

# Health and Care Research Wales

## All Wales Local Portfolio Management System (LPMS) Standard Operating Procedure (SOP)

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## 1 Introduction

This Standard Operating Procedure defines the procedure, roles and responsibilities for the Health and Care Research Wales infrastructure using the Local Portfolio Management System (LPMS).

The Research Delivery Operational Group (RDOG) have agreed the All Wales LPMS SOP is a working document for agreement by Research System Advisory Group, with published updates included on the next available Research Delivery Operational Group (RDOG) meeting for information of the members.

In June 2016, and after completing a robust procurement process, Infonetica won the contract to provide Wales LPMS, **Research Database Application (ReDA)**. Since that time, Health and Care Research Wales have collaborated with Infonetica to develop and configure ReDA to ensure it meets the needs of research support and delivery teams across Wales.

### Overview

ReDA is a web-based study management system used to manage studies on the Research Portfolio and Directory, which includes:

- Health and Care Research Wales Portfolio studies
- Pathway to portfolio and other non-portfolio studies

ReDA is the information management system for research and encompasses:

- Recording of all research related data (Wales minimum data set, which includes the UK wide minimum dataset)
- Recording of study recruitment and queried recruitment activity
- Study set up and amendments
- Performance reporting, monitoring and generation of Business Intelligence

## 2 System Administration

The Research Systems Advisory Group provides operational input to the Support and Delivery Centre on requirements for providing central LPMS system administration, on behalf of Health and Care Research Wales. The role and responsibilities of the group can be found in the Research System Advisory Group Terms of Reference and include:

- Providing a Wales wide agreed approach for the use of LPMS
- Providing a co-ordinated approach to the implementation of LPMS to all sites in Wales
- Considering local requests for change and the impact on national implementation
- Providing input into plans for Wales to align with work across the UK around local portfolio management systems and links to the Central Portfolio Management System
- Providing a co-ordinated approach to the management of LPMS service management and assist the Information Service Team with release management, testing of fixed issues and changes to LPMS system and processes, including changes to this SOP.

## Requests for change

All requests for change (with the exception of system access requests) are processed centrally by the Information Services Team and should be agreed by the LPMS user group and supported by the Research Systems Advisory Group member for the requesting site before being submitted to [Research-Information@Wales.nhs.uk](mailto:Research-Information@Wales.nhs.uk).

High impact or national change requests for LPMS will always be referred to the Research Systems Advisory Group for consideration and approval prior to implementation. However, standard changes with a pre-defined process can be pre-approved by the Research Systems Advisory Group allowing low risk changes to be implemented more efficiently.

On receipt of a LPMS request for change the Information Services Team will assess, categorise and record the request on the LPMS Request for Change Log. This log is published on the Research Systems Advisory Group Teams site. If a request for change matches one of the pre-approved changes, the Information Services Team will:

- Manage the change using the agreed process for the type of change
- Ensure relevant documentation (e.g. the LPMS Data Dictionary) is kept up to date
- Advise the Research Systems Advisory Group of any changes for all Wales consideration

## Standard change scenarios

### Scenario one

Change to an individual's LPMS access

Process:

- Change implemented by local, LPMS admin user.
- Information Services Team to provide system access reports every 6 months for Research Systems Advisory Group review.

Research Systems Advisory Group role: to review report and ensure users who should not have access are disabled in the system.

### Scenario two

Request submitted for a local custom field

Process:

- Information Services Team to check the field is not already in the system and if it is, inform the requestor.
- If information is not available in LPMS, the Information Services Team will create a custom field or switch on the existing field for the requesting Health Board.
- Local custom fields will be added to the upcoming LPMS Research Systems Advisory Group agenda for all Wales consideration.

Research Systems Advisory Group role: to review and advise if data field should be switched on for all Wales.

### Scenario three

Minor changes e.g. System field spelling.

Process:

- Information Services Team to log change and assess impact. If change is categorised as a standard change, the Information Services Team will either implement or request Infonetica to implement change.

Research Systems Advisory Group role: to review LPMS Request for Change log.

