Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	50.024	Version	1.0
Title	Management of the Central Portfolio Management System		

Prepared by	Radoslaw Penar		
Signature		Date	
Approved by	Melissa Robert		
Signature		Date	
Released by	Julie Brittenden		
Signature		Date	

SOP category					
Staff category					
Staff Category	R	Α	С	1	
Research Infor		Х			
Senior Researc	Х				
Research Adm	X				
Research Facili	X				
Sponsor Resea	Х				
NRS Portfolio	Performance Manager	X			
Innovation Pro	X				
Innovation Cor	Х				

1. Scope

This procedure applies to the Central Research and Innovation Office within NHS Greater Glasgow and Clyde

2. Purpose

This SOP is intended to act as a reference document to give clear instructions on how to identify and register a non-commercial study on the Central Portfolio Management System (CPMS).

3. Procedures

3.1. Central Portfolio Management System (CPMS) Overview

The NIHR CRN Portfolio is part of the UK Clinical Research Network Portfolio, which comprises the network Portfolios for England, Northern Ireland, Scotland and Wales. These four Portfolios are held on a single information system called the CPMS.

The Portfolio Database is a public, searchable database. Studies included in the NIHR CRN Portfolio have access to NHS infrastructure for research. This support includes NHS Service Support and Research Management and Governance Support via the Network. Study teams can also register for an International Standard Randomised Controlled Trials Number (ISRCTN) directly via the CPMS Portfolio Database.

Glasgow Clinical Trials Unit Standard Operating Procedure

3.2. Initialising a CPMS Study in NHS GG&C (Please refer to Appendix A)

During the R&I Approval process, the Portfolio Team and Innovation Team should identify if a study is suitable to be initialised on the CPMS portfolio by using Form 52.009D. The criteria for these studies are:

- That it is funded by an Eligible Funder¹
- That it has a "Glasgow"² Chief Investigator
- That it answers a research question/have a research hypothesis
- That consent is taken

If a non-commercially sponsored study is not eligibly funded but is:

- Funded by overseas Government, or
- Funded by overseas charity, or
- Funded by commercial company as collaborative research (or Investigator initiated trial), it can still be submitted to NIHR CRN PET for NIHR adoption by the Portfolio Team, and once it has been adopted the below process will be followed.

It is important that the portfolio team identifies the suitability of a study as early as possible in the R&I process, ideally in the initial set-up phase. The Research Administrator/Senior Research Administrator/Innovation Project Manager will then work on completion of the CPMS Minimum Dataset Template (Form 50.024A). At this juncture the portfolio team/Innovation team should contact the research team to enquire who will be the nominated recruitment contact for the study. The recruitment contact is the individual who may need to upload the recruitment information for Exemption studies (called 'Manual Research Activity Upload' method on CPMS) to the CPMS portfolio. The Exemption studies are for example questionnaire studies where all recruitment figures are centrally collected, and only the central team knows the exact figures (all other studies' accruals will be automatically transferred from SReDA onto CPMS once the 'Portfolio id' (CPMS id) has been entered on SReDA and the 'Portfolio' checkbox has been ticked). The recruitment contact can be:

- A nominated individual in the study team who has access to the recruitment accrual data
- A nominated individual from the Research & Innovation Team who is able to contact the study team to access their data. This individual can be a Research Facilitator, the Information Officer, a Glasgow CRF Administrator, Innovation Project Manager, Senior Research Administrator or a Research Administrator in the R&I Office.

If a study team member is the nominated recruitment contact, the R&I Department can offer training and support to enable them to upload the appropriate recruitment data.

¹ **Eligible Funder:** Details of Eligible Funders can be found on the NRS website: <u>NRS Website Link</u>

² **Glasgow CI**: Employee of NHS GG&C and/or affiliated University (University of Glasgow, University of Strathclyde, Glasgow Caledonian University, University of the West of Scotland

When the CPMS Minimum Dataset Template (Form 50.024A) has been completed by the Senior Research Administrator/Research Administrator/Innovation Project Manager and the recruitment contact has been identified, it will be forwarded to the Information Officer, who initialises the study on the CPMS portfolio, enters the 'Portfolio id' and ticks the 'Portfolio' checkbox on SReDA. There is a minimum dataset for each study that has to be uploaded before the study is successfully initialised, and when this is completed, the study can be published and released to the live CPMS website.

