and improve the work of research support and delivery. This data also currently feeds into the process of allocating Research and Development funding to ensure that support and delivery resources are directed to where they are required. Recruitment data for portfolio studies also prompts payments of NHS Support Costs and Excess Treatment costs. Having this information uploaded in a timely way will reduce the work required to process such payments.

Recruitment data may relate to the following (not an exhaustive list):

- Patients recruited to a study or a treatment regime;
- Staff members who have completed a questionnaire(s) or been interviewed in research;
- Individual members of focus groups;
- The collection of tissue or blood samples during research;
- Participants who have answered questions during research.

Each participant recruited into a study should only be counted in one recruitment figure i.e. where the same individual is consented more than once into a study they should only be included in the recruitment figure once.

## 5.2 Recruitment upload route (Portfolio Studies)

All portfolio recruitment activity will automatically feed through to the CPMS, when the CPMS recruitment upload route is set to LPMS. The CPMS recruitment upload route (LPMS, Manual Research Activity Upload or Not Applicable) will be determined at the time the study is set-up on CPMS using an agreed UK-wide Standard Operating Procedure.

- **LPMS** - LPMS recruitment activity is recorded in LPMS. Site recruitment totals are then uploaded automatically to CPMS once per day (after midnight).
- **Manual Research Activity Upload** – Research activity is added to the CPMS by the sponsor or study team and to the LPMS by the research teams. Both systems must match.
- **Not Applicable** – The study is not eligible to add recruitment to the LPMS.

For portfolio studies where the upload route is LPMS, it will be the responsibility of the research teams to enter timely study recruitment and to answer any recruitment activity queries raised by the central study team in CPMS. The NIHR central study teams will review and confirm/query the LPMS recruitment activity data in CPMS on a regular basis. Queried monthly recruitment activity figures will appear in LPMS and can be corrected/re-submitted to CPMS.

Each study team is responsible for determining which research teams/individuals will be responsible for supporting activity entering in to the LPMS.

## 6. References

### Local Portfolio Management System (LPMS) – NIHR Portfolio Studies

This overarching Network SOP is available from the SOP store within LPMS.

Please get in touch with [nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net) if you require a copy

## 7. Appendices

### 7.1 Study status table

| Study Status                                | Information   |
|---|---|
| Application (Full)                          | Funding Team Status - Study is a one stage application or moves from first stage to second stage                            |
| Application (Outline)                       | Funding Team Status - Two stage study and the application is at the first stage   |
| Application (Unsuccessful)                  | Funding Team Status - Notified by the PI that an application has been unsuccessful  |
| Application (Withdrawn)                     | Application has been withdrawn by PI  |
| Archived                                    | Study completed and archived by NJRO  |
| Closed – In Follow up                       | Study in follow up  |
| Closed to recruitment                       | Study closed to recruitment and ready for completion  |
| Closed to recruitment – No Follow Up        | Study is completed at NuTH but still ongoing at other sites and NuTH are unable to archive until all other sites are closed |
| Completed                                   | Study is now out of date and awaiting clarification if study is completed   |
| In set-up                                   | Research & Development number issued and study is being prepared for submission   |
| In set-up – pending approval                | Study submitted to NJRO and passed to officer for confirmation and capacity   |
| Investigator declined study AFTER selection | A team/investigator decides they are no longer able to run the study at NuTH following selection by sponsor                 |

|                                       |  |
|---------------------------------------|--|
| Notification Only                     | R&D number has been issued for NuTH sponsored study – no documents have been submitted for sponsorship review  |
| NUP Number                            | Newcastle University Status - given to studies with no NuTH Involvement  |
| Open                                  | Study is approved and open to recruitment  |
| PIC only                              | Participant Identification Centre study approved and open  |
| Proposed                              | Commercial Team Status - Confidential Agreement Contracts (CDA) –for commercial partners                       |
| Sponsor declined site AFTER selection | Sponsor decides they no longer wish to run the study at NuTH following site selection.                         |
| Study withdrawn                       | Local information pack provided and team decline the study or a NuTH sponsored study is no longer going ahead. |
| Suspended                             | Clarification from team or sponsor that study is suspended   |