## 3 System Issues

### Escalation process

On experiencing an issue with LPMS, it is the responsibility of the site, where possible, to investigate if the issue is caused by something local before contacting the Information Services Team.

System Issues are to be reported to the Information Services Team via [Research-Information@wales.nhs.uk](mailto:Research-Information@wales.nhs.uk). All issues will be investigated by the Information Services Team to establish the impact of the issue and recorded on the LPMS Issue Log available on Research Systems Advisory Group Teams site. All LPMS issues will be categorised as follows:

#### Impact - Critical

Definition:

- The issue impacts critical functionality or data
- It does not have a workaround

Example:

- Unsuccessful installation, complete failure of a feature
- A significant group of users unable to complete essential work on the system

Resolution:

- Information Services Team to inform Infonetica immediately and work with them to implement a timely resolution.
- Information Services Team to keep LPMS Site key contacts informed of progress and expected resolution times
- LPMS Site key contacts to cascade updates to system users.
- Where appropriate, an incident report will be produced and made available to the Research Systems Advisory Group to record and mitigate similar occurrences in the future.

#### Impact – Major

Definition:

- The issue impacts major functionality of data
- It has a workaround but it is not obvious and is difficult to implement

Example:

- A feature of the system is not available, but the task can be completed using another feature of the system
- A significant number of users will be inconvenienced by the issue or there is a difficult workaround.

Resolution:

- Information Services Team to fix issue or inform Infonetica and work with them to implement a resolution.
- Information Services Team to inform LPMS Site key contacts of workaround and expected resolution times
- LPMS Site key contacts to cascade workaround to system users.

## Impact – minor

Definition:

- The issue impacts minor functionality or non-critical data
- It has an easy workaround

Example:

- The issue impacts a single or small number of users
- The workaround has little impact on efficiency

Resolution

- Information Services Team fix issue or inform Infonetica and work with them to implement a resolution.
- Information Services Team to inform LPMS user of workaround.

## Impact – cosmetic

Definition

- The issue does not impact functionality or data
- It does not require a workaround
- It does not impact productivity or efficiency

Example:

- Layout discrepancies
- Spelling/grammatical errors

#### Resolution:

- Information Services Team fix issue or inform Infonetica and work with them to implement a resolution.

It is the responsibility of the Research System Advisory Group members to review the LPMS issue log and advise the Information Services Team if categorisation of individual issues should be reviewed or amended.

### Local system administration

It is the role of local LPMS system administrators to manage local user system access. Any access issues that cannot be resolved locally should be escalated to the Information Services Team for further analysis and resolution. Responsibilities of

Local Administrators include:

- Creating and managing users (see LPMS user settings)
- Disabling and changing user access when staff leave or change roles to prevent unauthorised access
- Organising training when required
- First point of contact for users of LPMS and escalation of issues to the Information Services Team when required
- Implementation and management of locally agreed processes and system changes

**LPMS user settings** Access levels are:

- **Administrator** – write access to studies and management of system users
- **Write access** – write access to studies
- **Health Care Professional access** – limited write access to studies and access to person identifiable information for participant level information
- **Bulk Recruitment Activity user** – limited access to information and write access to bulk upload tab
- **Read only access** – read only access to studies

### Network (Support & Delivery Centre)

Restrictions to individual fields can be set. Example users for each access level are:

- Administrator - Overall system administrator.
- Write access - Central Portfolio, Industry or Primary Care team.
- HCP access - not normally applicable
- Bulk Recruitment Activity user - not normally applicable
- Read only access - users requiring information only across all Sites

## Non-network (NHS Wales sites)

Restrictions to individual screens can be set. Example users for each access level are:

- Administrator - site administrator
- Write access - site research and development team
- HCP access - research nurse
- Bulk Recruitment Activity users - user only updates Bulk Recruitment Activity
- Read only access - users requiring information across only one site

## 4 Managing Research Directory Studies

### Adding a study to LPMS

As agreed by the Research Systems Advisory Group, all studies will be added to LPMS by the Support and Delivery Centre. If a site is unable to find a study on LPMS, the site is to send the study details via email to request it is added to ReDA to the following email address:

- Non-commercial studies [Portfolio@wales.nhs.uk](mailto:Portfolio@wales.nhs.uk)
- Commercial studies to [Research-information@wales.nhs.uk](mailto:Research-information@wales.nhs.uk)

### Adding your site to a study

LPMS uses site 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 is linked between LPMS and Central Portfolio Management System (CPMS).

