



Rotherham Doncaster and  
South Humber

NHS Foundation Trust

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 1 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
ReDA Maintenance	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

Signatures:

Role	Name	Function	Date (DD-MM-YYYY)	Signature
Author	Emma Hannaford	Research Management & Governance Manager	28-02-2013	
Reviewer	Amy Beckitt	Clinical Research Development Manager	28-02-2013	

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 2 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: <b>Not applicable.</b>
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## 1 Definitions

Please refer to the current version of the SOP RM&G0002 for a glossary of all terms and acronyms.

## 2 Purpose

The purpose of this SOP is to cover the maintenance of the Research Database Application (ReDA). ReDA is the central database for Doncaster Clinical Research and holds most of the pertinent study information used for running reports.

## 3 Scope

This SOP covers all members of Research team in terms of database entry, and all research personnel who need study information from the ReDA system.

## 4 Procedure

All members of the Research team have access to ReDA. If anyone does not have the logon details, then they can contact the RM&G Manager or the Clinical Research Development Manager in order to obtain the details. Please note that access is limited to read-only for all but the following members of the Research staff:

- Research Management & Governance Manager
- Clinical Research Development Manager
- Senior Research Management & Governance Administrators
- Research Management & Governance Administrator

ReDA should ideally be populated with relevant study information throughout the review process, however this is not always possible. Studies should be entered onto ReDA as a new study as soon possible after receipt of the study information. This is often at receipt of the initial document set, but can be at the time of an expressed interest from the study team.

ReDA must be checked and updated at approval and for every amendment. In order to help with what needs checking, the 'Study Approval/Amendment Form' has been developed. This form is held in the 'Templates' folder of the Research Governance folder and must be used for every study approval and amendment (one form per study approval/amendment).

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 3 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: <b>Not applicable.</b>
	Attachments: <b>None</b>
	Effective date: <b>28 February 2013</b>

#### 4.1 Creating a new study

Log in to ReDA and select the 'Projects' tab at the top of the screen, then select 'New' under the actions tab on the left side of the screen.

The 'Licence/Location' should be 'Doncaster East PCT', as per default and the 'R&D Lead' should remain 'Miss Emma Hannaford'.

Enter the R&D Number for the new study (please see the current version of 'RM&G 0004 Study number setup' for information on how to do this) and add the REC number, if known (this can be added at a later date if required).

Finally, click 'Add new' in order to create the project on the system.

#### 4.2 Populating the 'Information' tab

ReDA is used to run quick reports about the various studies running in each of the Trusts incorporated in the joint office; for this reason, as much relevant information as possible needs to be included on the database. To ensure these reports are accurate, the fields listed below need to be completed. Please be aware that the information will not be retained in the 'Information' tab unless the 'Update' button is clicked.

##### 4.2.1 R&D No.

This needs to reflect the study type accurately. If entered incorrectly, or if the study type changes, then this number can and should be updated (see the current version of 'RM&G 0004 Study number setup' for more information).

##### 4.2.2 REC No.

This can be found on any REC letter and is often the main identifier outside of the Trust.

##### 4.2.3 LREC No.

This number is used for archiving purposes and must not be entered prior to the end of the study (please see 'RM&G 0008 Archiving procedure' for further details).

##### 4.2.4 CSP No.

This number is specific to NIHR Portfolio studies that are going through CSP and/or the SYCLRN Portal. This number can be found on all IRAS

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 4 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

documents (REC form, R&D form, SSI form and so on) in the bottom right corner. It is the first series of numbers prior to the oblique (forward slash) and is usually four or five digits in length. This is the main identifier for studies progressing through CSP and/or the SYCLRN Portal.

#### **4.2.5 IRAS Project Code**

This number is the same as the CSP number, but is pertinent to all studies rather than just ones adopted onto the NIHR Portfolio. Other than very old 'legacy' studies, all studies should have an IRAS project code number. This number is particularly important with IRAS signature pages, as they are often separated from the full document. As all pages of the IRAS forms have this number on them, the signature page can be identified as belonging to a specific study.

#### **4.2.6 Eudract**

This number is specific to studies where an application has been made for approval by a competent authority, eg the MHRA. This can be found on most REC letters for the study and also on any MHRA correspondence. This study is the main identifier for any CTIMP study.