At this stage, the study has been successfully initialised and released onto the live CPMS website and begins to transfer accruals once entered on SReDA. It is also ready for the uploading of data accruals for Exemption studies.

3.3. Ongoing Management of Studies

The accruals for 'Manual Gathering' studies are collected by email on a monthly basis by the Informatics Team and entered on SReDA. Upon receipt of the EDGE reports from CRF and the Beatson in the beginning of the second week of each month, the Information Officer will upload all EDGE recruitment onto SReDA. All accruals entered on SReDA will then be automatically transferred onto CPMS.

For Exemption studies ('Manual Research Activity Upload' on CPMS) the recruitment contact is expected to add the accrual for each of their studies on a monthly basis. This involves the completion of the Standard Accrual Data Template available on the CPMS site, which is an Excel spreadsheet that is used to cumulatively record all the ongoing recruitment data.

Again, the Information Officer from the R&I Department can offer training and support to enable the successful upload of the appropriate recruitment data.

3.4. Communication

The importance of communication between all parties involved with the management and administration of CPMS studies cannot be stressed enough. It is imperative that the Portfolio Teams and Innovation Team (as the initial point of contact between the study team and the R&I Department) constantly update the Information Officer with any changes and/or amendments to CPMS studies, which should then be reflected on the CPMS database by the Information Officer.

This includes changes to a study's status:

- From 'In setup' to ' Open to Recruitment' when a study gets R&I approval
- From 'Open to Recruitment' to 'Suspended' when a study is being suspended to recruitment
- From 'Open to Recruitment' to 'Closed to Recruitment, In follow up' when a study has finished recruiting and is moving to In follow up phase, or to 'Closed to recruitment, No follow up' when study does not include the follow up phase
- From 'Closed to Recruitment, In follow up' to 'Closed to Recruitment, Follow up complete' when a study has finished the follow up phase

Change to a study's proposed end date:

 When a study is being extended e.g. an amendment to extend the recruitment period is being processed, the Portfolio Teams and Innovation Team will contact the Information Officer as soon as they start processing the amendment. The Information Officer will then update the 'Recruitment closure date – planned' on CPMS with the new proposed end date of recruitment (equivalent of the CTRE on SReDA) Change to a study's actual end date: Glasgow Clinical Trials Unit Standard Operating Procedure

- When a study is being closed to recruitment, the Portfolio Teams and Innovation Team will contact the Information Officer. The Information Officer will then update the 'Recruitment closure date – actual' on CPMS with the date the study has finished recruitment (equivalent of the 'Recruitment End' on SReDA)

If a recruitment contact is having difficulty uploading accrual information to the database, it is essential that they contact the Information Officer (internal) or the NIHR Service Desk (external) to rectify any problems that they are having. Non-compliance of uploading the accrual data is not an option as it can (and will) lead to financial penalties to the Health Board.

If the Information Officer experiences any issues with study teams refusing to upload accrual data or not making their data available to the nominated recruitment contact, it is crucial that an escalation process is followed. Although the likelihood of complete non-compliance from a study team is minimal, the warning that R&I Senior Management Team will become involved if this case-scenario arises, should be made to all research teams.

4. Referenced documents

- Appendix A New Study Identification and Initialisation (attached to this SOP)
- Form 50.024A CPMS Minimum Dataset
- Form 52.009D Project e-File Checklist
- The Standard Accrual Data Template (available to download from CPMS (nihr.ac.uk))
- NRS Funding Guidnace Eligible Funders https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20Funding%20Guidance% 20-%20Annex%202%20-%20Eligible%20Funders%20Working%20Document%20(4).pdf

5. Related documents

- NIHR Guidance Document Getting Started and Logging into CPMS
- NRS-GUI-020 NRS ReDA CPMS Recruitment User Guideline (available here <u>Getting started</u> and logging in to CPMS | NIHR)

6. Document history

Version	Date	Description
1.0	29/08/2023	Number changed from 52.010 to 50.024. Change of
		Process. Admin updates. R&D change to R&I. Change of
		Author.

This SOP is a controlled document. The current version can be viewed on the GCTU website. Any copy reproduced from the website may not, at time of reading, be the current version.

Appendix A CPMS: New Study Identification and Initialisation