NHS sites can add their own locations to a study via the locations screen in LPMS.

To add a research location:

- Click on the plus button above the participating location list
- Tick the location you wish to add to the study in the pop-up screen
- Check that the location has been added to list of research sites in the research locations section
- Ensure the correct site type is selected from the Site Type dropdown. In particular, if the site is a Participant Identification Centre or other type on non-recruiting site.

Once added to the study, it is the responsibility of the site to maintain mandatory site, location and status information in the system and record monthly recruitment for those studies. For studies where “Supported by Support and Delivery Centre Primary Care Team” has been ticked, the Support and Delivery Centre will upload monthly recruitment and an agreed subset of Minimum Data Set (MDS) Items where information has been provided. However, where appropriate, NHS Organisations should still endeavour to upload relevant MDS items that are site specific for these studies (see MDS and appendix 1)



## Removing a study

Study deletion should only be undertaken by the Support & Delivery Centre, as deleting a study means that it will be deleted for all sites.

If a location is no longer involved in a study or 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. Sites can delete studies for their use whilst leaving the study record available to other sites by marking all of their locations as deleted using this process.

## Archiving a study

Some sites have implemented custom fields in LPMS for managing local archiving processes. However, when agreeing local processes, the local team is responsible for adhering to the condition of the LPMS Privacy Impact Assessment approved by the Information Governance Management and Advisory Group and is required to remove all participant identifiable information from the study record before archiving the study on LPMS.

## Maintaining the study record on LPMS

In line with the implementation of the LPMS for Wales, there is now requirement that all research studies enter a minimum data set and keep this maintained in LPMS.

The minimum data set for Wales includes the UK-wide minimum data set. This has been agreed through discussions with the 4 nations working group and as such, aims to be in line with the rest of the UK reporting requirements. The Wales minimum data set also includes other data fields required to ensure that Wales’ performance data can continue to be monitored on a routine basis and to provide Wales with the ability to generate robust and meaningful analysis for business intelligence related to research in Wales.

The LPMS minimum dataset for Wales can be found in the LPMS SOP Store along with this document and includes the roles, responsibilities and where the data items can be found for maintaining each of these data items in LPMS. Changes or amendments to this document are managed through the LPMS Request for Change process.

A summary of the data items to be captured within LPMS for all studies in Wales is provided below. Text in bold indicates that the responsibility for those data items sit with the Support & Delivery Centre. Those not in bold indicate that the responsibility for entering the data into LPMS sits with the NHS organisation. Those with asterisks\*, indicate that the responsibility for entering Location level data, for Primary Care studies, sit with the Support & Delivery Centre:

*Table 1 Data Items*

Item	Item Name	Item	Item Name
1	<b>IRAS ID</b>	31	Investigator name*
2	Date Site Invited	32	Study Receiving Delivery Support?*
3	Date Site/Locations Selected*	33	Site Actual Protocol Activity Complete Date
4	<b>HRA and HCRW approval date</b>	34	Site Status
5	Date Site Confirmed By Sponsor	35	Location Status*
6	Date site/location confirmed*	36	Location Type*