#### **4.2.7 UKCRN ID and UKCRN Project**

These two sections on ReDA confirm whether the study has been adopted onto the NIHR Portfolio. If a study has been adopted, the UKCRN Project box needs to be ticked.

The UKCRN ID is the NIHR Portfolio number that has been assigned to it. This is different to the CSP number, and can be found on the NIHR Portfolio website (see the current version of 'RM&G 0010 External websites and links' for the link to this site). This number is not always available at the time of approval, so if the number cannot be located the CSP number (or the IRAS project code) should be added, but in parentheses, ie (nnnn). This triggers additional checks throughout the study to see if the correct number is available.

The reason for having the checkbox is so that reports can be run that only contain studies that have been adopted onto the NIHR Portfolio. As this information is not always clear to those not involved in the study governance, this should only be completed by the Senior RM&G Administrators, the RM&G Manager and the Clinical Research Development Manager.

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 5 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: <b>Not applicable.</b>
	Attachments: <b>None</b>
	Effective date: <b>28 February 2013</b>

#### **4.2.8 ISRCTN No.**

This number can be found on the protocol, the NIHR Portfolio website (see the current version of 'RM&G 0010 External websites and links' for the link to this site) or the IRAS R&D form. This number should always be present for randomised control studies and can be present for other studies as well.

#### **4.2.9 Short study title**

This is presented in the IRAS forms (REC, R&D and SSI) and should include any study title acronyms. When searching ReDA for a study title, both the short and long study titles are searched.

#### **4.2.10 Research title**

This is the long study title and is presented in the IRAS forms (REC, R&D and SSI). When searching ReDA for a study title, both the short and long study titles are searched.

### **4.3 Populating the 'Management' tab**

The 'Management' tab primarily covers the dates of the study, but also covers the current status of the study and also the recruitment information. The sections that need to be completed are listed below. Please be aware that the information will not be retained in the 'Management' tab unless the 'Update' button is clicked.

#### **4.3.1 NRES form start date**

This is the start date as stated in the SSI form (or R&D or REC forms if the information is not available from the SSI form) and is the date the researcher would like to start the study within the Trust.

#### **4.3.2 NRES form end date**

This is the end date as stated in the SSI form (or R&D or REC forms if the information is not available from the SSI form) and is the date the researcher aims to complete the study within the Trust.

#### **4.3.3 Actual start date**

This is the date the approval letter is issued by the Trust.

#### **4.3.4 Actual end date**

This is the date the research is confirmed as being finished and the data can be archived. This date cannot be entered in advance and should only be entered when the study is due to be archived.

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 6 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

#### 4.3.5 Local start date

This is the date the study is archived (please see 'RM&G 0008 Archiving procedure' for further details). This date cannot be entered in advance and should only be entered when the study is archived.

#### 4.3.6 Local end date

This is the date the study archiving is complete (please see 'RM&G 0008 Archiving procedure' for further details). This date cannot be entered in advance and should only be entered when the study is archived.

#### 4.3.7 Status

This should be updated to reflect the current status of the study. There are five different status options: Active, Completed, Proposed, Suspended and Withdrawn.

Ideally, when a new study has been entered onto ReDA, the status should be set to 'Proposed'. This describes any study going through the Research Governance process that has not yet received Trust approval.

Once a study has been approved, the status must then be set to 'Active'. This means that it is possible for reports to be generated to see how many live studies are running within the Trusts. This study status must be set as soon as possible after the study has received approval (no more than two days after Trust has issued approval).

The 'Suspended' status is used for any study that needs to be put on hold for any reason. This can be during the approval process, or after approval has been given. This is usually because the research is going to go ahead in the near future, but there is a specific reason which means it cannot go ahead at that time. The reasons for study suspension are varied but can include long-term leave of Principal Investigator, specific safety issues that need to be resolved before continuing, or changes in Sponsorship.

The 'Withdrawn' and 'Completed' statuses are only used during the archiving process (please see 'RM&G 0008 Archiving procedure' for further details).

