NHS Research Scotland

Central Management Team

Temporary Guidance on CPMS – LPMS Migration

V 1.1 04/19

1. Purpose

This guidance document is for NRS staff who are:

-involved in gathering non-commercial recruitment for a Scottish Health Board.

-reporting non-commercial recruitment for a study led from Scotland.

Please note this guidance is temporary and is likely to be updated or amended over time. Updates will be circulated to Board R&D offices and will be available on the NRS website.

2. Background

On the 1st May 2019 NIHR will implement a new method of recruitment upload to Central Portfolio Management System (CPMS).

Prior to the 1st May, recruitment upload to CPMS was the responsibility of a named contact for each study. This included uploading data for all UK sites involved in the study. For studies led from Scotland, the lead Scottish Board was responsible for ensuring that this upload took place for all non-commercial, eligible and extended review studies led from their Health Board.

This method of uploading to CPMS directly will cease after 1st May (apart from a small number of exemption studies).

The named contact for each study will no longer be expected to upload recruitment to either CPMS directly or report recruitment to leading R&D board for all participating sites. Instead, the named contact within the study either being the CI or a named representative will now be responsible for confirming the data entered onto CPMS.

Recruitment will instead be gathered at a local, regional level, using a "Local Portfolio Management System" (LPMS). Information from the LPMS will then be uploaded to CPMS and collated to provide a UK-wide picture.

In Scotland, this means that, after the 1st May Health Boards will be responsible for capturing recruitment information from all non-commercial, eligible and extended review studies which are active within their Health Board area. This includes both studies led by the Health Board, as well as studies led from elsewhere, and hosted by the Board. There is no need to capture or upload recruitment taking place outside the Health Board area.

NRS will be using the existing Research Database (ReDA) system as the Scotland–wide LPMS, however information can be uploaded into ReDA from existing electronic systems such as EDGE, CRF Manager.

In this document "non-commercial" means studies which are non-commercial, and meet the criteria to be considered either eligible or extended review in NRS Funding Guidance.

This document is for guidance and information only, and in any conflicts with existing guidance or policy, the existing guidance will take precedence.

3. How NRS Will Gather Recruitment Information

From the 1st May 2019, non-commercial recruitment (except for exemption studies see section 3.5) will be gathered using SReDA.

Non-commercial recruitment data should be added to ReDA no less frequently than once a month. ReDA be linked to CPMS to allow recruitment data to upload to CPMS. This information will continue to be visible in Open Data Platform (ODP) for those who use this.

Please note that in the initial months after 1st May, it is expected there will be a delay in allowing data from ReDA to upload to CPMS. This is to ensure hospital and Health Board research sites in ReDA are compatible with CPMS.

Therefore until otherwise notified, after 1 May 2019, data in CPMS and consequently ODP **will not be accurate except for exemption studies**. Please do not rely on CPMS/ODP for your recruitment information. Until further notice ReDA will hold the most up to date recruitment for your studies. Exemption study recruitment will continue to be uploaded to CPMS and therefore information will be considered accurate for these studies in CPMS only. CMT will advise when the full upload from ReDA to CPMS capability is in place, and ODP data is expected to be correct.

"Recruitment source" field

NHS R&D offices have agreed to identify the source of recruitment data for active non-commercial studies in their Board area.

R&D should choose the appropriate value from the "recruitment source" dropdown for each study.

R&D should continue to identify at study set up if studies and sites will use a system such as EDGE or CRF Manager, or if recruitment will be collected "manually" by direct contact with study teams.

Information in the recruitment source field should be as up to date as possible to avoid recruitment from studies being missed or causing more workload than necessary.

3.1 Upload of manually collected recruitment data to SReDA

After 1st May 2019 ReDA should be populated not less than once per month with recruitment figures for each study. Information should be added for each study by bringing up the study record at site level by looking under the "Recruitment" tab, then adding to the sub tab "recruitment totals" as figures per month.

ReDA currently only allows for health board level monthly recruitment figures to be added to the Recruitment tab. Once all study locations have been linked to ODS code locations, the recruitment matrices will be changed to site level to allow the recording of site/hospital level monthly recruitment.

The ability to add the exact date that a patient was recruited will be unavailable and data from EDGE/CRF Manager will be the source for this type of information. Any changes on this information will be communicated.

It will also be possible to bulk upload multiple studies to ReDA using an Excel spreadsheet. Training will be provided for this, however the ability to bulk upload will only be provided for staff who have Administrative access to ReDA. This level of access is carefully limited, since it allows write access to all ReDA records across NRS.