Item	Item Name	Item	Item Name
7	Non-confirmation status	37	<b>Study Supported by S&amp;DC Primary Care*</b>
8	Date Site/Location Ready To Start	38	Date Site/Location No Objection Issued*
9	First Participant Recruited Date at Site/Location*	39	Site/Location Actual End of Follow Up Date*
10	Reason for Delay in Recruiting First Participant	40	Is there a Local Collaborator at Location?*
11	Source Of Delay In Recruiting First Participant	41	Confirmation Withdrawn Status
12	Comments/Reasons (Delay In Recruiting First Participant)	42	One Wales Lead Site
13	Site Recruitment Target	43	Only Primary Care locations at Site?*
14	Target Number of Participants Not Available*	44	Study Site Suspension Actioned By?
15	Minimum Agreed Recruitment Target*	45	Date Study Suspended at Site
16	Maximum Agreed Recruitment Target*	46	Reason Study Suspended At Site
17	Target Date To Recruit Participants Not Agreed?*	47	Study Site Suspended Detail
18	Date Agreed To Recruit Target Number Of Participants*	48	Study Site Suspended Detail - Comments
19	Total Number Of Participants Recruited At The Agreed Target Date*	49	Study Site Suspended – COVID–19 Reason
20	Monthly Recruitment*	50	Study Site Suspension End Actioned By?
21	Site/Location Actual Recruitment Close Date*	51	Date End of Suspension at Site
22	Closure Reason	52	Reason Study Suspension at Site Unable to End (if applicable)
23	Comments/Reasons (Recruitment to Time and Target)	53	Reason Study Suspension at Site Unable to End (if applicable) - Comments
24	<b>Date Study Initiated</b>	54	<b>Wales Study Recruitment Target</b>
26	No Confirmation of C&C Required	55	<b>Research Delivery Hub Supported Study?</b>
27	<b>Study Actual Close Date</b>	56	<b>Research Delivery Hub Function</b>
28	Site/Location Actual Recruitment Open Date*	57	Source of Site Not Achieving Recruitment Target
29	Site/Location Planned Recruitment Close Date*	58	Reason for Not Achieving Site Recruitment Target
30	PIC Activity Only/Location Type*	59	Comments / Reasons - RTT Not Achieved

The Support and Delivery Centre will normally maintain study level fields, however sites may take on this responsibility by agreement on a study-by-study basis e.g. site sponsored non-portfolio studies would normally be maintained by sites. Sites can request study-level data changes by emailing details to [Portfolio@wales.nhs.uk](mailto:Portfolio@wales.nhs.uk) for non-commercial studies and [Research-information@wales.nhs.uk](mailto:Research-information@wales.nhs.uk) for Commercial studies.

When recording information against a study record it is the responsibility of the person recording the information to ensure that the information is recorded at the appropriate level (Study, Site or Location Specific).

## Adding recruitment figures

Recruitment is the enrolment of an individual person meeting specific inclusion criteria into a research study. Each study participant who has both provided 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 also be included in recruitment figures recorded in LPMS.

Recruitment activity should be recorded in LPMS as soon as possible after the activity has occurred, ideally **within 5 working days of the end of the month of recruitment.**

This will enable Wales to have near real-time data, which has not been possible previously, meaning that data required for study teams to monitor progress of studies and recruitment to target proactively in one system.

Recruitment data is a key part of the information used to monitor and improve the work of Health and Care Research Wales Support and Delivery. 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 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.

An interface has been developed to integrate LPMS and CPMS recruitment activity which means that recruitment figures maintained in LPMS after 1 June 2019 by local study teams automatically feeds through to CPMS for portfolio studies where the CPMS recruitment upload route is set to LPMS. 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 then appear in LPMS where they can be corrected and re-submitted to CPMS.

The CPMS recruitment upload route (LPMS, CPMS or N/A) will be determined at the time the study is set-up on CPMS, using an agreed UK-wide Standard Operating Procedure and automatically populated in LPMS for portfolio studies.

For portfolio studies where the upload route is LPMS, it will be the responsibility of local study teams to enter timely study recruitment into LPMS and to answer any recruitment activity queries raised by the central study team in CPMS.

Sites are responsible for determining which teams/individuals will be responsible for supporting local study teams in entering and correcting recruitment figures for recruitment at secondary care locations.

The Support and Delivery Centre will support primary care study teams by entering and correcting their recruitment figures in LPMS.

### **Adding participant information (where recorded)**

LPMS has functionality to support Health Care Professional (HCP) users of the system manage study participants. The HCP system user is the only ReDA user type that can access and is responsible for Participant Identifiable Information included in the system.

System users with “write” or “admin” accounts can record non identifiable participant and recruitment information, either against the participant number or via the bulk upload screen.