#### 4.3.8 Date Research Governance fee invoiced

This should be updated to reflect the Research Governance fee was invoiced for the study. This fee is only payable by commercial sponsors and a request should be sent to the Research Management & Governance Manager or the Clinical Research Development Manager to raise an invoice as soon as the approval letter is issued for a commercial study.

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 7 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: <b>Not applicable.</b>
	Attachments: <b>None</b>
	Effective date: <b>28 February 2013</b>

#### 4.3.9 Research Governance fee applicable

There are three options in this drop down menu: 'Invoice raised' 'Invoice requested' and 'Not applicable'.

For all non-commercially sponsored studies, the 'Not applicable' option should be selected. For commercially sponsored studies, the 'Invoice requested' option should be initially selected, but this should be updated to 'Invoice raised' very quickly. As the invoice should be requested as soon as the approval letter has been issued, there should not be a need for any further options.

#### 4.3.10 Nursing support

There are four options for this drop-down menu: 'CLRN funded nursing support only', 'Trust funded nursing support only', 'Both CLRN and Trust funded nursing support' and 'No nursing support'. This drop-down is very important in terms of ensuring the Trust is fully recompensed for the nursing activity involved in the study. These options are detailed more fully below.

'CLRN funded nursing support only' is selected when nurses from the SYCLRN network, or nurse employed by the Trust but fully paid for by the SYCLRN (for example Oncology and Stroke nurses) without any involvement of any Trust funded nurses, then this should be selected.

'Trust funded nursing support only' is selected where there is nursing activity carried out by nurses who are funded by the Trust, without any support from nurses funded by the SYCLRN.

Both CLRN and Trust funded nursing support' is selected when nursing support comes through from both Trust and CLRN funded nurses are involved in the study. When this is selected, an additional comment needs to be added in the 'Nursing support narrative (%)' section (please refer to Section 4.3.13 Nursing support narrative (%) of this SOP for full details). Please note that as the Trust is moving towards an integrated nursing model, the majority of studies with nursing support will involve both Trust funded and SYCLRN funded nurses.

'No nursing support' should be selected if there is no nursing support for the study being provided by either the Trust or the SYCLRN. If there is nursing

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 8 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: <b>Not applicable.</b>
	Attachments: <b>None</b>
	Effective date: <b>28 February 2013</b>

support being provided by the Sponsor, with no financial impact on the Trust, then this should be selected.

#### **4.3.11 Local recruitment sample required**

This is stated in section 10 of the SSI form, and refers to the number of participants the Trust is expected to recruit for the study.

#### **4.3.12 Local sample actual**

This number refers to the actual number of participants recruited to study and can only be entered when recruitment ends for the study at the Trust. This will be entered at the time of archiving, where known.

#### **4.3.13 Nursing support narrative (%)**

This section needs to be completed where both Trust funded and SYCLRN funded nurses are working on a study. A breakdown of the approximate split percentage needs to be included in this section. Please note that as the Trust is moving towards an integrated nursing model, the majority of studies with nursing support will involve both Trust funded and SYCLRN funded nurses.

#### **4.3.14 IMP study**

This must be ticked for any CTIMP study. For confirmation of whether the study is a CTIMP or not, the IRAS checklist should be consulted.

#### **4.3.15 Device study**

This must be ticked for any medical device study. For confirmation of whether the study involves a medical device or not, the IRAS checklist should be consulted.

#### **4.3.16 Pathology**

This must be ticked for any study that involves pathology. These studies should have been sent to the Pathology team for review and sign-off. For studies where samples are being taken but the Pathology team are not involved, this section should not be ticked.

#### **4.3.17 Tissue block provision**

This must be ticked for any study that involves us retrieving tumour blocks and sending them elsewhere.



Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 9 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

#### 4.3.18 Imaging

This should be ticked for any study involving imaging. These studies should have been sent to the Imaging team for review and sign-off.

#### 4.3.19 ECGs/Cardiology

This should be ticked for any study involving the Cardiology team. These studies should have been sent to the Cardiology team for review and sign-off.

#### 4.3.20 Commercially sponsored

This should be ticked for any study that is commercially sponsored. This information can be found in the IRAS R&D or IRAS REC form. For these studies, a Research Governance fee should be invoice.