3.2 Validation of CPMS entered data

In June (date tbc) NIHR will be expected to have enabled the confirmation step within CPMS allowing the data flowing into CPMS to be validated by the CI or a nominated representative of the study.

For NRS this means when the data flow from SReDA to CPMS is activated NRS led studies only will require the CI or a study representative to access the system to verify the data. R&D boards should be aware of the studies they are leading on and contact their CI to inform them of this additional confirmation step. Training and guidance will be provided and circulated by CMT on behalf of NIHR in due course.

3.3 Manual Gathering studies

"Manual gathering" is the term used to refer to studies where Boards collate recruitment by direct contact with the local study team, or other staff delivering the study.

R&D will need to identify recruitment activity contacts (RAC) within each of the study sites in the Board (see section 4).

Under the new process, it does not matter whether a study is led from the Health Board, or hosted and led from elsewhere in Scotland or the UK. R&D must establish recruitment for all board studies by communicating with the local study team on a monthly basis. Data will be uploaded to ReDA as described in section 3.1.

3.4 Patient Recruitment Data Captured by EDGE or CRF Manager

Where recruitment information is already collected by an existing system in a Board area, such as EDGE or CRF Manager, CMT will work with boards to simplify or automate upload of studies where studies are from electronic systems.

Where EDGE or CRF Manager are used (as determined by the recruitment source), and information provided to CMT, R&D **do not** need to contact each study team and site in their area for monthly recruitment.

An information systems contact in each board should be identified and provided to CMT to facilitate the generation and import of monthly EDGE/CRF manager recruitment reports. CMT will initially import the EDGE/CRF Manager recruitment, but once the import processes are embedded and functioning as expected, training will be provided to the board contacts to allow each board to upload their own EDGE/CRF Manager data into ReDA.

3.5 Exemption Studies

In a small number of cases, it will not be sensible or possible to accurately gather recruitment activity locally. This includes:

- studies which will close on CPMS before end of Q2 2019/20
- Studies where the recruitment information is known at one site only in a multisite study. An example of this would be a questionnaire study where the sites provide the questionnaire but the questionnaire is sent directly to a main centre for counting.

CMT will inform NIHR of studies led from NRS which fall into either of these categories. R&D must inform CMT of any studies which fall into either category highlighted above which is not already listed as an exemption study. CMT are working with NIHR to identify those studies meeting the criteria for exemption studies led by other UK nations when this affects Scotland. This would include for example studies led from NIHR with NRS participating sites.

Studies considered exemption studies will continue to upload recruitment directly to CPMS by the process in place prior to 1st May.

R&D have been provided with a list of these studies prior to 1st May. If the recruitment phase is extended beyond Q2 then they should switch to being uploaded manually to ReDA unless they are captured by an electronic system as noted above (see section 3.4). In such cases, the selection field in "Recruitment source" should also be amended to reflect this.

After the 1st May, an exemption study list will be updated monthly and published on the NRS website. It is expected over time the number of these will substantially reduce, though R&D should still be aware of these and note in the "recruitment source" tab.