### **Study contact information**

Sponsor, Funders and Chief investigator will be prepopulated in LPMS as studies are added to system and are updated via the link from CPMS for portfolio studies. PI contacts and site or location contact details are kept up to date locally using the Stakeholders screen.

To avoid duplication of contact information in the system, it is the responsibility of the employing site to use the search functionality to ensure the contact does not already exist in the system before creating a new contact. It is also important to ensure any documentation associated with the contact e.g. CVs and Good Clinical Practice Certificates are also maintained within the contact record. Care must be taken when updating contact names, particularly where Funder/Sponsor names have originated from CPMS as this can result in creation of duplicate record. Funder/Sponsor contact details must only be updated by the Support and Delivery Centre.

On discovering a duplicate contact within LPMS, it is the responsibility of the employing site to email [Research-Information@wales.nhs.uk](mailto:Research-Information@wales.nhs.uk) requesting the two or more contacts be merged. On receipt of the request, the Information Team will seek approval from all sites that have these contacts as stakeholders before merging them.

### **Capacity and Capability**

Capacity and capability is recorded in LPMS within the Study Governance>events screen. It is the responsibility of individual sites to ensure this section is completed and to tick the “No confirmation of C&C required” field when these checks are unnecessary.

### **Study set-up**

Progress can be tracked in setting-up studies in LPMS within the Study Governance>set-up screen. Sites can determine which set-up activities to track, additional set-up activities can be requested via the LPMS Change Management process.

## Study amendments

It is the role of the Sponsor to advise study teams of any study amendments and the responsibility of sites to ensure they are aware of any amendments and have a local process in place to track the local status of amendments in LPMS.

## Storing documents in LPMS

It is possible to store and share documentation in LPMS. When uploading documentation to LPMS it is the responsibility of the person uploading the document to ensure the document is saved at the appropriate level (Study, Site or Location Specific), and is made visible to the correct user type.

It is also the role of the owning site to archive or delete any superseded documentation from the system when uploading a new document.

If an organisation comes across a document shared inappropriately, they should contact the document owner or the Support and Delivery Centre to correct the error.

## 5 Reporting

All 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 with the same organisational access as the report creator.

The following standard naming convention has been agreed by the Research Systems Advisory Group for any report shared in LPMS:

Location/Type of Report/Year Month

To ensure only the optimum number and type of reports are available in LPMS it is the responsibility of the report creator to:

- Make sure one off report templates are not stored in LPMS
- Only share reports thought to be useful to others
- Periodically delete reports no longer required

## 6 Glossary of terms

**Site** - The organisation with day-to-day responsibility for the location where a research project is carried out (UK Policy Framework for Health and Social Care Research, paragraph 9.14).

**Location** - Hospital or GP practice where the study is taking place.

## Version History

**Version number:** V1.0

**Effective date:** 14/02/2019

**Reason for change:** First issue for approval of Change Management Board

**Version number:** V1.1

**Effective date:** 18/02/2019

**Reason for change:** Updated to reflect comments from Change Management Board

**Version number:** V1.2

**Effective date:** 17/01/2019

**Reason for change:** Update to reflect Minimum Data Set Items (as per WalesMinimumDataSet\_Final v1.4.2)

**Version number:** V2.2

**Effective Date:** 03/12/2021

**Reason for change:** Update to SOP approval process and Minimum Data Set Items

**Version number:** V2.3

**Effective Date:** 05/01/2022

**Reason for change:** Update to SOP to comply with accessibility requirements

**Version number:** V2.4

**Effective Date:** 20/01/2022

**Reason for change:** Update to SOP to update email address from Industry to Information Services

**Version number:** V2.5

**Effective Date:** 12/09/2022

**Reason for change:** Update to reflect Minimum Data Set Items

**Version number:** V3

**Effective Date:** 18/04/2023

**Reason for change:** Update to reflect Minimum Data Set Items and removal of paragraph on exceptions for adding studies for locally sponsored studies to align with removal of add a study buttons for non-network users. Taken off exception for recording Covid-19 studies recruitment activity by midnight every Sunday.

**Version number:** V5

**Effective Date:** 14<sup>th</sup> July 2023

**Reason for Change:** Full review of document to ensure it aligns with current agreed processes.