### 4.4 Populating the 'Stakeholders' tab

This section of ReDA gives the names and contact details (where appropriate) for the key stakeholders for the study; namely the Principal Invesetigator, the Chief Investigator, the Sponsor and the Funder(s).

The Principal Investigator is stated on the SSI form. The Chief Investigator is stated on all IRAS forms (SSI, R&D and REC). The Sponsor is stated on the R&D and REC forms. The Funder(s) can be found on the R&D and REC forms.

In order to populate these sections of ReDA, first type the name into the relevant field and click 'Search'. If the name required is there, then select it from the list below the 'Search' button and click 'Add' (NB: In the case of the CI, you need to click the 'Add CI' button). In the case of the PI, the box for PI needs to be ticked once they have been added.

If the name of the person or company is not there, then click the 'Create new' button in the relevant section. For both the Sponsor and Funder(s), only the name of the company needs to be added (no address). For PIs and CIs, their title, forename and surname need to be added to the section and the 'Add New Investigator' button needs to be clicked. Once this has been clicked, the system will take you to another screen, in which the 'View/Edit Contact Details' button should be clicked. In this section, the following fields need to be completed, where the information is known: Address, Town, Country, Postcode, Telephone number, Fax and email.

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 10 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

## 4.5 Populating the 'Documents' tab

The 'Documents' tab contains all the documentation for studies and amendments approved (or acknowledged) after 01 April 2011. (Please note that documentation for studies and amendments approved prior to this date can be made available on request from the Research team, but there is currently no plan to upload these documents retrospectively.)

The aim of the 'Documents' tab is to ensure that all the relevant study documentation is available to the study team. To this end, the documents should be uploaded in a particular way, with the descriptions made as clear (and succinct) as possible, to allow documents to be quickly and easily located when required.

Folders need to be set up in order to upload the study documents. There should be one folder for approval letters, one for main study approval and one for each of the amendments. These folders should be created and populated within two working days of the Trust letter being issued.

In order to upload documents, select the folder you want to upload the document to (see the following sections relating to folder generation for further information) and click 'Add new document'. When the next screen comes up, click 'Select' and then locate the file you wish to add to the system. The description should then be added to the document, as per the details in the following section, then click 'Insert'.

The folders and file descriptions should be as detailed below.

### 4.5.1 Approval letters folder

This folder should be called 'Approval letters' and all Trust approval letters should be uploaded to this folder. The main approval letter for the study must be described as 'Approval letter'.

For all substantial amendments, they must have the description 'Amendment, REC approved [REC approval date]'.

For all non-substantial amendments that have been reported to the REC, they must have the description 'Amendment, REC acknowledged [REC acknowledged date]'.

For all non-substantial amendments that have not been reported to the REC, they must have the description 'Amendment, Trust acknowledged [letter on Trust letter]'.

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster	Page 11 of 11
Research Management & Governance	SOP No. RM&G 0009, Version 1
<b>ReDA Maintenance</b>	Supersedes: Not applicable.
	Attachments: None
	Effective date: 28 February 2013

In the case where amended approval/acknowledgement letters are issued, the original one should be deleted and the new one uploaded as above.

#### 4.5.2 Main study approval folder

This folder should be called 'Main study approval'. The following documents must be uploaded:

- All study documentation listed on the approval letter
- Trust signature pages

The Trust signature pages must be described as 'Trust signature pages'. Other documentation must be described as per the approval letter.

#### 4.5.3 Amendment folders

Amendment folders for substantial amendments must be called 'Sub Am REC App [date of REC approval]'.

Amendment folders for non-substantial amendments that have been sent to the REC for acknowledgement must be called 'Non-sub Am REC Ack [date of REC Acknowledgement]'.

Amendment folders for non-substantial amendments that have not been sent to the REC for acknowledgement must be called 'Non-sub Am Trust Ack [date of Trust acknowledgement]'.

In all cases, the date on the folder must reflect the date on the approval/acknowledgement letter description.

The documents that need to be uploaded to the folders for all amendments are as follows:

- Trust signature pages (where applicable)
- REC approval/acknowledgement letter (where applicable)
- MHRA approval letter (where applicable)
- All documentation approved/acknowledged in the letter

## 5 Health and Safety

There are no health and safety risks associated with this SOP.