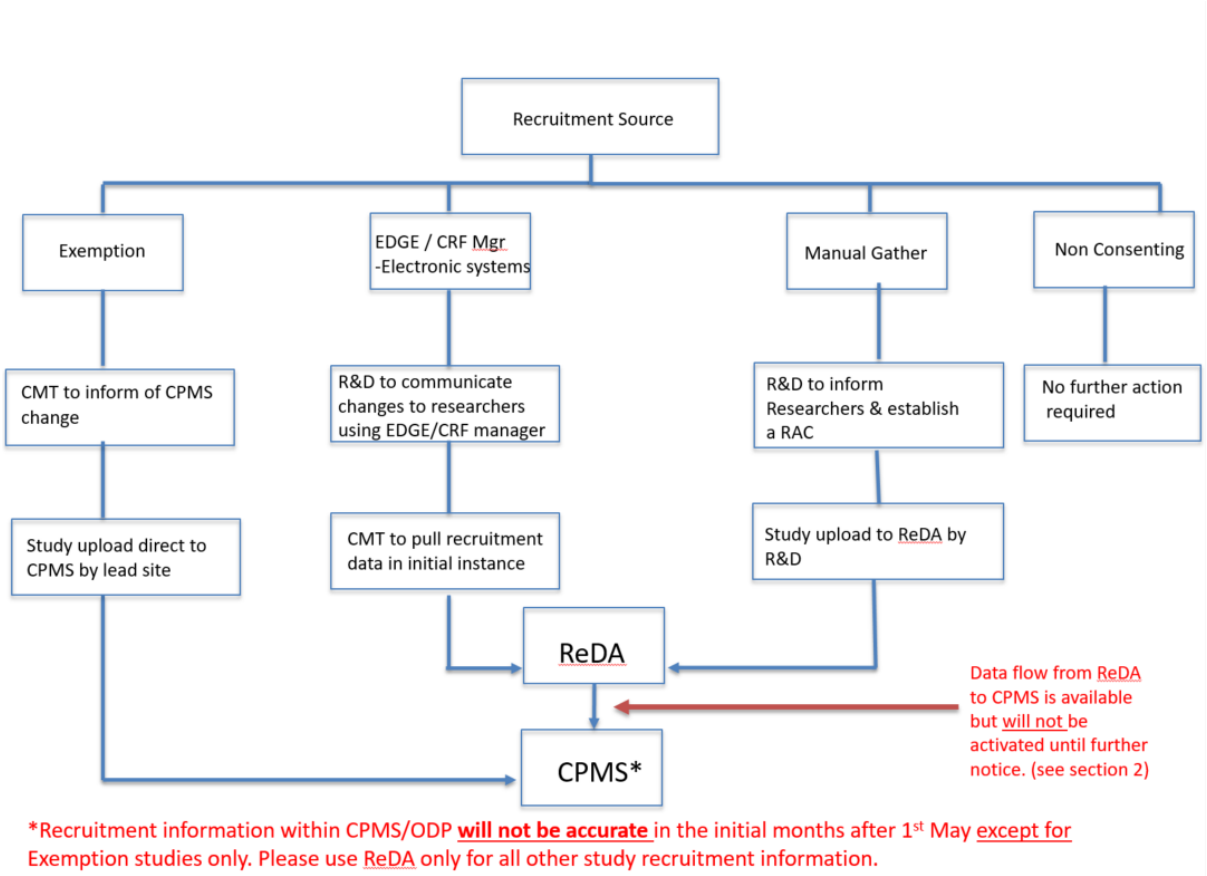
Only exemption study recruitment should be considered as accurate within CPMS after the 1st May. NIHR are establishing an API link which will eventually allow CPMS to backfill ReDA with recruitment data from exemption studies. The launch date of this API is yet to be confirmed by NIHR.

3.6 Non-Consenting Studies

A number of non-commercial studies listed on CPMS and with a CPMS ID do not require consent – such as studies using existing tissue or data. CMT prior to 1st May informed R&D of the studies which are considered non-consenting so no recruitment upload is required.

To ensure that these studies are recognised they should be highlighted as "N/A" on the drop down "Recruitment source" tab in ReDA and to avoid any additional workload.

Figure 1 below highlights the routes of communication (see section 4) and data flow for studies (see section 3) which are currently active and badged into one of the four categories as explained in previous sections.



4. Identifying Recruitment Activity Contacts & Communicating Changes

Prior to 1st May R&D were responsible for ensuring that all non-commercial studies led from the Board had a recruitment contact who was responsible for uploading recruitment to CPMS.

After 1st May R&D will also be required to identify contacts for all *hosted* studies (except for exemption studies).

R&D will be responsible for uploading recruitment to ReDA for **both** hosted and led studies (except for exemption which will be uploaded direct to CPMS).

CMT have circulated a standardised email intended to be sent to researchers highlighting impending changes to each R&D office. R&D have been asked to contact each "manual gathering" study using the standardised email, and to identify a recruitment activity contact (RAC), where appropriate, a contact willing to provide recruitment information to their local R&D office on a monthly basis.

Recruitment currently recorded on electronic systems such as EDGE and CRF manager, R&D are advised to establish contact and highlight the impending changes and inform the study team that recruitment data will be uploaded directly from their electronic system to ReDA. There is no need to communicate recruitment to R&D boards on a monthly basis. It would however, be advisable to establish an RAC for future reference.

RAC for studies should be recorded on ReDA for each study on the “stakeholders” tab under “recruitment activity contact”.

CMT have also asked the NRS Network and Speciality Groups to help identify any studies where known individuals at study sites could act as a recruitment activity contact. CMT will inform R&D offices where necessary.

CMT will communicate to the CI of all NRS led exemption studies to inform them of the impending change and to highlight that their study will remain as per the process prior to 1st May. Other nations will be communicating to the CI of their exemption led studies. It is expected that information provided to CI should cascade to the study teams across the UK.